

A survey conducted using health claims records and questionnaires to investigate the prevalence of migraine in Japan

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Abstract

Background

Migraine is a chronic disease characterized by episodic headache attacks. No recent studies have, however been conducted on the epidemiology of migraine or the treatment landscape in Japan. This study was conducted as a fact-finding survey using medical claims receipt data and an online survey on migraine and headaches, conducted among members of health insurance associations with the objective of gaining an understanding of migraine prevalence and the treatment status in Japan.

Methods

The study methodology utilized a unique approach of combined data sources. The data sources used in this study are medical claims receipt data and online survey data provided by DeSC Healthcare Inc (DeSC). The primary outcomes (from survey responses) were: the overall number and proportion of migraine patients; and the overall prevalence of migraine, stratified by age and sex. The secondary outcomes (from survey responses) were use of medical care; and clinical features/headache symptoms. The analysis population included all individuals who had response data for surveys conducted by DeSC. The online survey data and medical claims receipt data were summarized.

Results

The data population comprised 21,480 individuals. On the basis of the survey results, including probable cases, the overall prevalence of migraine was 3.2%. The highest prevalence of migraine was observed in patients aged 30-39 years. The prevalence of migraine in women was 4.4 times higher than in men. The percentage of migraine patients who had not been seen by a doctor was 81.0%. More than 80% of patients were taking over-the-counter drugs and 4.8% took prescription medicines only. Approximately 52.9% of patients considered that the intensity of pain symptoms was severe. Moreover, the majority of patients (72.9%) considered that the impairment of daily life activities was of moderate or severe degree.

Conclusions

In Japan, the percentage of people with migraine who did not receive medical attention is as high as 80%. Additionally, the majority of patients tend to endure symptoms and continue with everyday activities. With innovative treatment approaches becoming available it is necessary to disseminate information that migraine is not a simple headache but an illness that requires medical treatment and consultation.

Background

Migraine is a chronic disease characterized by episodic headache attacks. The headache attacks are described as unilateral and pulsating, of moderate to severe intensity, and lasting 4–72 hours [1]. In addition to “headache”, migraine may also be accompanied by symptoms such as nausea and vomiting, photophobia, phonophobia, and osmophobia, as well as visual abnormalities, including aura (jagged geometric patterns of glittering lights that gradually obscure vision, mosaic of parts of vision, etc.), which greatly interfere with daily life [2].

There are eight reports of epidemiological studies of headache disorders in Japan, [3, 4, 5, 6, 7, 8, 9, 10], of which six are in adults [4, 7, 8, 9, 10, 11]. According to a nationwide telephone survey by Sakai & Igarashi reported in 1997 [3], the prevalence of tension-type headache was 15.6% and that of migraine was 8.4%. The prevalence of migraine by sex was higher in females (12.9% compared to 3.6% in males), with the highest incidence in the 30–40 age group. The results also showed that 74% of people that experienced migraine symptoms reported that their headache attacks interfered with their daily lives, but they were generally able to conduct work and other social activities. The percentage of those who had never been to a medical institution for migraine was 69.4%. In terms of medication status, only 5.4% of patients took prescription medication, and 56.8% used over-the-counter (OTC) analgesics only. Overall, these reports showed that many people with migraine do not seek medical attention; rely on OTC analgesics for headache treatment; and do not take time off from social activities (or endure them) even when headaches interfere with daily life. This situation has been described as Japanese migraine patients “suffering in silence [12]”.

In the field of headache medicine, triptans, which are serotonin 1B/1D receptor agonists, were approved in Japan in 2001 for the acute treatment of migraine. Until then, analgesia with non-steroidal anti-inflammatory drugs (NSAIDs) had been the mainstay of migraine treatment, but the introduction of a mechanism-of-action treatment that matched the migraine onset mechanism was expected to improve treatment effectiveness by reducing the number of headache attacks and attack severity. In addition, it was expected that use of triptans would increase the number of people who visited medical institutions rather than enduring headaches. The 2021 Guidelines for the Management of Chronic Headache placed triptans as the first-line treatment for the acute phase of moderate-to-severe migraine headache [1], which was a change in migraine treatment policy. Due to the fact that no actual research studies evaluating triptans have been reported, it is still unclear, however, how the low consultation rate; reliance on OTC analgesics; changes in disruption of daily life, quality of life; and consultation trends have changed due to the use of triptans.

In 2019 monoclonal antibodies drugs targeting the calcitonin gene-related peptide (CGRP) or the CGRP receptor with a novel mechanism of action for migraine were launched in the United States and Europe. CGRP is a neuropeptide that was first reported to be associated with migraine in 1982, and subsequent studies have also shown an association with migraine. In Japan, monoclonal antibodies drugs targeting CGRP or its receptor are approved, or under evaluation in current clinical trials, and are expected to provide further improvement in migraine medication.

Two studies, on the actual condition of migraine were reported in 2019: an analysis of disease burden and treatment patterns in migraine patients using the Adelphi Migraine Disease Identification Program (a survey developed in the UK) [7], and an analysis of drug dosing patterns for migraine medications using the Japan Medical Data Center (JMDC) (medical claims database) database [8]. These reports are based on surveys of migraine patients and the analysis of prescription patterns using receipt data. Due to the limits of this approach the current status in Japan, however, is that the actual prevalence of migraine is not clear. Additionally, it is not clear how the migraine sex ratio, migraine severity, migraine impact on daily life, medication status, and consultation trends in the general population, which were reported about 20 years ago [3], have changed since the launch of triptans.

The main purpose of this study was to gain an understanding of the actual prevalence of migraine and the treatment status in Japan. Additionally, the results of this study help clarify the current status of medical consultation and the reasons for discontinuing existing preventive medications.

Methods

Study design and data source

The study was conducted as a fact-finding survey using the unique combination of medical claims receipt data and the results of an online survey on migraine and headaches conducted among members of health insurance associations contracted by DeSC Healthcare Inc (DeSC), and individuals registered with the health promotion support service application provided by DeSC. This combined use of data sources is thought to be unique and a particular strength of this study design.

The data sources used in this study are medical claims receipt data and online survey data provided by DeSC. This data source is anonymously processed information comprising medical claims receipts and survey data provided by the Society-Managed Employment-Based Health Insurance prior to the start of this study. Therefore, the research that was conducted in this study used only anonymously processed information that had already been created. The study subjects included in the data used are as follows. Employees (approximately 550,000 people) aged 19-74 who work for large companies on a nationwide scale, including subscribers (approximately 200,000 people) who registered for the mHealth web service "kencom" provided by DeSC. In addition, this study included subscribers who participated in two surveys implemented by DeSC. These were conducted in November 2020 and December 2020 respectively, with a month response period.

The DeSC database contains individual-level demographic information (e.g., age, sex) and dated medical information for inpatient and outpatient service provided by health care organizations and pharmacies (e.g., start of treatment, name of procedure, name of prescription and disease coded in the International Statistical Classification of Diseases and Related Health Problems, 10th revision, name of medical service, cost, name of medical institution). Provided that the employee did not leave the insurance program (e.g. retiring, changing jobs), it was possible to trace the medical and treatment history from multiple institutions.

Ethics statement

As this survey used only anonymized data, and because Otsuka Pharmaceutical Co., Ltd., Clinical Study Support Inc. (CSS), and the medical experts did not possess or receive data correspondence sheets, it was impossible to identify any individual. In addition, DeSC does not have a correspondence table for the data provided to Otsuka Pharmaceutical Co., Ltd, and it is, therefore, impossible to identify individuals from this data. Therefore, no new individual level consent was obtained for the use of the data in this study. However, the study protocol was approved by the ethics committee of the Research Institute of Healthcare Data Science (approval No.: RI2020012). Additionally, this survey was, however, conducted in consideration of the Declaration of Helsinki (revised October 2013) by the World Medical Association and the Ethical Guidelines for Medical Research Involving Human Subjects.

Study population

We extracted online survey response data and medical claims receipt data from the database for the past three years including the month in which the survey was conducted from 1 December 2017 to 30 November 2020. The study population included in the study was defined as “all individuals whose response data were available”.

Outcome measures

Primary outcomes:

The primary outcomes (based on the online survey response) were:

1. The overall number and proportion of people with migraine.
2. The overall prevalence of migraine, stratified by age and sex.

The definition of migraine (Supplementary Table 1) was based on the structured survey response, including internal diagnostic criteria, as migraine with and without aura, including probable migraine according to the International Classification of Headache Disorders, 3rd edition (ICHD-3) [13]. Additionally, prevalence of tension-type headache and cluster headache which were also classified according to ICHD-3 were also examined. Individuals not classified in any of these headache types are included in other headache types.

Secondary outcomes:

Use of medical care (based on the online survey response).

The use of medical care was categorized as follows: The number of individuals with migraine who made hospital visits for headache (regularly visited, not regularly visited, not visited) within 6 months before answering the survey, overall and stratified by age and sex; frequency of hospital visits (<once/month, once/month, once/2 months, once/3 months, <once/3 months); reasons for visiting a hospital (unable to tolerate headaches, worried about other brain diseases, increased headache frequency, and OTC drugs no longer effective; and reasons for not visiting a doctor OTC drugs effective, used to having headache, spontaneously resolving after endurance, or pain not sufficiently severe)

Clinical features and symptoms of headache (based on the online survey response).

Clinical features/symptoms were classified as follows: symptoms of headache (nausea or vomiting, stiff shoulder, and neck pain); site of pain (unilateral, bilateral, frontal, occipital, periorbital, other locations); time of day of headache onset (Upon waking, morning, afternoon, evening, other, no particular time of day); headache triggers (fatigue physical or mental stress, bad weather such as the time of typhoon, lack of sleep, turning points of the seasons, sunny or rainy days, work or housework, and menstruation); activities that were refrained from or reduced by headache (Operating a computer or smart phone, drinking alcohol, exercising such as playing sports or walking, going to crowded places, driving a car, housework (excluding grocery

shopping, laundry, and cooking), cooking, socializing with friends and playing with children, going grocery shopping, and taking public transportation)

Medication use (based on the online survey response and medical claims receipt data) and comorbidity (medical claims receipt data).

Medical use was classified as follows: current medication use (OTC and prescription drugs, prescription drugs only (both acute and prophylactic medications), OTC drugs only, and none); number of OTC drug class use (1 or ≥ 2 types); prescription drugs for prophylactic treatments (antidepressants, anti-epileptics, calcium channel blockers, angiotensin-receptor blockers/ angiotensin converting enzyme inhibitors, Beta blockers, and others); prescription drugs for acute treatments (acetaminophen, NSAIDs, triptans, ergotamine, and antiemetic drugs); and comorbidity (hypertension, cardiovascular disease, cerebrovascular disease, gastrointestinal disorder, psychiatric and psychosomatic disorder, depression, epilepsy, asthma, allergy, and autoimmune disorder)

Activity impairment, MS-QOL, and Work Productivity and Activity Impairment WPAI score (based on the online survey response).

Activity impairment was classified as follows: severity of migraine when taking medicines or not taking medicines (severe, moderate, mild); impairment in daily activities (severe, moderate, mild); Migraine-Specific Quality of Life (MS-QOL) estimated using the MSQ version 2.1, which is a 14-item questionnaire measuring the impact of migraine across 3 domains during the past 4 weeks: role function-restrictive (RR) that measures functional limitations on daily, work, and social activities (7 items); role function-preventive (RP) that measures functional prevention on daily, work, and social activities (4 items); and emotional function (EF) that measures the impact on emotion (3 items) [14,15,16]. The source data responses were scaled to range from 0 to 100; the higher score indicating better quality of life. Work Productivity Activity Impairment (WPAI) scores were estimated using the WPAI Questionnaire-General Health for the last 7 days before questionnaire response as follows: 1) percentage of work time missed in the last week due to health conditions (absenteeism); 2) percentage of impairment while working due to health conditions (presenteeism); 3) percentage of overall work impairment due to health conditions; and 4) percentage of activity impairment due to health conditions [17].

Statistical analysis

The analysis population included all individuals who had response data for the surveys conducted by DeSC. Demographic and clinical characteristics were descriptively summarized for overall individuals with migraine. For continuous variables, the mean \pm standard deviation and median (minimum, maximum) were presented. For categorical variables, the number and percentage were presented. Post-hoc analysis of other headaches was conducted using criteria from the ID-Migraine [18] and the 4-item simple migraine screener [19]. Additionally, a sensitivity analysis of the health outcomes of kencom users was conducted, to evaluate whether kencom users showed greater health conscious behaviors than other patients. All statistical analyses were performed in SAS Release 9.4 (SAS Institute, Inc., NC, USA).

Results

Prevalence

The study flow is displayed in Fig. 1. The data population comprised 21,480 individuals. On the basis of the online survey results, that included probable cases, the overall prevalence of migraine was 3.2% (691/21,480) (Fig. 2). After weighting the data by age and sex among kencom registrants (Supplementary Table 2) the prevalence of migraine was 3.5%. Whereas, after weighing the data by sex and age among health insurance association members, the prevalence of migraine was 4.2%. From medical claims receipt data (Table 1) the prevalence of migraine was 1.0% (208/21,480).

Table 1 Characteristics of people with migraine

Variables	Analysis population (N=21,480)	Migraine* (N=691)							
		Migraine total (N=691)		Chronic headache (N=19)		Episodic headache (N=672)			
		n	%	n	%	n	%	n	%
Sex	Male	15,802	73.6	272	39.4	5	26.3	267	39.7
	Female	5,678	26.4	419	60.6	14	73.7	405	60.3
Age, Total	19-29 years	1,151	5.4	60	8.7	1	5.3	59	8.8
	30-39 years	2,944	13.7	184	26.6	7	36.8	177	26.3
	40-49 years	6,095	28.4	262	37.9	7	36.8	255	37.9
	50-59 years	8,265	38.5	175	25.3	4	21.1	171	25.4
	≥60 years	3,025	14.1	10	1.4	0	0.0	10	1.5
Male	19-29 years	675	3.1	19	7.0	0	0.0	19	7.1
	30-39 years	1,921	8.9	84	30.9	3	60.0	81	30.3
	40-49 years	4,035	18.8	94	34.6	2	40.0	92	34.5
	50-59 years	6,483	30.2	71	26.1	0	0.0	71	26.6
	≥60 years	2,688	12.5	4	1.5	0	0.0	4	1.5
Female	19-29 years	476	2.2	41	9.8	1	7.1	40	9.9
	30-39 years	1,023	4.8	100	23.9	4	28.6	96	23.7
	40-49 years	2,060	9.6	168	40.1	5	35.7	163	40.2
	50-59 years	1,782	8.3	104	24.8	4	28.6	100	24.7
	≥60 years	337	1.6	6	1.4	0	0.0	6	1.5
Years lived with headache	-5 years	-	-	57	8.2	2	10.5	55	8.2
	6 - 10 years	-	-	54	7.8	3	15.8	51	7.6
	11 - 15 years	-	-	50	7.2	2	10.5	48	7.1
	16 - 20 years	-	-	57	8.2	2	10.5	55	8.2
	21 - 25 years	-	-	49	7.1	1	5.3	48	7.1
	26 - 30 years	-	-	34	4.9	2	10.5	32	4.8
	≥31 years	-	-	62	9.0	4	21.1	58	8.6
Area of residence	Hokkaido	-	-	6	0.9	0	0.0	6	0.9
	Tohoku	-	-	23	3.3	0	0.0	23	3.4

	Kanto-Koshinetsu	-	-	399	57.7	9	47.4	390	58.0
	Hokuriku	-	-	8	1.2	0	0.0	8	1.2
	Chubu	-	-	86	12.4	4	21.1	82	12.2
	Kinki	-	-	121	17.5	4	21.1	117	17.4
	Chugoku	-	-	10	1.4	1	5.3	9	1.3
	Shikoku	-	-	10	1.4	0	0.0	10	1.5
	Kyushu	-	-	28	4.1	1	5.3	27	4.0
Job category**	Administrative positions	-	-	231	33.4	8	42.1	223	33.2
	Professional and technical personnel	-	-	186	26.9	5	26.3	181	26.9
	Housewife (husband)	-	-	58	8.4	2	10.5	56	8.3
	Managers	-	-	47	6.8	0	0.0	47	7.0
	Others	-	-	169	24.5	4	21.1	165	24.6
Annual household income (including tax)	<1,000,000 JPY (<9,000 USD [†])	-	-	11	1.6	1	5.3	10	1.5
	≥1,000,000 to <5,000,000 JPY (≥9,000 to <44,000 USD [†])	-	-	136	19.7	4	21.1	132	19.6
	≥5,000,000 to <10,000,000 JPY (≥44,000 to <87,000 USD [†])	-	-	360	52.1	10	52.6	350	52.1
	≥10,000,000 JPY (≥87,000 USD [†])	-	-	119	17.2	2	10.5	117	17.4
	Don't know	-	-	54	7.8	2	10.5	52	7.7
	No reply	-	-	11	1.6	0	0.0	11	1.6
Aura	With aura	-	-	230	33.3	-	-	-	-
	Male	-	-	89	38.7	-	-	-	-
	Female	-	-	141	61.3	-	-	-	-
	Without aura	-	-	461	66.7	-	-	-	-

	Male	-	-	183	39.7	-	-	-	-
	Female	-	-	278	60.3	-	-	-	-
Number of days with a headache in the past 3 months	n	-	-	691	100.0	19	100.0	672	100.0
	Mean	-	-	11.1		60.5		9.7	
	SD	-	-	12.3		14.6		8.9	
	Min	-	-	1.0		45.0		1.0	
	Median	-	-	7.0		60.0		7.0	
	Max	-	-	90.0		90.0		60.0	
Number of days with a headache in the past 30 days	n	-	-	691	100.0	19	100.0	672	100.0
	Mean	-	-	5		19		4	
	SD	-	-	5.0		5.1		4.3	
	Min	-	-	0.0		15.0		0.0	
	Median	-	-	3.0		20.0		3.0	
	Max	-	-	30.0		30.0		30.0	
Receipt code for migraine in the past 6 months [‡]	Yes	-	-	61	8.8	-	-	-	-
Diagnosed with migraine at the medical institution	Yes	-	-	167	24.2	6	31.6	161	24.0

Abbreviations: JPY, Japanese yen; USD**, United States dollar; SD, standard deviation; min, minimum; max, maximum.

Notes:

* Migraine included individuals classified as probable migraine.

** Details are listed in supplementary Table 1.

† USD was estimated based on the exchange rate of 1 JPY =0.0087 USD on 09 February 2022.

‡ Data were derived from the medical claims database.

Of those individuals classified as having migraine in the survey, 8.8% (61/691) had a migraine diagnosis in their medical claims receipt data (Table 1). Among this population of people with migraine that were identified

in both the survey and in the medical claims receipt data, the prevalence of chronic migraine was 2.7% (19/691) (Fig. 1).

Prevalence of other headache types are shown in Fig. 2. Among individuals that had "other headache types", 261 patients had at least two matches for ID-Migraine and 286 patients had at least two matches in the 4-item-simple migraine screener (Fig. 1).

By age, among people that experienced migraine, the highest proportion was observed in 37.9% (262/691) of patients aged 40–49 years; followed by 26.6% (184/691) of patients aged 30–39 years; and 25.3% (175/691) of patients aged 50–59 years (Table 1). Additionally Fig. 3 shows the prevalence of migraine stratified by age and sex, with the number of same age and sex category used as the denominator. After stratifying by age and sex, the prevalence of migraine in men and women aged 30–39 years was 4.4% and 9.8% respectively, showing that individuals in the range 30–39 are most likely to experience migraine headache.

Regarding sex, the prevalence of migraine in women was 4.4 times higher than in men (men: women = 1.7%: 7.4%; Fig. 3). After weighting the data by sex and age among kencom registrants the ratio of women experiencing a migraine episode was 3.75 times that of men (men: women = 2.0%: 7.5%; Supplementary Table 2). Whereas after weighting the data by sex and age among health insurance association members, the ratio of women experiencing a migraine episode was 3.1 of that in men (men: women = 2.2%: 6.9%).

Use of medical care

The percentage of people with migraine who had not visited a doctor was 81.0% (560/691) (Table 2). For people that did attend a hospital, the percentage of individuals that visited a clinic was 3.1 times that of general hospitals. The specialties of the clinics in descending order were internal medicine, neurosurgery, and neurology (including multiple responses from online survey for hospitals/clinics).

The majority of people with migraine visited a doctor less than once a month (Table 3). The reasons for seeing a doctor were as follows: because they were unable to tolerate headaches (15.3%, 106/691); because they were worried about other brain diseases (9.4%, 65/691); because of increased headache frequency (8.0%, 55/691); and because OTC drugs were no longer effective (6.9%, 48/691) (Table 3).

A total of 2.6% of people with migraine (18/691) stopped attending a hospital after one visit (Table 3) and the reason provided was because they were relieved not to have a brain disease that threatened life.

Among people with migraine (Table 3) the reasons for not seeing a doctor were as follows: because OTC drugs were effective (37.6%, 260/691); because they were used to having a headache (22.4%, 155/691); because the symptoms would spontaneously resolve after endurance (20.7%, 143/691); and pain not sufficiently severe (16.5%, 114/691).

Table 2
Current medical visits for headaches in the migraine group*

	Regularly visited		Not regularly visited		Not visited	
	n	%	n	%	n	%
Migraine total (N = 691)	44	6.4	87	12.6	560	81.0
Male (N = 272)	14	5.1	37	13.6	221	81.3
19–29 years	0	0.0	2	0.7	17	6.3
30–39 years	0	0.0	11	4.0	73	26.8
40–49 years	7	2.6	9	3.3	78	28.7
50–59 years	7	2.6	14	5.1	50	18.4
≥ 60 years	0	0.0	1	0.4	3	1.1
Female (N = 419)	30	7.2	50	11.9	339	80.9
19–29 years	4	1.0	0	0.0	37	8.8
30–39 years	5	1.2	9	2.1	86	20.5
40–49 years	14	3.3	28	6.7	126	30.1
50–59 years	6	1.4	12	2.9	86	20.5
≥ 60 years	1	0.2	1	0.2	4	1.0
* Migraine included individuals classified as probable migraine.						

Table 3 Summary of medical visits in people with migraine

Variables		Migraine* (N=691)	
		n	%
Frequency of medical visits (past 6 months)	>Once/week	2	0.3
	Once/2 weeks	0	0.0
	Once/month	22	3.2
	Once/2 months	10	1.4
	Once/3 months	5	0.7
	<Once/3 months	5	0.7
Reasons for initially seeing a doctor for headache** (multiple answers)	Unable to tolerate headaches	106	15.3
	Worried about other brain diseases	65	9.4
	Increased headache frequency	55	8.0
	OTC analgesics no longer effective	48	6.9
Reasons for seeing a doctor once for headache and not seeing thereafter** (multiple answers)	Relieved not to have a brain disease that threatened life	18	2.6
Reasons of not seeing a doctor in the past 3 years** (multiple answers)	OTC analgesics effective	260	37.6
	Used to having a headache	155	22.4
	Spontaneously resolving after endurance	143	20.7
	Pain not sufficiently severe	114	16.5

Abbreviations: OTC, over-the-counter.

* Migraine included individuals classified as probable migraine.

** Details are listed in supplementary Figure 1.

Clinical features and symptoms

The reported symptoms of headaches included nausea and vomiting (49.9%, 345/691), stiff shoulders (35.9%, 248/691), and neck pain (26.8%, 185/691) (Table 4). The most common locations for headaches were unilateral (84.7%, 585/691) and periorbital (36.0%, 249/691).

The most common triggers provided for headache onset (Table 4) was, fatigue (47.3%, 327/691); and physical or mental stress (44.4%, 307/691). Other reasons included bad weather such as typhoon (41.4%, 286/691); and weather related situations including; turning points in the season (30.1%, 208/691); and on sunny or rainy

days (27.6%, 191/691). For women with menstruation 52.6% (171/325) selected the reason for headache onset as menstruation-related. The most common problem that migraine brings to daily life is "inability to concentrate on work or study."

Activities refrained from or reduced by migraine symptoms in men in decreasing order (Table 4), were as follows: operating a computer or smart phone (32.7%, 89/272); drinking alcohol (32.4%, 88/272); and exercising such as playing sports or walking (21.3%, 58/272). Women selected going to crowded places (37.5%, 157/419); operating a computer or smart phone (35.1%, 147/419); drinking alcohol (30.1%, 126/419); housework (excluding grocery shopping, laundry, and cooking) (21.7%, 91/419); and grocery shopping (21.5%, 90/419).

In order to improve daily life, 55.7% of the respondents felt that they would "like the headache to disappear almost completely," and 29.6% felt that they would "like it to decrease even a little." As the level of difficulty increased, the percentage of those who felt that "even a small decrease would be enough" decreased, while the percentage of those who felt that "almost all of the headaches should disappear" increased.

Table 4-1 Symptoms and triggers of migraine

Variables		Migraine* (N=691)	
		n	%
Symptoms associated with headache** (multiple answers)	Nausea or vomiting	345	49.9
	Stiff shoulder	248	35.9
	Neck pain	185	26.8
Site of pain (multiple answers)	Unilateral	585	84.7
	Bilateral	198	28.7
	Frontal	181	26.2
	Occipital	178	25.8
	Periorbital	249	36.0
	Other	17	2.5
Time of day (single answer)	Upon waking	195	28.2
	Morning	143	20.7
	Afternoon	302	43.7
	Evening	142	20.5
	Other	13	1.9
	No particular time	223	32.3
Headache triggers** (multiple answers)	Fatigue	327	47.3
	Mental or physical stress	307	44.4
	Bad weather, such as a typhoon	286	41.4
	Lack of sleep	261	37.8
	Turning points of the seasons	208	30.1
	Sunny or rainy days	191	27.6
	Work or housework	178	25.8
	Menstruation†	175	25.3

* Migraine included individuals classified as probable migraine.

** Details are in supplementary Figure 2.

† Among those who had menstruation (325 patients), 171 patients (52.6%) answered "menstruation".

Table 4-2 Activities refrained from to reduce the frequency of headaches in people with migraine (stratified by sex)

Variables		Migraine*					
		Migraine total (N=691)		Male (N=272)		Female (N=419)	
		n	%	n	%	n	%
Activities refrained from or reduced by headache	Operating a computer or smart phone	236	34.2	89	32.7	147	35.1
	Drinking alcohol	214	31.0	88	32.4	126	30.1
	Exercising such as playing sports or walking	129	18.7	58	21.3	71	16.9
	Going to crowded places	215	31.1	58	21.3	157	37.5
	Driving a car	92	13.3	45	16.5	47	11.2
	Housework (excluding grocery shopping, laundry, and cooking)	122	17.7	31	11.4	91	21.7
	Socializing with friends and playing with children	83	12.0	25	9.2	58	13.8
	Going to grocery shopping	108	15.6	18	6.6	90	21.5
	Taking public transportation	65	9.4	14	5.1	51	12.2
	Cooking	104	15.1	11	4.0	93	22.2

* Migraine included individuals classified as probable migraine.

Medication use

More than 80% of people with migraine were taking OTC drugs (89.6%, 561/626) (Table 5). Only 6.1% (38/626) of patients took prescription medicines only and 31.8% (199/626) of patients took both OTC and prescription medicines. Regarding OTC drugs, 22.9% (158/691) of people with migraine took more than one type of OTC medication. Acute care prescription medications were prescribed to 34.9% (241/691) of the respondents. Acetaminophen and NSAIDs were prescribed to 29.8% (206/691) of patients; and triptans to 5.9% (41/691) of patients. Prescription drugs for prophylaxis were prescribed to 8.1% (56/691) of patients. These medications included antidepressants (3.3%, 23/691), antiepileptics (1.9%, 13/691), and calcium channel blockers (1.6%, 11/691). Whilst 59 patients were prescribed triptans for "other headaches," as triptans are only used for migraine, it is highly likely that the "other headache" category includes migraine patients.

Table 5 Headache medications in migraine

Variables		Migraine* (N=691)	
		n	%
Medication use** (past 6 months)	OTC and prescription drugs†	199	31.8
	Prescription drugs only (acute and prophylactic)‡	38	6.1
	OTC drugs only	362	57.8
	No prescription drugs‡	27	4.3
Number of OTC analgesic types	1	403	58.3
	2 or more	158	22.9
Types of prescription drugs‡ (prophylactic, past 6 months)	Total	56	8.1
	Antidepressants	23	3.3
	Anti-epileptics	13	1.9
	Calcium channel blockers	11	1.6
	ARB/ACE inhibitors	6	0.9
	Beta-blocker	4	0.6
	Others	6	0.9
Types of prescription drugs‡ (acute, past 6 months)	Total	241	34.9
	Acetaminophen/NSAIDs	206	29.8
	Triptans	41	5.9
	Antiemetics	28	4.1
	Intravenous steroids	14	2.0
	Tranquilizer/anesthetic preparations	6	0.9
	Tramadol	1	0.1
	Magnesium preparations	1	0.1
	Ergotamine	0	0.0
	Comorbidity‡ (past 6 months)	Hypertension	51
Cardiovascular disorders		23	3.3
Cerebrovascular disorders		6	0.9
Gastrointestinal disorders		386	55.9
Constipation		50	7.2

Psychiatric/Psychosomatic disorders	104	15.1
Depression	48	6.9
Epilepsy	6	0.9
Asthma	51	7.4
Allergy	123	17.8
Autoimmune disorders	38	5.5

Abbreviations: OTC, over-the-counter; ARC, angiotensin II receptor blocker; ACE, angiotensin converting enzyme; NSAID, non-Steroidal Anti-Inflammatory Drugs.

* Migraine included individuals classified as probable migraine.

** Denominator was the number who answered "yes" to a question of taking any drugs (n=626).

† Data used from questionnaire responses and the medical claims database.

‡ Data derived from the medical claims database.

Activity impairment, MS-QOL, and WPAI

Regarding pain intensity (Table 6), approximately 52.9% (365/691) of respondents considered that the intensity of pain symptoms was severe. Moreover, the majority of patients (72.9%) considered that the impairment of daily life activities was of moderate or severe degree.

The mean (SD) MSQ scores for migraine were 71.6 (17.1) for RR, 83.5 (16.0) for RF, and 77.9 (20.1) for EF. The mean (SD) WPAI score was 2.5% (8.9) for absenteeism, and 15.4% (21.8) for presenteeism (Figure 4).

Table 6 Severity of impairment associated with medication use in migraine

	Migraine* (N=691)			
	Not taking medicines		Taking medicines	
	n	%	n	%
Severity of migraine**				
Severe	365	52.9	47	6.8
Moderate	316	45.7	69	10.0
Mild	10	1.4	510	73.8
Impairment in daily activities [†]				
Severe	204	29.5	31	4.5
Moderate	300	43.4	56	8.1
Mild	187	27.1	539	78.0

*Migraine included individuals classified as probable migraine.

** Severity of migraine was grouped into 3 level from the patients' response for evaluating the severity of a migraine attack in 5 levels: Severe: extreme or quite a bit of pain; Moderate: moderate pain; and Mild: little pain or no pain.

[†] Impairment in daily life was also grouped into 3 level from the patients' response for evaluating the impairment in daily life when having a migraine in 5 levels: Severe: extreme difficulty or severe disruption in daily life; Moderate: moderate difficulty in daily life; and Mild: slightly interferes with daily life or no trouble at all.

Discussion

This study was conducted using a unique methodology, combining medical claims receipt data and the results of an online survey on migraine and headaches, conducted among members of health insurance associations with the objective to gain an understanding of the prevalence of migraine and the treatment status in Japan. It is the first study to investigate the prevalence of migraine in Japan for more than 20 years. [3]

On the basis of the survey results, including probable cases, the migraine prevalence was 3.2% (691/21,480). After weighting the data by sex and age among kencom users the prevalence of migraine was 3.5%. These migraine prevalence values were lower than the population prevalence of 8.4% reported by Sakai & Igarashi [3] in 1997. The relatively low value of migraine prevalence reported in this study's survey results may partly be due to the fact that, whilst the questionnaires were structured, they were self-administered, and did not involve semi-structured interviews, which may have underestimated the population migraine prevalence. The relative increase in migraine prevalence after weighting among kencom registrants may partially be explained by the

fact that it is believed that kencom members have a higher level of health consciousness than the general Japanese population. There were, however many similar findings between our study and Sakai & Igarashi [3] that indicate that whilst migraine knowledge and treatment has progressed since 1997, many patients do not view migraine as a special disease that requires specific treatment. These findings indicate migraine treatment and behaviors have not significantly changed since 1997.

Figure 3 shows the prevalence of migraine stratified by age and sex, with the number of same age and sex category used as the denominator. The results show that the prevalence of migraine in men and women aged 30-39 years was 4.4% and 9.8% respectively. In men and women aged 40-49 the migraine prevalence was 2.3% and 8.2% respectively. This age profile was similar to previous findings [3,4] who reported that the highest migraine prevalence was in men and women aged 30-40 years. In our study 89.8% of patients were aged 30-59 years, and of working age. This finding may be partially explained by the fact that the kencom database includes individuals of working age.

In our study the prevalence of migraine in women was 3.1 times higher than that in men (men: women = 2.2%: 6.9%). This shows that whilst the etiology of migraine is poorly understood, the prevalence ratio among men and women remains relatively unchanged, since 1997 as Sakai & Igarashi [3] reported that the prevalence of migraine in women was 3.6 times higher than that in men (Men: Women ratio=3.6%:12.9%).

A high percentage of people with migraine (81%) did not attend a medical institute to consult with a doctor. Consequently, as in previous studies, the percentage of undiagnosed cases was high [3,4]. From the reasons provided for medical consultation and the reasons for not seeing a doctor, it was suggested that people usually attempt to ameliorate pain symptoms with OTC drugs and do not see a physician until the pain becomes unbearably severe. It was also clarified that even if patients do see a physician, they will often discontinue medical institution visits if the diagnosis confirms that they don't have a brain disease that threatened life. In addition, 57.8% of the respondents took only OTC drugs, suggesting that they continue to take OTC drugs of their own volition without consulting a doctor, despite the fact that they may be experiencing symptoms of migraine.

Regarding migraine onset, it appears there is a sex difference regarding when headaches are likely to occur. Overall, regardless of sex, the most common reason was when feeling fatigue. Additionally, there is an increased tendency for migraine onset in the following circumstances: when there is bad weather such as a typhoon; at the turning point of seasons; and on sunny or rainy days. Furthermore 52.6% of female respondents selected the reason of migraine onset to be related to menstruation. Of women who believed that menstrual pain was the reason for migraine onset, the majority of respondents reported that they endure the pain symptoms and attempted to ameliorate the pain by using OTC drugs.

Migraine symptoms were reported to cause individuals to refrain from or to reduce the conduct of everyday activities. Common activities included operating a computer or smartphone, drinking alcohol, and exercise such as playing sports or walking. Many women reported that they refrain from housework (excluding grocery shopping laundry and cooking) (21.7%) and grocery shopping (21.5%) due to headaches. Frequently the onset of migraine symptoms prevented people from conducting even essential household activities.

In assessing pain intensity, approximately 52.9% of respondents considered that the intensity of pain symptoms was severe. Moreover, the majority of patients (72.9%) considered that the impairment of daily life activities was of moderate or severe degree. This indicates that despite experiencing moderate/severe pain symptoms, the majority of patients continued with daily activities, rather than seeking medical attention or resting.

In common with other studies [3,4] the majority of patients used only OTC drugs (57.8%) to ameliorate pain. Only 6.1% of patients took only prescription medicines; and 31.8% of patients took both OTC and prescription medicines. Acetaminophen and NSAIDs were prescribed to 29.8% of patients; and triptans to 5.9% of patients. Prescription drugs for prophylaxis were prescribed to 8.1% of patients. Whilst 59 patients were prescribed triptans for "other headaches", as triptans are only used for migraine, it is highly likely that the "other headache" category includes migraine patients, as described below.

In our study a large number of "other headaches" was observed (24.2%). Among these "other headaches", 261 patients had two or more matches amongst three items for ID-Migraine [18] and 286 patients had two or more matches for the 4-item-simple migraine screener developed in Japan [19]. The high number of people classified as "other headache" who had two or more items on the ID-Migraine and the-4-item-simple-migraine screener suggest that a doctor's interview is important for the diagnosis of migraine. A correct migraine diagnosis, therefore, requires a detailed interview of symptoms with a doctor. This is not possible with questionnaires alone, and as it is difficult to select all patients, a combination of semi-structured interviews and questionnaires is useful for diagnosing migraine. Overall in our study it may be suggested that migraine headaches with symptoms of a degree of severity less than moderate were more likely to be unrecorded as migraines but as other headaches.

Limitations of the Study

This study has limitations. Our findings are not generalizable to the entire adult population with headache in Japan due to the following reasons. Firstly, we used data from employees and their family members of large companies that are members of the health insurance association contracted by DeSC. Self-employed persons, civil servants, employees of small and medium-sized companies, and retired elderly persons are, therefore, not included. It is assumed that employees of the companies in the DeSC database have a relatively high socioeconomic status, live in areas with access to medical care, and that their occupations are limited to certain types rather than being all encompassing. Secondly, the survey was distributed only to the Kencom users. The users are considered to be more health-conscious than non-users and are more likely to take positive health actions in their daily lives, which may have affected QOL and WPAI scores. Thirdly, headache types were classified according to ICHD-3 based on an online survey. As medical consultations with doctors were not conducted it was, therefore, not possible to obtain detailed information regarding symptoms. Furthermore, it is possible, as described above, that the "other headache types" may include individuals with migraine. Lastly, a large portion of our data were self-reported, and questionnaire responses are subject to recall bias. Such bias is not present in certain variables (e.g., drug prescriptions and comorbidities); however, as we used an existing medical claims database that is used for billing purposes, such data are subject to misclassification and entry error. A correct migraine diagnosis, therefore, requires a detailed interview of

symptoms with a doctor. This is not possible with questionnaires alone, and a combination of semi-structured interviews and questionnaires.

Conclusion

Based on a unique method of linking medical claims and online survey data, we reported up-to-date epidemiological data of several headache disorders in Japan and showed that the current prevalence of migraine in Japan is approximately 3.2%.

In Japan, the percentage of people with migraine who did not receive medical attention is as high as 80%. Additionally, the majority of people with migraine tend to endure symptoms and continue with everyday activities. With innovative treatment approaches becoming available it is necessary to disseminate information that migraine is not a simple headache but an illness that requires medical treatment and consultation. We consider that the findings of this study are of clinical value for future diagnosis and treatment of migraine headaches.

Abbreviations

OTC: over-the-counter; NSAIDs: non-steroidal anti-inflammatory drugs; CGRP: calcitonin gene-related peptide; JMDC: Japan Medical Data Center; DeSC: DeSC Healthcare Inc.; CSS, Inc.: Clinical Study Support. Inc.; ICHD-3: International Classification of Headache Disorders, 3rd edition; WPAI: Work Productivity and Activity Impairment; MS-QOL: Migraine-Specific Quality of Life; RR: role function-restrictive;

RP: role function-preventive; EF: emotional function; ARC: angiotensin II receptor blocker; ACE: angiotensin converting enzyme; MSQ: Migraine-Specific Quality of Life Questionnaire

Declarations

Ethics approval and consent to participate

This survey used only anonymized data, and the ethical committee review was therefore not required, and no new individual level consent was obtained for the use of the data. However, the survey was conducted in consideration of the Declaration of Helsinki (revised October 2013) by the World Medical Association and the Ethical Guidelines for Medical Research Involving Human Subjects.

Consent for publication

Not applicable

Availability of data and materials

The data that support the findings of this study are available from DeSC Healthcare, Inc. (Tokyo, Japan) but restrictions apply to the availability of these data, which were used under license for the current study, and so

are not publicly available. Data are however available from the authors upon reasonable request and with permission of DeSC Healthcare, Inc.

Competing interests

HS, HK, YS and NK are employees of Otsuka Pharmaceutical Co., Ltd.

FS received consultant fee from Otsuka Pharmaceutical Co., Ltd., during the conduct of the study; consulting fees from Otsuka Pharmaceutical Co., Ltd., Eli-Lilly Co., Ltd., and Amgen Co. Ltd.; lecture Honoraria from Otsuka Pharmaceutical Co., Ltd., Eli-Lilly Co., Ltd., and Amgen Co., Ltd., outside the submitted work. KH received consulting fees from Otsuka Pharmaceutical Co., Ltd., during the conduct of the study; consulting fees from Otsuka Pharmaceutical Co., Ltd., Eli Lilly Japan K.K., Amgen Astellas BioPharma K.K., and Lundbeck Japan K.K.; lecture Honoraria from Otsuka Pharmaceutical Co., Ltd., Eli Lilly Japan K.K., Eisai Co., Pfizer Japan, Daiichi Sankyo Co., Ltd., MSD Co., Ltd., Amgen Astellas BioPharma K.K., Ltd., and Lundbeck Japan K.K., outside the submitted work. HI received consulting fees Otsuka Pharmaceutical Co., Ltd., during the conduct of the study; consulting fees from Takeda Pharmaceutical Company Ltd., Otsuka Pharmaceutical Co., Ltd.; Daiichi Sankyo Co., Eli Lilly Japan K.K, lecture Honoraria from Otsuka Pharmaceutical Co., Ltd., Eli Lilly Japan K.K, Amgen K.K., Daiichi Sankyo Co., Ltd., and Eisai Co., Ltd.; manuscript writing fee from Sawai Pharmaceutical Co., Ltd.; educational event fees from Lundbeck Japan K.K., outside the submitted work. TT received consulting fees from Otsuka Pharmaceutical Co., Ltd., during the conduct of the study; grants or contracts from Eisai Co., Ltd., Amgen Inc., Eli Lilly Japan K.K., and Allergan Japan K.K.; consulting fees from Otsuka Pharmaceutical Co., Ltd.; honoraria for lectures from Otsuka Pharmaceutical Co., Ltd., Eisai Co., Ltd., Amgen Inc., and Eli Lilly Japan K.K., outside the submitted work. TN received consulting fees from Otsuka Pharmaceutical Co., Ltd., during the conduct of the study; consulting fees from Dainippon Sumitomo Pharmaceutical Co., Ltd., Otsuka Pharmaceutical Co., Ltd. ; grants or contracts from I&H Co., Ltd., and Nakagawa Pharmacy Co.; lecture Honoria from Pfizer Japan Inc., MSD K.K., Chugai Pharmaceutical Co., Ltd., Takeda Pharmaceutical Co., Ltd., Janssen Pharmaceutical K.K., Boehringer Ingelheim International GmbH, Eli Lilly Japan K.K., Baxter Ltd., Mitsubishi Tanabe Pharma Co., Otsuka Pharmaceutical Co., Ltd. and Novartis Pharma K.K., outside the submitted work.

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Authors' contributions

All authors made substantial contributions to all of the following: (1) the conception and design of the study, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be submitted and meeting the ICMJE authorship criteria. Additionally, HS, HK, YS and NK contributed to the acquisition of data.

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Figures

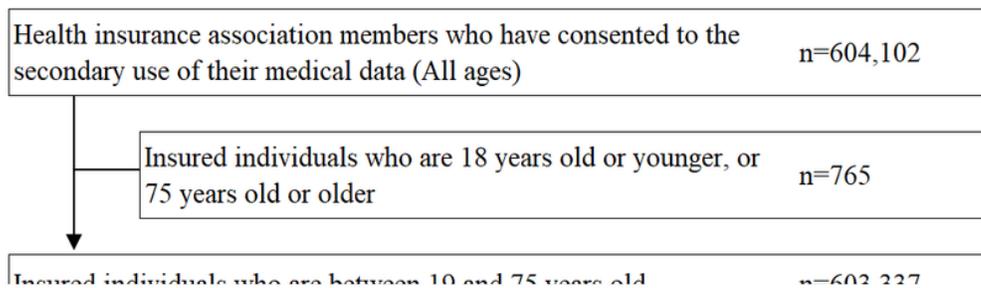


Figure 1

Patient disposition

* Each group except the group of other headache types included individuals classified as probable migraine, probable tension-type headache, or probable cluster headache, respectively.

** There were 42 individuals who were classified into both migraine and tension-type headache.

† There were 8 individuals who were classified into both migraine and cluster headache.

‡ Post-hoc analysis of the “other headache types” showed 261 people who had two or more matches with ID Migraine [18] and 286 people who had two or more matches with the 4-item simple migraine screener [19].

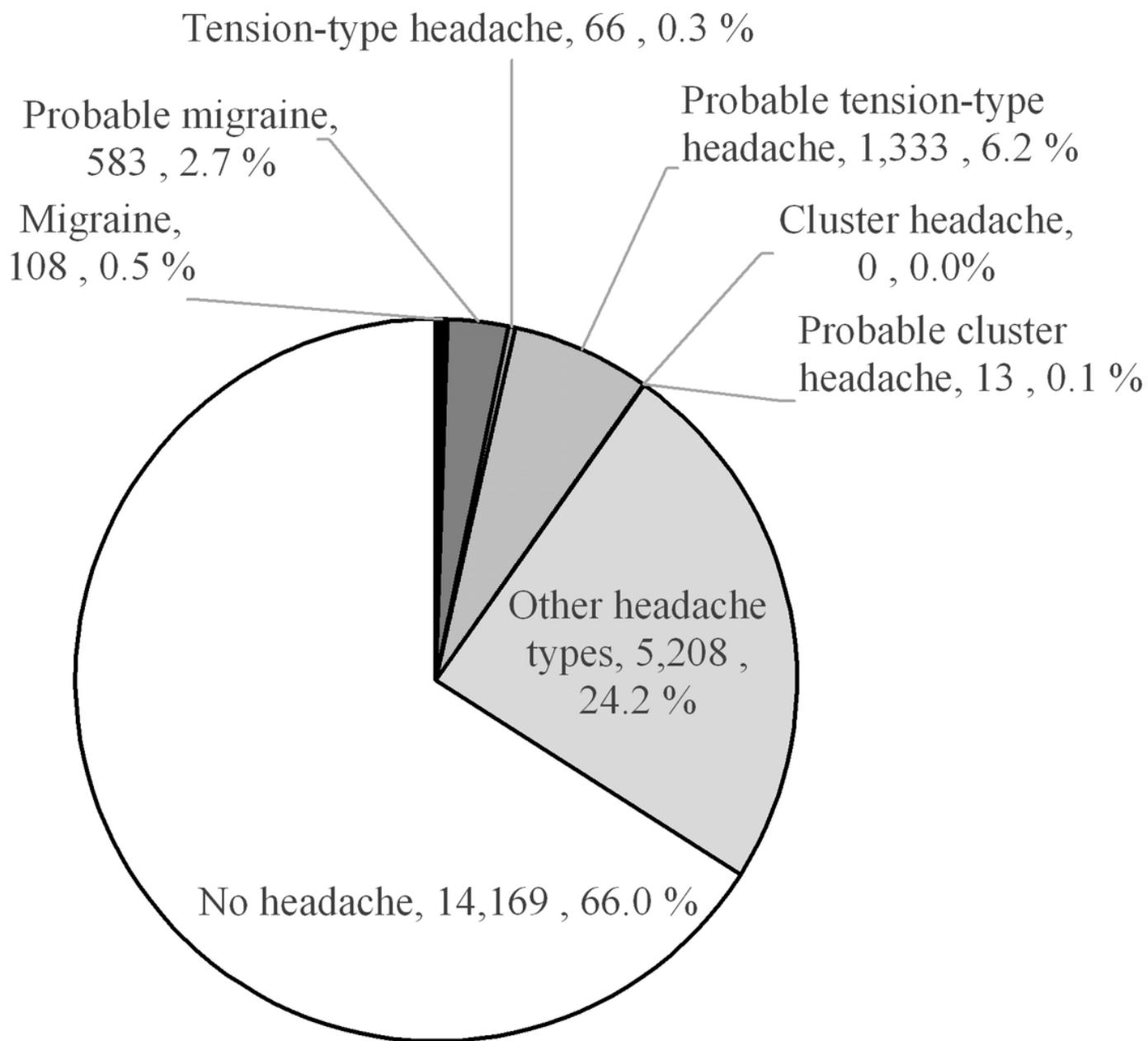


Figure 2

Prevalence of headaches

The prevalence of migraine and probable migraine is as shown in the figure above.

The prevalence of tension-type headache was 0.3% (69 patients), including concomitant probable migraine (3 patients); the prevalence of tension-type headache-suspected was 6.4% (1,372 patients), including

concomitant migraine (3 patients) and probable migraine (36 patients); the prevalence of cluster headache was 0% (0 patients); the prevalence of probable cluster headache was 0.1% (21 patients), including the concomitant migraine (2 patients) and probable migraine (6 patients).

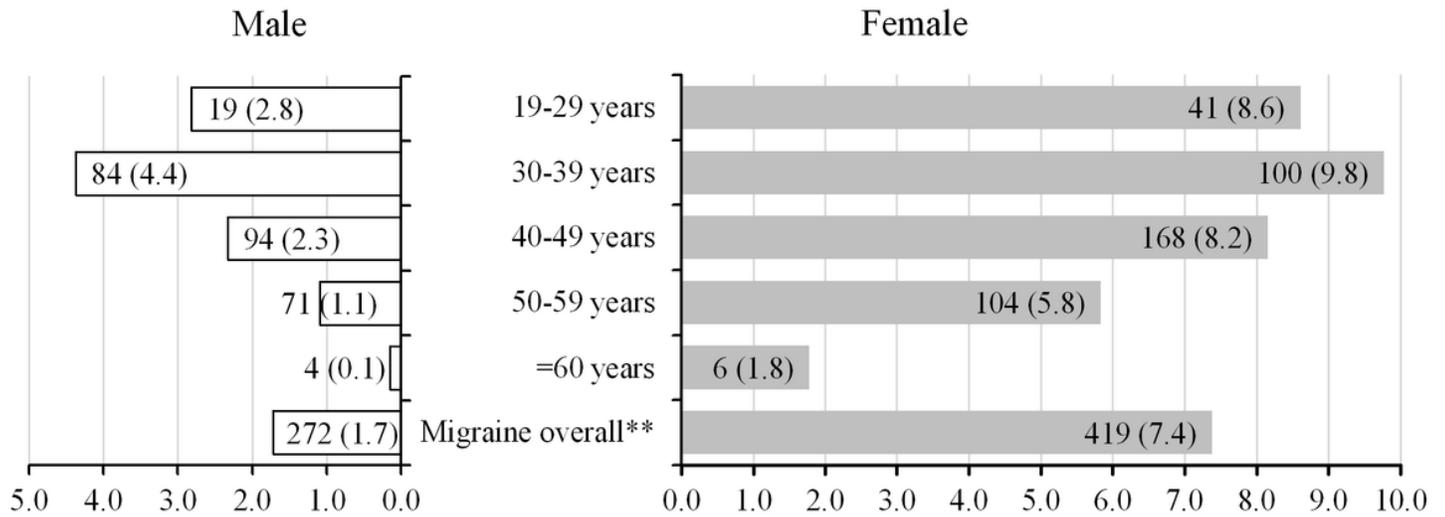


Figure 3

Prevalence* of migraine stratified by sex and age[†]

* Number and percentage with the number of same age and sex category was used as a denominator.

** Number of migraine overall in male is 272 and female is 419.

[†] Refer the summary of number of patients for each sex in Table 1.

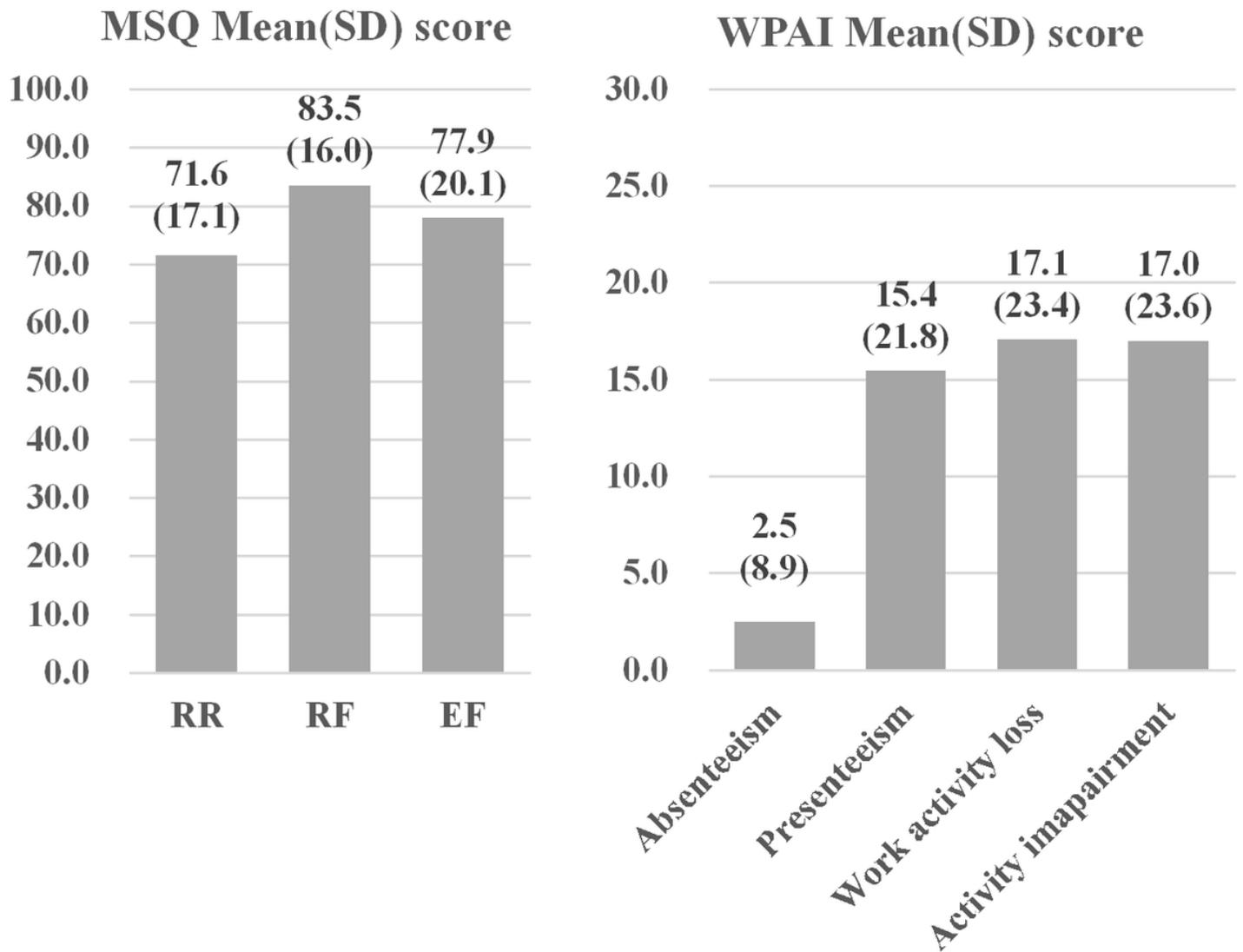


Figure 4

Domain scores of MSQv1.2 and WPAI in people with migraine (n=691).

Abbreviations: MSQ, Migraine-Specific Quality of Life Questionnaire; WPAI, Work Productivity and Activity Impairment Questionnaire; RR, role function—restrictive; RF, role function—preventive; EF, emotional function.

Supplementary Files

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