

Original Article

Anti-obesity drug use before professional treatment in Taiwan

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Between July 2004 and June 2005, a cross-sectional study was performed to determine the prevalence and patterns of anti-obesity medicine use among subjects seeking obesity treatment in Taiwan. Eighteen obesity outpatient clinics were selected via a random stratified sampling method and 1,060 first-visit clients (791 females and 269 males) aged above 18 years were enrolled and then completed a self-administered questionnaire. The prevalence of anti-obesity medicine use was 50.8%; more females than male used anti-obesity medicines (53.6% vs. 42.4%). Of the 1,060 subjects, 17.1% had used orlistat, 21.1% had taken sibutramine, and 18.3% had utilized unproven drugs such as cocktail therapy and other anti-obesity drugs. Furthermore, 23.6% and 22.4% of subjects indicated that they concurrently used Chinese herbal preparations and dietary supplements, respectively. Logistic regression analyses demonstrated that the odds ratio (OR) for anti-obesity medicine use was substantially higher in females (OR, 1.9; 95% CI, 1.3-2.6), those aged 18-24 years (OR, 1.6; 95% CI, 1.0-2.6), those with a body mass index (BMI) >35 kg/m² (OR, 3.4; 95% CI, 2.1-5.7) and respondents concurrently using Chinese herbal preparations (OR, 1.7; 95% CI, 1.2-2.4) and dietary supplements (OR, 2.2; 95% CI, 1.6-3.1). In conclusion, the prevalence of anti-obesity drugs use is high among Taiwanese adults before they seek obesity treatment. Young, obese females, and those who had taken Chinese herbal preparations/dietary supplements had a high likelihood to report using anti-obesity medicines. Use of unproven weight-loss drugs is common and warrants further investigation.

Key Words: Orlistat, sibutramine, dietary supplement, off-label drugs, drug utilization

INTRODUCTION

Considerable evidence indicates that obesity is associated with numerous diseases and metabolic abnormalities, such as type 2 diabetes, hypertension, dyslipidemia, coronary heart disease, and certain cancers,^{1,2} many of which have a high morbidity and mortality rates. Notably, these diseases and conditions can be reduced substantially by moderate weight reduction.^{3,4} For the sake of health and any reason, The Behavioral Risk Factor Surveillance System (BRFSS) report identified a significant increase in the dieting population in the United States.^{5,6}

Consensus for obesity treatment is that clinical therapy should begin with lifestyle changes that focus on behavioral modification, diet, and exercise.⁷ When lifestyle modification schemes are unsuccessful, drug therapy is an attractive option. Anti-obesity drug use has become increasingly common in the last 30 years. Leavy and Heaton⁸ found that 20% of females and 11% of males reported using weight control products including weight-loss drugs, dietary supplements, and laxatives. Khan, who utilized 1998 BRFSS data, estimated that 4.6 million American adults used

prescription weight-loss pills between 1996 and 1998.⁹ Blank, who also analyzed 1998 BRFSS data, identified that 10.2% of obese women and 3.1% of obese men used prescribed weight-loss medications between 1996 and 1998.¹⁰ The U.S. Department of Health and Human Services estimated that between 1995 and 1997, 1.2-4.7 million residents in the U.S. took fenfluramine or dexfenfluramine for weight loss.¹¹ Stafford *et al.*¹² determined that 2.5 million Americans took anti-obesity medications in 1997, a 4-fold increase over the figure for the previous 2 years. Furthermore, Blanck *et al.*¹³ identified that 7% of BRFSS respondents used nonprescription weight-loss products, 2%

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reported using phenylpropanolamine (PPA), and 1% used ephedra between 1996 and 1998. However, most anti-obesity drugs, such as fenfluramine-phenentermine (fenphen),^{11,14} PPA,^{15,16} and ephedra,¹⁷ have been withdrawn from the market due to serious adverse effects. Currently, only sibutramine and orlistat are FDA-approved for long-term obesity treatment. It is also rumored that unproven drugs, including off-label drugs¹⁸ are taken by certain number of obese subjects. To our knowledge, few studies have investigated the prevalence and use patterns of legally used anti-obesity drugs and unproven drugs in the general population.

Obesity is an increasing problem in the Asia-Pacific region as well as developed countries.¹⁹⁻²² In Taiwan, like other developed nations, only orlistat and sibutramine are approved for long-term obesity treatment. However, some physicians prescribe a so-called "cocktail therapy" comprising several off-labeled drugs¹⁸ to treat obesity, such as thyroxine, PPA, metformin, diuretics, etc. Moreover, use of Chinese herbal preparations and dietary supplements is prevalent among specific populations. Limited data exists on prevalence and patterns of weight-loss drug use^{10, 23} and the behaviors of those using prescription weight-loss medications in Taiwan and worldwide. This nation-wide survey assessed behavioral characteristics associated with use of weight-loss drugs in Taiwan.

MATERIALS AND METHODS

Obesity Clinic sampling

The 1200 members of the Taiwan Medical Association for the Study of Obesity (TMASO) encompasses almost all accredited obesity clinics, ranging from tertiary care medical centers to primary care centers in Taiwan. In this study, 18 clinics specializing in obesity treatment were selected from the TMASO member list using a random stratified sampling method based on the proportion of institutional levels and geographic regions.

Subjects

Between July 2004 and June 2005, a randomly selected 3-month period was chosen in which each clinic collated all new patients aged >18 years, who sought obesity treatment for any reason. Of the 1,296 respondents, those with incomplete information regarding anti-obesity drug use (n=109), had a missing (n=98) or unreasonable weight (n=17) or height (n=12) were excluded. Finally, 1,060 respondents were enrolled for final analysis. This study was approved by the Committee of Institutional Human Subject Review Board of Taipei Medical University-Wan Fang Hospital, Taiwan.

Questionnaires

Under the assistance of a well-trained instructor, a self-administered questionnaire was given to each subject. The questionnaire was divided into the following three sections: (1) a socio-demographic section for recording data such as age, gender, marital status, education level, smoking and drinking habits, monthly income, etc.; (2) a weight-loss history section for the previous year; and, (3) a section for weight-loss products used during the previous year. The questionnaires asked respondents, "In the past year, have you taken any pills, herbal preparations,

or dietary supplements for weight loss?" If respondents replied positively to pills, then they were asked, "Which of the following weight-loss drugs did you take: (1) orlistat, (2) sibutramine, (3) cocktail therapy, (4) others or unknown?" Body mass index (BMI) (kg/m^2) was calculated as weight in kilograms divided by height in meters squared. The following BMI categories were utilized: <24, normal weight; 24–26, overweight; ≥ 27 , obese.²²

Statistical analysis

Statistical analyses were performed using SPSS for Windows version 12.0 (SPSS, Inc., Chicago, IL, USA). Prevalence data for anti-obesity drug use are presented as percentages (%). Chi-square tests were applied for univariate analysis. Multiple logistic regression analyses were performed for multivariate analysis to assess any correlation between anti-obesity drug use and demographic variables (gender, age, and educational level), current BMI (normal weight, overweight, and obese), and concurrent use of anti-obesity herbal drugs and dietary supplements. Multiple logistic regression analyses were also utilized to estimate the adjusted odds ratios (ORs) for different drugs. A value of $p < 0.05$ was considered statistically significant.

RESULTS

Basic characteristics of respondents and prevalence

Table 1 shows the basic demographic data and that for prevalence of anti-obesity medicine use among all respondents. Of the 1,060 respondents, 53.7% of respondents (569/1,060) were college educated and 51.5% (546/1,060) were married. Sixteen percent (172/1,060) of respondents had normal weight, 22% (231/1,060) were overweight and 62% (657/1,060) were obese. Overall prevalence of anti-obesity drug use was 50.8% (538/1,060). Significant differences exist between people who attended primary and secondary, and primary and tertiary health care institutional levels (Chi-square test, $p < 0.05$), and no difference exists between secondary and tertiary levels. Participants at the primary level had a lower rate of anti-obesity medicine use than those from secondary and tertiary levels. Females and young adults (25–34 years) (53.6%; 58.9%) were most likely to use anti-obesity drugs. Those with senior high school diplomas or higher were more likely to use anti-obesity drugs than those with less education ($p = 0.02$). Anti-obesity drug use increased markedly as BMI increased; the highest prevalence was for both genders with a BMI $\geq 35 \text{ kg}/\text{m}^2$. Anti-obesity drug use was also common among singles (54.7%; 115/464) and less common among those with high monthly incomes (44.9%; 61/136). In this study, 1,005 participants reported their co-morbidities. Two-fifths (39.1%) reported having at least one obesity-related co-morbidity, such as hypertension (16.2%), hyperlipidemia (13.1%), gout and hyperuricemia (10.9%), diabetes (7.1%), or obstructive sleep apnea (4.9%). The reasons why they used anti-obesity medicines (multiple choices) were for health (94%), improved appearance (57%), asked by spouse and friend (26%), and/or to gain employment (20%).

Table 1. Prevalence of anti-obesity drug use presented by demographic characteristics of 1,060 new patients of 18 obesity special clinics in Taiwan

	All (n=1,060)				Women (n=791)				Men (n=269)			
	No. of subjects	No. of drug user	Prevalence (%)	<i>p</i>	No. of subjects	No. of drug user	Prevalence (%)	<i>p</i>	No. of subjects	No. of drug user	Prevalence (%)	<i>p</i>
Age, year				<0.01				<0.01				0.73
18~24	196	98	50.0		134	71	53.0		62	27	43.5	
25~34	331	195	58.9		244	156	63.9		87	39	44.8	
35~44	268	144	53.7		209	118	56.5		59	26	44.1	
≥45	265	101	38.1		204	79	38.7		61	22	36.1	
Body mass index, kg/m ²				<0.01				<0.01				<0.01
<24	172	70	40.7		160	67	41.9		12	3	25.0	
24~26	231	105	45.5		197	96	48.7		34	9	26.5	
27~29	226	118	52.2		174	99	56.9		52	19	36.5	
30~34	256	130	50.8		158	91	57.6		98	39	39.8	
≥35	175	115	65.7		102	71	69.6		73	44	60.3	
Marital status				0.05				0.02				0.18
Unmarried	464	254	54.7		326	192	58.9		138	62	44.9	
Married	546	257	47.1		419	205	48.9		127	52	40.9	
Others	50	27	54.0		46	27	58.7		4	1	25.0	
Educational level				0.02				<0.01				0.71
≤ senior high school	148	63	42.6		129	54	41.9		19	9	47.4	
Senior high school	343	192	56.0		268	158	59.0		75	34	45.3	
≥ College/University	569	273	49.7		394	212	53.8		175	71	40.6	
Monthly income, NT dollar				<0.01				<0.01				0.54
≤10,000	260	114	43.8		205	93	45.4		55	21	38.2	
10,001-30,000	358	190	53.1		285	160	56.1		73	30	41.1	
30,001-50,000	253	147	58.1		174	108	62.1		79	39	49.4	
≥50,001	136	61	44.9		76	37	48.7		60	24	40.0	

p value for χ^2 test: comparison between each category

Table 2. One-year prevalence (%) of anti-obesity products use among 1,060 new patients

Name	All (n=1,060)		Women (n=791)		Men (n=269)		<i>p</i> value for χ^2 test
	No. of drug user	Prevalence (%)	No. of drug user	Prevalence (%)	No. of drug user	Prevalence (%)	
Anti-obesity drug	538	50.8	424	53.6	114	42.4	<0.01
Proven drug	339	32.0	259	32.7	80	29.7	0.41
Orlistat	181	17.1	132	16.7	49	18.2	0.31
Sibutramine	224	21.1	181	22.9	43	16.0	<0.01
Unproven drug	194	18.3	167	21.1	27	10.0	<0.01
Cocktail therapy	90	8.5	76	9.6	14	5.2	0.14
Others/unknown	128	12.1	113	14.3	15	5.6	<0.01
Herbal preparations	251	23.6	208	26.2	43	16.0	<0.01
Dietary supplements	237	22.4	198	25.0	39	14.5	<0.01

Prevalence of use of specific anti-obesity drug

Although apparently not completely followed, sibutramine and orlistat should only be obtained with a doctor's prescription in Taiwan. Of the 1060 respondents, 339 (32%) had used at least 1 legal anti-obesity drug for weight loss, 181 (17.1%) used orlistat and 224 (21.1%) used sibutramine. Notably, 194 (18%) respondents had used unproven drugs for weight loss: cocktail therapy, 90 (8.5%); and, others/unknown, 128 (12.1%). 251 (24 %) had tried Chinese herbal preparations and 237 (22.4%) had used dietary supplements. Notably, females used

sibutramine, unproven drugs, and others/unknown drugs significantly more than males ($p<0.01$). Females were also more likely than males to use Chinese herbal preparations and dietary supplements ($p<0.01$) (Table 2).

Pattern of anti-obesity drug use

Multiple logistic regression analyses demonstrated that after adjusting for smoking, drinking, monthly income, educational level and marital status, females reported more anti-obesity drug use than males with an OR of 1.9 (95% confidence interval (CI), 1.3–2.6). Compared with

Table 3. Adjusted odds ratio and 95% confidence interval of any use of anti-obesity drug in the previous year among people seeking obesity treatment (N = 1,060)

Characteristic	All drugs		orlistat		sibutramine		cocktail therapy		others or unknown	
	AOR	95% CI	AOR	95% CI	AOR	95% CI	AOR	95% CI	AOR	95% CI
Gender (female vs. male)	1.9	1.3-2.6	0.8	0.6-1.3	1.6	1.0-2.4	2.0	1.0-3.8	3.1	1.7-5.7
Age, year										
18-24 (n=196)	1.6	1.0-2.6	0.5	0.3-1.0	2.0	1.0-3.8	2.1	0.7-6.3	1.8	0.7-4.2
25-34 (n=331)	1.1	0.7-1.7	0.6	0.3-1.2	0.7	0.4-1.3	1.0	0.5-2.2	0.7	0.3-1.3
35-44 (n=268)	0.8	0.6-1.3	0.8	0.5-1.5	0.9	0.6-1.5	0.5	0.3-1.1	0.6	0.3-1.2
≥45 (n=265)	1.0		1.0		1.0		1.0		1.0	
BMI, kg/m ²										
<24 (n=172)	1.0		1.0		1.0		1.0		1.0	
24-26 (n=231)	1.7	1.1-2.7	1.3	0.8-2.3	1.7	1.0-2.7	1.5	0.7-3.0	1.1	0.6-2.0
27-29 (n=226)	1.9	1.2-3.1	1.0	0.6-1.7	1.6	1.0-2.7	1.4	0.7-3.0	2.5	1.3-4.9
30-34 (n=256)	2.8	1.7-4.5	1.6	0.9-2.9	2.2	1.3-3.7	1.5	0.7-3.2	1.8	0.9-3.4
≥35 (n=175)	3.4	2.1-5.7	2.2	1.1-4.3	1.7	1.0-3.0	2.2	0.9-5.1	2.2	1.1-4.4
Use of herbal preparations	1.7	1.2-2.4	1.9	1.3-2.8	1.2	0.8-1.8	1.7	1.0-2.8	1.7	1.1-2.7
Use of dietary supplements	2.2	1.6-3.1	2.0	1.4-3.0	2.3	1.6-3.3	2.1	1.3-3.4	1.7	1.1-2.6

Initial variables include gender, age, BMI, use of herbal drug, use of dietary supplement, education level, marital status, monthly income, smoking and drinking habit

subjects with normal weight, the ORs for anti-obesity drug use were 1.7, 1.9, 2.8, and 3.4 times higher among those who were overweight, obese I, obese II, and morbidly obese, respectively. The likelihood of anti-obesity drug use was 1.6 times higher among those aged 18–24 years than those aged >45 years. Those using Chinese herbal preparations and dietary supplements in the previous year had ORs of 1.7 and 2.2 for anti-obesity drug use as compared with those who did not use these products. (Table 3)

Multiple logistic regression analyses, applied to evaluate use patterns among those who had taken specific anti-obesity drugs, showed that analytical results were similar for overall anti-obesity drug use. The young (aged 18–24 years) and female groups, and those with a BMI >24 used significantly more sibutramine than their reference groups. The young group used orlistat less frequently than those aged >45 years. Females used cocktail therapy and others/unknown drugs more than males. Females were 3.1 times more likely than males to use other or unknown weight-loss products. Those using Chinese herbal preparations and dietary supplements in the previous year were 1.7–2.3 times more likely to use specific anti-obesity drugs than their counterparts (Table 3).

DISCUSSION

This is the first study providing comprehensive data on the prevalence of, and use patterns for, anti-obesity drug use in Taiwan. In this outpatient clinic-based study of patients before their seeking obesity treatment, 50.8% subjects had used anti-obesity drugs, of which females, young adults and obese subjects were the most frequent users. In a U.S. population-based study, Khan *et al.*²³ indicated that the 2-year prevalence for weight-loss drug use was 2.5% (4.6 million adults). As this is an obesity

clinic-based survey, the prevalence of anti-obesity drug use is likely substantially higher than that in a population-based study.^{10,23}

As in this study, not all clients requesting obesity treatment were overweight or obese.^{6,23} In this study, 38% of all respondents primarily females did not meet the criterion for pharmacotherapy (BMI ≥ 27kg/m²) proposed by National Institute of Health.²⁴ Females were 2 times more likely than males to use drugs for weight loss. Additionally, females in each BMI category, except for those with a BMI >35, used more anti-obesity drugs than males in this study. Khan *et al.*²³ indicated that females are 4 times more likely than males to report weight-loss drug use. Blanck *et al.*¹³ also observed that females were 5 times more likely than males to have taken prescription weight-loss drugs.²⁵ In a population-based study, females were almost 9 times more likely than males to report using a PPA weight-loss product.¹³ This gender-specific difference may result from females having a greater concern for thinness,²⁶ and a higher degree of dissatisfaction with their bodies than males.²⁷ Moreover, females attempted to lose weight at a lower BMI than males.²⁵

Consistent with findings obtained by Khan and Kruger^{23,28}, this study demonstrated that respondents with a high BMI used the weight-loss drugs more frequently than those with low BMIs. These correlations were dose dependent; that is, prevalence increased as BMI increased. Blanck *et al.*¹³ observed that young subjects had a higher OR for anti-obesity drug use than older subjects, a finding compatible with that obtained by this study. It is probable that the young adults care about body shape and appearance more than older adults. Analytical results demonstrated that a low level of education was positively correlated with a low level of weight-loss drug use. That is, a positive linear correlation may exist between educational

level and anti-obesity drug use; however, education level is generally utilized as a covariate when examining correlations among health behaviors and seldom as an independent variable.

Notably, 18.3% of respondents in this study reported using unproven drugs, such as a cocktail therapy and unknown drugs, for weight loss. Blanck *et al.*¹³ determined that in excess of one-third of prescription drug users also took nonprescription weight-loss products. Nonprescription weight-loss products, such as ephedra/caffeine and PPA, were commonly used in the U.S. prior to being withdrawn from the market. Although officially prohibited in Taiwan, PPA and ephedra/caffeine were easily available as over-the-counter (OTC) drugs during this study period. This study also identified that those using anti-obesity herbal preparations or dietary supplements had a high likelihood of concurrently using anti-obesity drugs (OR, 2.1–3.1). Blanck indicated that those who had taken prescription weight-loss drugs in the previous 2 years were likely to use non-prescription drugs (OR, 3.1).¹³ Furthermore, prescription drug users were 9 times more likely than non-users to have also taken an ephedra product during the 2-year period and twice as likely to have taken PPA products.¹³ Taken together, these analytical findings indicate that those seeking obesity treatments were dissatisfied with the outcome, and, therefore, converted to another treatment. Health care professionals should therefore be aware of all prescription and nonprescription drugs, herbal and dietary weight-loss products used by a patient. Dietary supplements and alternative therapies, which are typically considered safe and regulated as foods rather than drugs, comprise a significant challenge for physicians as numerous patients fail to inform their physicians about their use of such products.²⁹ Physicians must be aware of which multiple weight-loss products are taken concurrently, as possibility exists for herb-drug and drug-drug interactions.⁶

Both legal drugs, sibutramine and orlistat, were most frequently used prescription drugs for weight-loss in this study. Sibutramine was taken more than orlistat, particularly by subjects aged 18–24 years. The reason for this discrepancy remains unclear and warrants further investigation. Conversely, use of unproven anti-obesity drugs was also common among those seeking weight loss, particularly among females. One of 5 (20%) female subjects reported taking unproven drugs, 9.6% of female respondents had taken a cocktail therapy and as many as 14.3% had tried weight-loss drugs, even drugs whose names they could not recall. The effectiveness and safety of such weight-loss drugs has not been scientifically established.¹⁸ With regard to drug safety, health care professionals must play an active role in assisting their patients in making appropriate choices. Use of such drugs for weight-loss should be regulated by official pharmacy authority.

This study had several limitations. First, a bias would exist when questionnaires were completed by patients without professional assistance. However, to prevent misunderstanding in this study, a well-trained instructor was on standby to help subjects fill out the questionnaire. Second, the anti-obesity products actually taken by study patients may differ from those reported. As most brand

names are in English, the difficulty in obtaining the brand names from patients should be considered in self-administered questionnaires in Taiwan. As prescriptions for orlistat and sibutramine are paid by patients rather than by the government prescription drug plan, subjects were aware of these names. Third, the use of OTC, herbal therapies, and off-label drugs may have been underreported.³⁰ That is, the recall bias of this study may underestimate their use in Taiwan. Finally, analytical results are based on patients at outpatient clinics. Consequently, caution should be used when extrapolating finding to the general population.

In conclusion, this study confirms that anti-obesity drugs are frequently used by Taiwanese adults seeking obesity treatment. Use of unproven weight-loss drugs, such as off-label drugs, is also considerably popular. Females, the young and obese, and those who have tried Chinese herbal preparations/dietary supplements had a high likelihood of reporting use of anti-obesity drugs.

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Original Article

Anti-obesity drug use before professional treatment in Taiwan

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臺灣民眾尋求專業減肥前使用減肥藥物情況之調查

本研究於西元 2004 年 7 月到 2005 年 6 月進行一項橫斷式調查，希望瞭解臺灣民眾在尋求專業減肥之前使用減肥藥物的情形，經由隨機分層抽樣的方法，選取十八家專業減肥醫院或診所，並由這些門診挑選 18 歲以上的受訪者共 1,060 位，其中女性 791 位、男性 269 位，每位受訪者皆填寫完成一份問卷。統計發現這些受訪者使用減肥藥物的盛行率是 50.8%，其中女性高於男性（53.6%比 42.4%）。1,060 位受訪者中，17.1% 曾經使用過 orlistat、21.1% 使用過 sibutramine、18.3% 使用過雞尾酒減肥療法或未經證實的減肥藥，此外 23.6% 受訪者指出在減肥期間合併使用中藥減肥、22.4% 合併補充減肥健康食品。邏輯式迴歸分析發現，女性、年齡介於 18-24 歲、身體質量指數（BMI）大於 35、同時合併使用減肥中藥/健康食品的受訪者使用減肥藥物的機會較高。總而言之，臺灣成年民眾在尋求專業減肥之前，使用減肥藥物的情形相當普遍，尤其是女性、超重和那些同時合併使用中藥及健康食品減肥的民眾；此外，相關單位對於未經證實的減肥藥物使用情形必須進一步了解。

關鍵字：Orlistat、sibutramine、健康食品、禁藥、藥物使用。