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## Factors influencing the use of over-the-counter drugs and health foods/supplements

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Over-the-counter (OTC) drugs and health foods/supplements are used as means of self-medication with the aim of preventing diseases and maintaining health. No reports have yet addressed the relationship between healthcare systems and self-medication. Here, we carried out a retrospective survey to identify healthcare system factors affecting OTC drug and health food/supplement usage. Patients hospitalized at Gifu Municipal Hospital between October 1, 2014 and March 31, 2015 were given a survey. The items surveyed were age, gender, disease, alcohol intake/smoking status, insurance classification, and medical pharmaceuticals, OTC drugs, and health foods/supplements used immediately before hospitalization. We performed multiple logistic regression analysis using OTC drugs and health foods/supplements as dependent variables with patient attributes, medical insurance, etc. as independent variables. A total of 5,965 patients were analyzed. OTC users comprised 2.6 % (156 people) of the total. The use of OTC drugs was significantly higher for females and alcohol consumers than in other categories. In contrast, the use of OTC drugs was significantly lower for participants in public expense/medical subsidy programs. Health foods/supplements were used by 4.0 % of all subjects (240 people); their use was significantly higher among females and users of medical pharmaceuticals. On the other hand, the use of health foods/supplements was significantly lower for smokers, users of the latter-stage elderly healthcare system, and users of public expense/medical subsidy programs.

### 1. Introduction

In recent years, there have been dramatic developments in Japanese healthcare, largely focused on advanced treatments, and very high healthcare standards are being maintained from an international perspective (Murray et al. 2000). However, with the ever worsening low birth rate and aging population in Japan, problems related to the increased need for diverse future healthcare needs, along with a rapid increase in social security expenses, have come to the fore (Ministry of Health, Labour and Welfare 2015). As such, there are concerns that the current system of healthcare is unsustainable—a situation described as the “Year 2025 Problem.” Based on this, in addition to short-term measures, medium/long-term measures are required. As an example of a medium/long-term policy, the Ministry of Health, Labor and Welfare in Japan has promoted the construction of a regional comprehensive care system for 2025 (Ministry of Health, Labour and Welfare 2016), and the “Healthcare 2035 Proposal Document” looks further into the future (Ministry of Health, Labour and Welfare 2015). This proposal document advocates for self-medication to reduce medical expenses and as a promotive and preventive measure for the health of citizens. According to the World Health Organization (WHO), self-medication is defined as the selection and use of medicines by individuals to treat self-recognized illnesses or symptoms (World Health Organization 1998), and one aspect of this is the use of over-the-counter (OTC) drugs and health foods/supplements. As part of a group of policies to promote the use of self-medication in Japan, a new “self-medication tax system” was deployed in 2017 (Ministry of Health, Labour and Welfare 2017). Under this system, individuals who take active measures to promote their health and prevent disease, such as having regular health check-ups, undergoing cancer examinations, and receiving

vaccinations, may receive an income tax exemption to cover the cost for purchasing specific OTC drugs.

The use of self-medication is also increasing overseas (Bennadi 2013). Correspondingly, there have been numerous reports on the use of OTC drugs and health foods/supplements targeting various groups (Brownie and Rolfe 2004; Dale et al. 2015; Er et al. 2008; Farina et al. 2014; Feinberg et al. 2017; Gardiner et al. 2007; Hassali et al. 2013; Luc et al. 2015; Radimer et al. 2004; Vitolins et al. 2000). In Japan, on the other hand, although there have been reports analyzing the use of health foods/supplements, virtually no studies have been conducted concerning the use of OTC drugs (Satoh et al. 2014). Additionally, although a relationship has been demonstrated between the self-pay ratio for medical expenses in Japan and self-medication (Umehara and Yamada 2012), no reports have yet investigated the correlation between the existing healthcare system and the use of self-medication. It is important to study this relationship to review the current healthcare system and construct a new system in accordance with the demands of future citizens. In this study, therefore, we conducted a retrospective survey to identify factors in the healthcare system that may affect the use of OTC drugs and health foods/supplements.

### 2. Investigations and results

#### 2.1. Identification of study subjects and the number of analyzed patients

A total of 6,033 patients were surveyed, of whom 5,965 remained after applying the exclusion criteria (Fig. 1). Of these, the OTC drug user group consisted of 156 people (2.6 %), while the health food/supplement group contained 240 (4.0 %). The types of OTC drugs and health foods/supplements used are shown in Table 1.

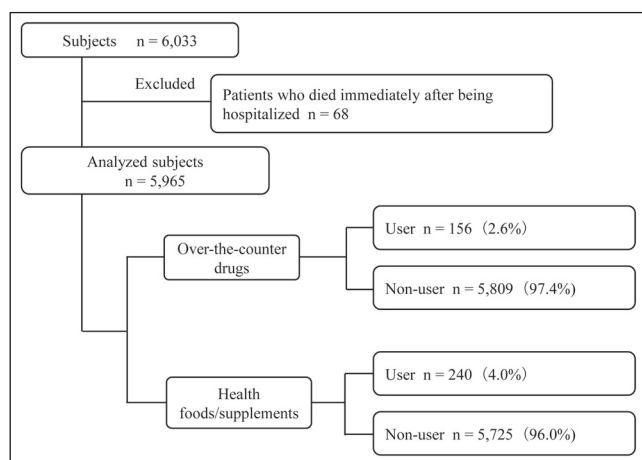


Fig. 1: Identification of study subjects

**2.2. Patient background and univariate analysis**

**2.2.1. OTC drugs**

Patient backgrounds and the results of univariate analysis for the OTC drug user and non-user groups are shown in Table 2. For the categories “female,” “alcohol consumer,” and “public expense/medical subsidy program,” significant differences were observed between the OTC drug user and non-user groups. In terms of diseases, there were significant differences between groups for “neoplasms,” “blood/hematopoietic disease and immune system disorders,” “mental and behavioral disorders,” “diseases of the nervous system,” “respiratory diseases,” “osteological and connective tissue diseases,” and “urogenital diseases.”

**2.2.2. Health foods/supplements**

The results of the univariate analysis for the health food/supplement user and non-user groups are shown in Table 3. Significant

**Table 1: Types of OTC drugs and health foods/supplements used**

A) OTC drugs	
Types	n (%)
Nutrient drinks	37 (23.7)
Constipation medicines	32 (20.5)
Gastrointestinal drugs	22 (14.1)
Cold medicines	19 (12.2)
Anti-allergen drugs	14 (9.0)
Eye drops	13 (8.3)
Antipyretic analgesics	12 (7.7)
Poultices	7 (4.5)
Smoking-cessation aids	3 (1.9)
Blood circulation-improving drugs	3 (1.9)
Weight-reducing drugs	3 (1.9)
Ointments	3 (1.9)
Throat sprays	2 (1.3)
Hematopoietic drugs	2 (1.3)
Motion sickness drugs	1 (0.6)
Nose drops	1 (0.6)
Urea creams	1 (0.6)
Unknown	6 (3.8)

B) Health foods/supplements	
Types	n (%)
Minerals	19 (7.9)
Garlic	18 (7.5)
Chondroitin	15 (6.3)
Green juice	12 (5.0)
Glucosamine	10 (4.2)
Herbal medicine	10 (4.2)
Chlorella	8 (3.3)
Euglena	7 (2.9)
Vitamins	6 (2.5)
Blueberries	6 (2.5)
Shark cartilage	5 (2.1)
Black vinegar	5 (2.1)
Açai	4 (1.7)
Chinese medicine	4 (1.7)
Spirulina	4 (1.7)
Dietary fibre	4 (1.7)
Agaricus	3 (1.3)
Ginkgo leaf	3 (1.3)
Nattokinase	3 (1.3)
Propolis	3 (1.3)
“Ochichi” royal jelly	3 (1.3)
Yeast extract	3 (1.3)
Folic acid	3 (1.3)
Amino acids	2 (0.8)
Omega-3 fatty acids	2 (0.8)
Gluconate	2 (0.8)
Coenzyme Q10	2 (0.8)
Nucleic acids	2 (0.8)
Reishi mushrooms	2 (0.8)
Sesamin	1 (0.4)
Royal jelly	1 (0.4)
Ginseng	1 (0.4)
Akadama	1 (0.4)
Unknown	51 (21.3)

differences were observed between the groups in the categories of “female,” “alcohol consumer,” “smoker,” “public assistance,” and “public expense/medical subsidy program.” In terms of diseases, differences between groups were observed for “infections and parasitic diseases,” “neoplasms,” “blood/hematopoietic disease and immune system disorders,” “mental and behavioural disorders,” “gastrointestinal diseases,” “skin and subcutaneous tissue diseases,” “osteological and connective tissue diseases,” and “injury, toxicity and effect of other external factors.”

**2.3. Multivariate analysis**

**2.3.1. OTC drugs**

A multivariate analysis was performed with “use of OTC drugs” as a dependent variable, and the 14 items with  $P < 0.25$  from the

**Table 2: Patient background and results of univariate analysis (OTC drugs)**

Background	Total (n = 5,965) (%)	User (n = 156) (%)	Non-user (n = 5,809) (%)	P
Female	2,577 (43.2)	109 (69.9)	2,468 (42.5)	<0.001*
65 years or over	3,820 (64.0)	105 (67.3)	3,715 (64.0)	0.447
Alcohol consumer	1,707 (28.6)	65 (41.7)	1,642 (28.3)	0.001*
Smoker	1,274 (21.4)	31 (19.9)	1,243 (21.4)	0.693
Main insurance				
Latter-stage elderly healthcare system	2,108 (35.3)	63 (40.4)	2,045 (35.2)	0.203
Public assistance	304 (5.1)	7 (4.5)	297 (5.1)	0.855
Public expense/medical subsidy program	1,115 (18.7)	17 (7.1)	1,102 (19.0)	<0.001*
Use of medical pharmaceuticals	4,760 (79.8)	120 (76.9)	4,640 (79.9)	0.364
Disease				
Certain infectious and parasitic diseases	985 (16.5)	29 (18.6)	956 (16.5)	0.512
Neoplasms	2,791 (46.8)	96 (61.5)	2,695 (46.4)	<0.001*
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	811 (13.6)	32 (20.5)	779 (13.4)	0.017*
Endocrine, nutritional and metabolic diseases	2,532 (42.4)	78 (50.0)	2,454 (42.2)	0.059
Mental and behavioural disorders	597 (10.0)	27 (17.3)	570 (9.8)	0.004*
Diseases of the nervous system	1,504 (25.2)	65 (41.7)	1,439 (24.8)	<0.001*
Diseases of the eye and adnexa	1,355 (22.7)	29 (18.6)	1,326 (22.8)	0.245
Diseases of the ear and mastoid process	507 (8.5)	20 (12.8)	487 (8.4)	0.058
Diseases of the circulatory system	3,436 (57.6)	85 (54.5)	3,351 (57.7)	0.460
Diseases of the respiratory system	2,032 (34.1)	67 (42.9)	1,965 (33.8)	0.021*
Diseases of the digestive system	3,783 (63.4)	101 (64.7)	3,682 (63.4)	0.801
Diseases of the skin and subcutaneous tissue	1,304 (21.9)	29 (18.6)	1,275 (21.9)	0.377
Diseases of the musculoskeletal system and connective tissue	2,554 (42.8)	91 (58.3)	2,463 (42.4)	<0.001*
Diseases of the genitourinary system	2,220 (37.2)	77 (49.4)	2,143 (36.9)	0.002*
Pregnancy, childbirth and the puerperium	139 (2.3)	1 (0.6)	138 (2.4)	0.272
Certain conditions originating in the perinatal period	39 (0.7)	0 (0.0)	39 (0.7)	0.626
Congenital malformations, deformations and chromosomal abnormalities	32 (0.5)	0 (0.0)	32 (0.6)	1.000
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	498 (8.3)	14 (9.0)	484 (8.3)	0.769
Injury, poisoning and certain other consequences of external causes	598 (10.0)	15 (9.6)	583 (10.0)	1.000

\* $P < 0.05$ 

univariate analysis as independent factors, including “female,” “alcohol consumer,” and “public expense/medical subsidy program.” The results of this analysis are shown in Fig. 2. The use of OTC drugs was significantly elevated for females [odds ratio (OR), 4.421; 95 % confidence interval (CI), 3.035-6.440;  $P < 0.001$ ], alcohol consumers [OR, 3.075; 95 % CI, 2.196-4.406;  $P < 0.001$ ], patients with neoplasms [OR, 1.460; 95 % CI, 1.029-2.072;  $P = 0.034$ ], patients with diseases of the musculoskeletal system and connective tissue [OR, 1.729; 95 % CI, 1.208-2.475;  $P = 0.003$ ], and patients with diseases of the genitourinary system [OR, 1.402; 95% CI, 1.002-1.961;  $P = 0.049$ ]. On the other hand, OTC drug use was significantly reduced for those enrolled in a

public expense/medical subsidy program [OR, 0.361; 95% CI, 0.200-0.648;  $P = 0.001$ ] and patients with diseases of the eye or adnexa [OR, 0.593; 95% CI, 0.387-0.908;  $P = 0.016$ ].

### 2.3.2. Health foods/supplements

Next, a multivariate analysis was performed with “use of health foods/supplements” as a dependent variable and 18 items as independent variables, including “female,” “alcohol consumer,” and “smoker,” which all had  $P < 0.25$  in the univariate analysis. The results of the analysis are shown in Fig. 3. The use of health foods/supplements was significantly higher among females [OR, 1.485; 95 % CI, 1.119-1.972;  $P = 0.006$ ], users of medical pharmaceuticals

**Table 3: Patient background and results of univariate analysis (health foods/supplements)**

Background	Total (n = 5,965) (%)		User (n = 240) (%)		Non-user (n = 5,725) (%)		P
Female	2,577	(43.2)	122	(50.8)	2,455	(42.9)	0.017*
65 years or over	3,820	(64.0)	168	(70.0)	3,652	(63.8)	0.054
Alcohol consumer	1,707	(28.6)	48	(20.0)	1,659	(29.0)	0.003*
Smoker	1,274	(21.4)	29	(12.1)	1,245	(21.7)	<0.001*
Main insurance							
Latter-stage elderly healthcare system	2,108	(35.3)	74	(31.0)	2,034	(35.5)	0.167
Public assistance	304	(5.1)	21	(8.8)	283	(4.9)	0.015*
Public expense/medical subsidy program	1,115	(18.7)	17	(7.1)	1,098	(19.2)	<0.001*
Use of medical pharmaceuticals	4,760	(79.8)	219	(91.3)	4,451	(79.3)	<0.001*
Disease							
Certain infectious and parasitic diseases	985	(16.5)	72	(30.0)	913	(15.9)	<0.001*
Neoplasms	2,791	(46.8)	147	(61.3)	2,644	(46.2)	<0.001*
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	811	(13.6)	45	(18.8)	766	(13.4)	0.021*
Endocrine, nutritional and metabolic diseases	2,532	(42.4)	102	(42.5)	2,430	(42.4)	1.000
Mental and behavioural disorders	597	(10.0)	14	(5.8)	583	(10.2)	0.027*
Diseases of the nervous system	1,504	(25.2)	56	(23.3)	1,448	(25.3)	0.544
Diseases of the eye and adnexa	1,355	(22.7)	57	(23.8)	1,298	(22.7)	0.694
Diseases of the ear and mastoid process	507	(8.5)	26	(10.8)	481	(8.4)	0.193
Diseases of the circulatory system	3,436	(57.6)	141	(58.8)	3,295	(57.6)	0.739
Diseases of the respiratory system	2,032	(34.1)	83	(34.6)	1,949	(34.0)	0.889
Diseases of the digestive system	3,783	(63.4)	172	(71.7)	3,611	(63.1)	0.008*
Diseases of the skin and subcutaneous tissue	1,304	(21.9)	90	(37.5)	1,214	(21.2)	<0.001*
Diseases of the musculoskeletal system and connective tissue	2,554	(42.8)	120	(50.0)	2,434	(42.5)	0.024*
Diseases of the genitourinary system	2,220	(37.2)	92	(38.3)	2,128	(37.2)	0.733
Pregnancy, childbirth and the puerperium	139	(2.3)	2	(0.8)	137	(2.4)	0.183
Certain conditions originating in the perinatal period	39	(0.7)	0	(0.0)	39	(0.7)	0.406
Congenital malformations, deformations and chromosomal abnormalities	32	(0.5)	0	(0.0)	32	(0.6)	0.639
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	498	(8.3)	17	(7.1)	481	(8.4)	0.552
Injury, poisoning and certain other consequences of external causes	598	(10.0)	45	(18.8)	5530	(9.7)	<0.001*

\* $P < 0.05$ 

[OR, 2.413; 95 % CI, 1.489-3.910;  $P < 0.001$ ], patients with certain infectious and parasitic diseases [OR, 1.762; 95 % CI, 1.290-2.406;  $P < 0.001$ ], patients with diseases of the skin and subcutaneous tissue [OR, 1.742; 95 % CI, 1.289-2.356;  $P < 0.001$ ], and those with injuries, poisoning or other consequences of external causes [OR, 2.409; 95 % CI, 1.688-3.437;  $P < 0.001$ ]. In contrast, health foods/supplements were used less often by smokers [OR, 0.577; 95 % CI, 0.378-0.881;  $P = 0.011$ ], users of the latter-stage elderly healthcare system [OR, 0.630; 95 % CI, 0.454-0.875;  $P = 0.006$ ], users of public expense/medical subsidy programs [OR, 0.306; 95 % CI, 0.183-0.511;  $P < 0.001$ ], and patients with mental and behavioral disorders [OR, 0.517; 95 % CI, 0.294-0.909,  $P = 0.022$ ].

### 3. Discussion

In this study, we retrospectively investigated the use of OTC drugs and health foods/supplements, and used a multivariate analysis to

identify factors impacting the use of OTC drugs and health foods/supplements among hospital patients.

In terms of OTC drug use, females had a significantly higher usage rate than males. The main objectives of using OTC drugs were to prevent disease onset at the illness/pre-disease stage, and as early treatment after the onset of symptoms or to prevent their exacerbation, and so OTC drugs are often used after symptoms have occurred. Symptoms applicable to illness/pre-disease stages such as constipation or migraine tend to be common for females. Additionally, symptoms specific to women, such as menstrual pains and menopause, are also considered to be factors contributing to their high usage of OTC drugs.

Similarly, alcohol users had a significantly higher usage of OTC drugs than non-drinkers. One explanation is that the instructions accompanying OTC gastrointestinal drugs frequently mention their effectiveness for preventing heartburn or hangovers after

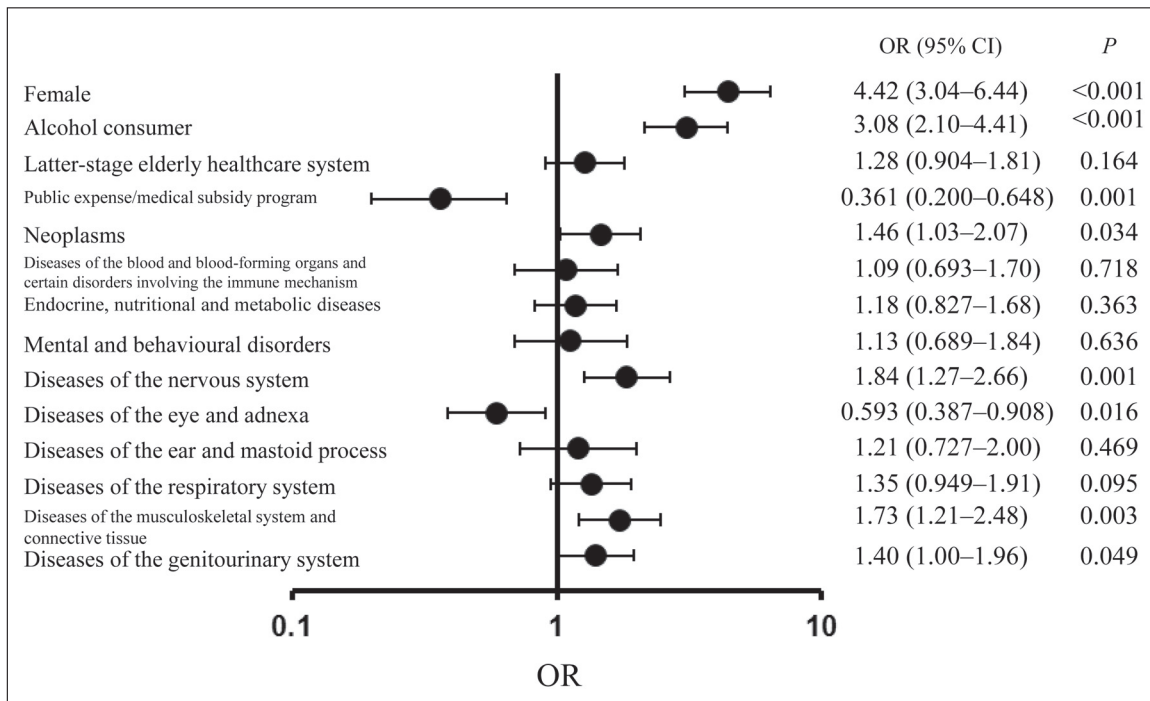


Fig. 2: Results of multivariate analysis (over-the-counter drugs) OR, odds ratio; CI, confidence interval

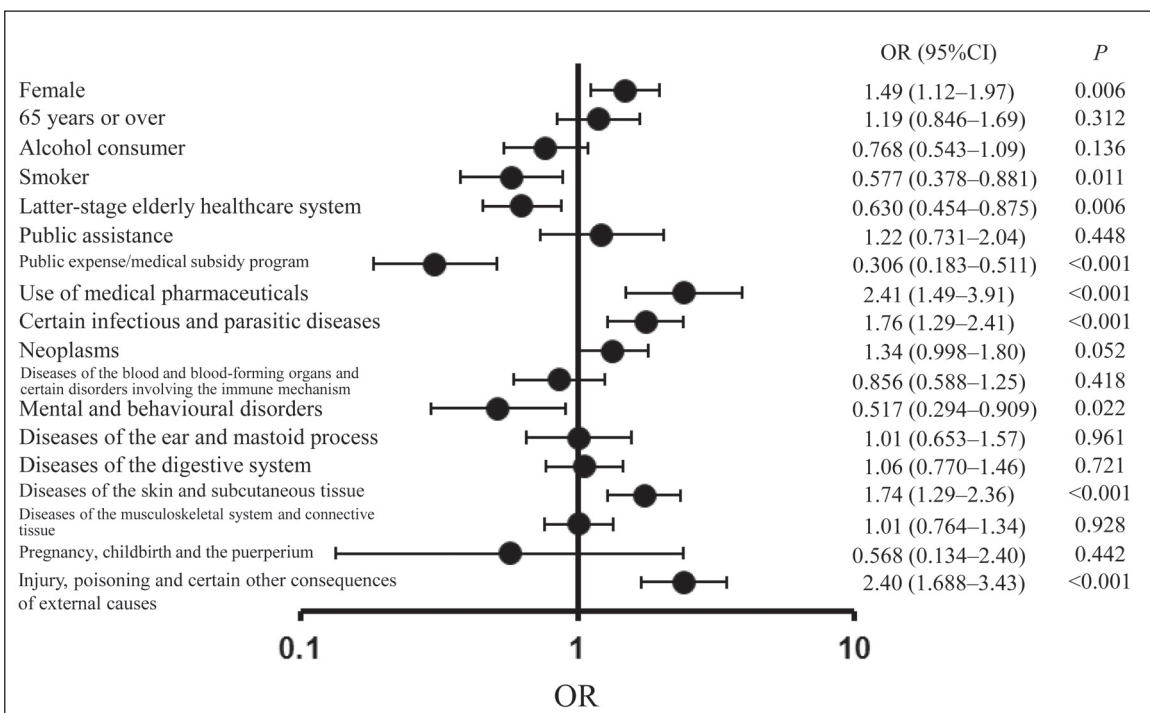


Fig. 3: Results of multivariate analysis (health foods/supplements) OR, odds ratio; CI, confidence interval

drinking alcohol, and there are other products recommended as preventative measures to be taken before drinking alcohol. These factors are thought to contribute to the high usage of OTC drugs, such as gastrointestinal drugs, by alcohol consumers. On the other hand, the use of OTC drugs was significantly lower in those receiving payments from public expense/medical subsidy programs. For patients with specific diseases considered to be incurable, patients with disabilities, and paediatric patients, the government or local authority is responsible for all or some of their medical fees, in the form of a public expense/medical subsidy. According to a 2012 report by Umehara et al., the demand for

medical services decreases and that for self-medication increases as the self-pay rate increases (Umehara and Yamada 2012). The self-pay rate, based on public expense/medical subsidy systems, may differ depending on the local government body or income level. A decrease in the self-pay rate under these systems may encourage patients to receive treatment from medical institutions, which may be a factor in the suppressing use of self-medication. Additionally, a significant difference in OTC drug use was seen among patients with neoplasms, eye or appendage diseases, osteological and connective tissue diseases, and urogenital diseases. There are no past reports on the correlations between OTC drug

use and such diseases; hence, further investigation is required moving forward.

For health foods/supplements, the usage rate was particularly high among females and patients using medical pharmaceuticals. High usage of health foods/supplements by women has been previously reported, both domestically and overseas (Homma et al. 2007; Imai et al. 2006; Luc et al. 2015; Mibu et al. 2012; Nakade et al. 2010; Radimer et al. 2004; Sato et al. 2011; Satoh et al. 2014; Stewart et al. 1985). Similarly, it has been reported that the usage of health foods/supplements tends to be high among those using medical pharmaceuticals, but the extent of this usage differs according to the number and type of pharmaceuticals used (Brownie and Rolfe 2004; Farina et al. 2014; Gardiner et al. 2007). While some health foods/supplements have been shown to be effective in preventing diseases, drug interactions with medical pharmaceuticals, due to the inhibition of metabolizing enzymes, have been reported. Depending on the specific pharmaceutical, health care providers may provide instructions regarding the use of health foods/supplements. In this study we did not investigate the number or category of medical pharmaceuticals, but as in preceding studies, we found that the usage of health supplements was significantly higher for users of medical pharmaceuticals.

On the other hand, smokers and those receiving payments under the latter-stage elderly healthcare system or public expense/medical subsidy programs had significantly lower usage rates of health foods/supplements. In terms of smoking, similar results were obtained as in preceding studies (Lyle et al. 1998; Radimer et al. 2004; Sato et al. 2011; Wada et al. 2003); it is thought that because non-smokers are more health conscious than smokers, they are more interested in self-medication using health foods/supplements.

Latter-stage elderly healthcare systems are essentially medical insurance programs aimed at those over the age of 75. Whereas the self-pay ratio for those up to the age of 74 is approximately 20 or 30 %, the self-pay ratio for those in the latter-stage elderly healthcare system is only 10 %. From this, we hypothesize that the usage rate of health foods/supplements is low among users of the latter-stage elderly healthcare system because they have greater motivation to receive treatment from medical institutions, and so are correspondingly less likely to use health foods/supplements. Finally, in terms of disease, significant differences in health food/supplement usage was seen in patients with infections and parasitic diseases, mental and behavioral disorders, skin and subcutaneous tissue complaints, and injuries, toxicity, and the effects of other external factors. Previous studies have also reported differences in the usage of health foods/supplements depending on a patient's disease status, and the usage of such products tends to be high among patients with malignant tumours, among other conditions (Farina et al. 2014; Takahashi et al. 2000). In the present study, the diseases for which significant differences were seen differed from those of preceding studies, and we propose that further investigation is required for these diseases.

The use of big data in healthcare has flourished in recent years. In Japan, large databases have been compiled and published by administrative institutions containing receipt and specific health check information. However, it is difficult to survey citizens nationally in terms of their usage of OTC drugs and health foods/supplements, as information has not been collected on a nationwide scale by administrative institutions. Large-scale studies on the use of health foods/supplements in Japan include surveys from the National Cancer Center of Japan, as a part of "research to establish evidence to benefit health maintenance and improvement including cancer prevention based on multipurpose cohort studies" (Ishihara et al. 2003). However, there are very few reports of this scale compared to the number of overseas studies (Feinberg et al. 2017; Luc et al. 2015; Radimer et al. 2004). The present study assessed 5,965 subjects, and hence had a large scale compared to previous Japanese studies. Therefore, our results are significant for understanding the state of self-medication in Japan.

The limitations of this study include the fact that it was limited to one general hospital in a single region, and it was a retrospective survey aimed at hospitalized patients.

In this study, we identified factors affecting the use of OTC drugs and health foods/supplements by hospitalized patients. OTC drugs were frequently used by females and alcohol consumers, while low use was observed for members of public expense/medical subsidy programs. As for health foods/supplements, factors promoting their use included whether the users were female or took medical pharmaceuticals, while lower use was noted in smokers, users of the latter-stage elderly healthcare system, and users of public expense/medical subsidy programs. It is essential to elucidate the correlations between self-medication and current healthcare systems, such as latter-stage elderly healthcare and public expense/medical subsidy programs, to construct a health care system that meets future demands in Japan.

## 4. Experimental

### 4.1. Subjects

This survey covered patients 16 years of age or older who were hospitalized at Gifu Municipal Hospital between October 1, 2014 and March 31, 2015. The exclusion criteria covered patients who died immediately after being hospitalized.

### 4.2. Survey items

The items surveyed were age, gender, disease, alcohol intake/smoking status, insurance classification, current diseases, disease history during hospitalization, drug history during hospitalization, and the use of OTC drugs and health foods/supplements. The survey was performed retrospectively using electronic charts. Diseases and past disease history during hospitalization were classified based on the broad categories described in the "International Statistical Classification of Diseases and Related Health Problems, 10th Revision" (ICD-10).

### 4.3. Statistical analysis

For statistical analyses, we used IBM SPSS statistics 24.0J (Armonk, New York). For the survey items, we performed a univariate analysis (Fisher's exact test) to investigate the differences between users and non-users of OTC drugs. With the use of OTC drugs as a dependent variable, we used factors with  $P < 0.25$  from the univariate analysis as independent variables for multiple logistic regression analysis. For each factor, differences were considered significant if  $P < 0.05$ . We then performed the same univariate and multivariate analyses for the use of health supplements.

### 4.4. Ethical considerations

This study was carried out with the approval of the Ethics Committees of Gifu Pharmaceutical University (approval no. 28-3(2016)) and Gifu Municipal Hospital (approval no. 239).

Conflict of interest: Hitomi Teramachi belongs to Laboratory of Community Health Pharmacy endowed by Welcia Yakkyoku Co., Ltd.

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