TSH Levels Associated with Slimming Pill Use in a Population-Based Study of Brazilian Women

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ABSTRACT

Objective: To determine the consumption of slimming pills (SP) and its association with TSH levels. Research Methods and Procedures: A survey was carried out in Rio de Janeiro (about 5 million inhabitants), Brazil, from June 2004 to April 2005. Households (1,500) were selected using three-stage probability sampling. Women were asked about use of SP, and blood sample was collected. Women were classified as users of SP any time in life, but not in previous two months (n = 293), current users (n = 150), and never users (n = 853). Weighted multivariate regression analyses compared TSH levels among these groups of users. **Results:** The frequency of use of SP any time in life was 34% and the use in the previous two months was 11%. Both frequencies were greater among younger and obese women, and among those of high socioeconomic level (pvalue < 0.001). TSH level was statistically lower among current users of SP (1.96 mUI/mI; 95%CI = 1.93-1.98) compared to previous users 2.83 mUI/mI (95%CI = 2.13-3.02) and never users 2.59 mUI/mI (95%CI = 2.20-3.21). These differences were still statistically significant after adjusting for age and body mass index. Conclusions: Use of SP decreased TSH levels among Brazilian women. (Arq Bras Endocrinol Metab 2007;51/9:1448-1451)

Keywords: Hyperthyroidism; Slimming pills; Obesity; Prevalence

RESUMO

Níveis de TSH Associados ao Uso de Fórmulas para Emagrecer em um Estudo Populacional de Mulheres Brasileiras.

Objetivo: Determinar a frequência de uso de fórmulas para emagrecer e sua associação com níveis de TSH. Metodologia: Pesquisa realizada no Rio de Janeiro (5 milhões de habitantes), Brasil, de junho de 2004 a abril de 2005. A população de estudo foram mulheres com 35 anos ou mais, residentes em domicílios particulares permanentes do município do Rio de Janeiro não grávidas e não lactantes. A amostra de domicílios foi obtida por amostragem probabilística conglomerada em três estágios de seleção. As mulheres tiveram amostras de sangue coletadas e responderam a questões sobre uso de fórmulas, chás ou remédios para emagrecer. Quanto ao uso de fórmulas as mulheres foram classificadas em usuárias alguma vez na vida (n = 293), usuárias nos últimos dois meses (n = 150) e não usuárias (n = 853). Os níveis de TSH desses grupos foram comparados através de análise de regressão multivariada, levando em conta o desenho da amostra. Resultados: O uso de fórmulas alguma vez na vida foi relatado por 34% das mulheres e 11% relataram tê-las consumido nos últimos dois meses. As freqüências foram maiores entre as mulheres mais jovens e obesas e de nível sócio-econômico mais elevado (valor de p < 0,001). Os níveis de TSH foram estatisticamente menores entre as usuárias de fórmulas (1,96 mUl/ml; IC 95% = 1,93-1,98) comparados com usuárias prévias 2,83 mUI/mI (IC 95% = 2,13-3,02) e não usuárias 2,59 mUI/mI (IC 95% = 2,20-3,21). As diferenças entre os grupos mantiveram-se estatisticamente significantes após o ajuste por idade e índice de massa corporal. Conclusão: O uso de fórmulas para emagrecer diminuiu os níveis de TSH em mulheres brasileiras. (Arq Bras Endocrinol Metab 2007;51/9:1448-1451)

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Descritores: Hipertireoidismo; Fórmulas para emagrecer; Prevalência de obesidade

ANTIOBESITY FORMULAS, ALSO called fat-burning pills or slimming pills (SP), are very popular among Brazilian women, even though being condemned by medical associations. Small studies conducted in other countries have shown that these pills can cause changes in thyroid function (1-3). A study in two Brazilian metropolitan cities have also shown that four to six active components predominated in these prescriptions, but there were prescriptions listing as many as 17 components. Diuretics, thyroid agents, laxatives, medicinal plants, and a variety of other substances were often included and the prescribed doses were frequently above recommended limits (4). Anecdotal reports suggest a depression of the thyroid function due to the use of these pills, since most of them have variable amounts of T3. However, to our knowledge no population-based study has shown the importance of these drugs on thyroid function. We evaluated the frequency of use of SP and their association with overweight/obesity and levels of TSH among a probabilistic sample of women 35 years and older.

MATERIAL AND METHODS

Survey population

The study population included all women aged 35 years or older living on the city of Rio de Janeiro, Brazil, after excluding pregnant and lactating women. This age range was sampled because prevalence of thyroid disease below this age is much smaller. The survey was carried out from June 2004 to April 2005. Rio de Janeiro had 5.598.953 inhabitants in the last census (2000). Based on the operational geographical basis of the 2000 Census 100 primary sample units were selected from all regions of the city. Listing of households are conducted every 10-year by the Brazilian Institute of Statistics (IBGE). Households (1500) were selected using three-stage probability sampling. In the first stage, 100 primary sample units (PSU) were selected from all regions of the city. PSU is a geographical area containing approximately 300 contiguous housing units. In the second stage, 15 households were sampled from each PSU. Third, in each household one resident woman 35 years or more was selected. Sample size for estimation of hypothyroidism assumed a prevalence of hypothyroidism of 10%, with precision of 5%, after accounting for a maximum non-response rate of 20% (N = 1500). A total of 1,299 women participated in the survey (non-response rate of 13.4%).

Procedures

During the household visit blood was drawn and a detailed questionnaire regarding previous diseases and treatments, SP lifetime, and the previous two months usage was administered. All formulas or pills used to burn fat or to control obesity in the previous two months were listed. SP included any potential drug identified by the interviewee that could lead to weight loss. SP users were asked to show the container or prescription when available. Eight five different pills or formulas were reported.

Questions also included educational level of the woman and her husband, family income, number of children ever born, weight and height. Of 1,299 participants 4 refused blood drawn because they had collected TSH in the previous months and results were checked with their clinicians. The fieldwork was done by trained research assistants and three supervisors.

Body mass index (BMI = kg/m²) was based on reported weight and height. Schooling was categorized in less than or primary school level (grade 4 or below), grade 5 to 8, and beyond grade 8. Per capita income was calculated based on reported family income of the previous month divided by the number of persons living on that budged.

Serum TSH was measured by microparticle enzyme immunoassay (Abbott Laboratories). Assay has a variation coefficient of 10%, a detection limit of 0.05 mUI/ml. Reference values of normal TSH were: $\leq 0.3 - \geq 4$ mUI/ml. High reliability of hormone assays was confirmed through replication of TSH assays for 5% of the blood samples (n = 60) in a blinded way. Of the 60 measures only one differ more than 0.5 mUI/ml. The Pearson correlation coefficient between assays was 0.99.

For analysis we excluded those women taking medications that could affect thyroid testing (11 cases of amiodarone and 5 users of lithium).

Statistical analysis

Weighted prevalence and means were calculated using Statistical Analysis System procedures (SAS, Institute Inc., Cary, NC, USA, version 8.2). All statistical analyses were conducted using the individual sample weights and taking into account the effect of the sample design. Multivariate linear regression analyses compared TSH levels among users and nonusers of SP, with adjustment for age and BMI (Proc surveyreg). Logarithmic transformation of TSH was used to normalize the distribution.

The study protocol and informed consent were approved by the Ethics committee of the State University of Rio de Janeiro IRB, in March 8, 2004.

RESULTS

The weighted frequency of SP usage any time in life was 34% and the usage in the previous two months was 11%. Both frequencies were higher among younger and overweight women and among those women on high socioeconomic level, as indicated by income quartile and years of schooling (table 1).

Table 1. Weighted frequency (%) of lifetime use and usage in the previous two months of fat burning pills, among women 35 years and older. Brazil, 2003–2004.

	N	Lifetime (%)	p-value	Two months	p-value*
All participants	1299	34,2		11.5	
Age group (y)					
35–44	395	40.2		17.2	
45–54	424	36.6		11.8	
55-64	257	35.4		8.6	
65–74	155	21.3		5.2	
> 74	68	8.8	< 0.001	2.9	< 0.001
Income (quartiles)					
] st	277	27.1		6.1	
2nd	346	29.5		9.2	
3 rd	314	38.2		12.7	
4 th	329	45.0	< 0.001	17.3	< 0.001
Schooling (y)					
≤ 4	827	28.8		9.4	
5–8	289	38.7		11.1	
> 8	183	51.3	< 0.001	21.9	< 0.001
Body mass index (kg/m²)					
< 25	555	19.1		5.8	
25–30	415	42.2		14.7	
> 30	246	59.3	< 0.001	21.9	< 0.001

^{*} p-values obtained from a model for linear trend across the specific category.

Table 2. TSH levels (mUI/mI) associated with slimming pills (SP) use, among women 35 y and older. Brazil, 2003–2004.

	SP previous users	Current SP users	SP never users
	(n = 293)	(n = 150)	(n = 853)*
TSH mean** (95% CI) TSH Median (90 th and 10 th percentile)	2.83 (2.13–3.02) b	1.96 (1.93-1.98) ^a	2.59 (2.20–3.21) b
	1.8 (4.3–0.79)	1.6 (3.5-0.62)	1.5 (3.9–0.59)

^{* 3} women did not answer the question about current use.

Users reported 85 different items including: medicinal plants to reduce weight, herbal teas, antiobesity approved drugs, and pills with addition of T3 or Triac. Women also reported use of benzodiazepines, anorectic substances, diuretics, and laxatives. We listed all the reported drugs or preparations, but we do not have them on an individual basis for each woman.

TSH levels (mIU/ml) were significantly lower (P = 0.005) among current users (those women reporting usage in previous two months) (n = 150; mean: 1.96; 95% confidence interval (CI): 1.69–2.20) vs. those who denied usage in this period (n = 1146; mean: 2.24; 95%CI: 2.24–3.06). TSH mean of the population was 2.57 (95% confidence interval 2.20–2.93).

When women were classified as users any time in life, but not in previous two months (n = 293), current users (n = 150), and never users (n = 853) the

only statistically significant difference was the lowest TSH levels among current users (table 2).

The overall prevalence of TSH > 4 mUI/ml or taking thyroid medication was 11.8% and the prevalence of TSH < 0.3 mUI/ml was 3.6%. Few women knew their clinical condition (only 15% among those 20 women with free-T4 lower than 0.7 ug/dl).

The increased level of TSH among previous users could be associated to their greater adiposity, as shown in table 1. However, after age and BMI-adjustments, differences were still significant only for current users.

DISCUSSION

This probabilistic sample of women demonstrates that serum TSH concentration was associated to the use of

^{**} Means with different letters are statistically significant ANOVA (p < 0.05).

antiobesity formulas. Therefore, our findings indicate that SP usage may pose a risk for thyroid dysfunction among Brazilian women. Current usage appears to decrease TSH level and remote usage (anytime in life) of SP was associated with non-significant increase of TSH independent on BMI.

The cross-sectional design is an important limitation of the study, particularly in relation to the findings for chronic or remote usage of SP. Even for the acute use we could not separate the usage of slimming pills not containing anything related to thyroid function because for many women this information was not available. However, by inflating the SP user group with these unrelated pills, the possible bias is towards the null hypothesis, indicating that the real association between thyroid dysfunction and SP usage should be greater than observed.

It has been described that TSH, even in the normal range, is positively associated with BMI (5). Thus, overweight women, the main group of consumers of unapproved treatments for obesity, are also at increased risk of having higher TSH independent on the use of SP. To control for this effect, BMI as continuous variable was included in the multiple regression analysis and a strong association was still observed. Other limitation was the sample size, which is not adequate to the study of hyperthyroidism, a condition of very low prevalence. Nevertheless, the high frequency of use of unapproved treatments for obesity associated to the increasing prevalence of obesity indicates the importance of exploring further the acute and chronic effect of SP on thyroid function.

CONCLUSION

Taken together our results suggest that usage of SP has an impact on thyroid function, decreasing TSH levels among those in current use. A prospective study would need to be performed to definitively address this observation from our epidemiological data.

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