Associations between Supplement Information Sources and Menopausal Women's Consumption of Herbal Supplements

Natalie Crnosija and David Baker*

Department of Obstetrics, Gynecology and Reproductive Medicine, Stony Brook University School of Medicine, Stony Brook NY 11794, USA

*Corresponding author: David Baker, Department of Obstetrics, Gynecology and Reproductive Medicine, Stony Brook University School of Medicine, Stony Brook NY 11794, USA, Tel: (631) 444-7650 (or) (516) 318-3697; E-mail: david.baker@stonybrookmedicine.edu

Objective: It is unclear whether supplement information sources associate with menopausal women's herbal supplement consumption. We investigated associations between information sources: 1) friends, family members, co-workers, or self; 2) their healthcare provider (including doctors, pharmacists, drugstore); 3) the Internet; 4) books, newspapers, newsletters, radio, magazines, television shows or commercials; 5) a health store, and one-time herbal supplement consumption.

Methods: Using Stony Brook University’s Dietary Supplements in Menopause dataset of 403 women, collected between May 7 and July 9, 2013, we developed a multivariable logistic regression model controlling for demographics, menopausal symptoms and knowledge of the FDA’s role in supplement regulation.

Results: Women who consult healthcare providers had 39% reduced odds of ever consuming an herbal supplement (OR=0.61; CI=0.38, 0.96). Women responding “No” to the question: “To the best of your knowledge, does the FDA require research evidence or clinical trials to demonstrate safety and efficacy?” had a 94% increased odds of ever consuming an herbal supplement (OR=1.94; CI=1.22, 3.08). We stratified our regression model by this response, producing distinct models.

Conclusion: Knowledge of the FDA’s role in supplement regulation plays a moderating role between information sources and menopausal women’s herbal supplement consumption, demonstrating the need for healthcare providers’ communication with women about supplement regulation.

Keywords: Supplements; Knowledge; Menopause

Introduction

There is a growing, multifaceted body of literature that focuses on herbal supplement consumption in the United States and around the world. A unique subsection within the corpus centers on supplement use among menopausal women, who are some of the most prolific consumers of herbal supplements in the United States; as of 2002, 28.7% and 30% of women aged 44-64 and 65 and older, respectively, consumed herbal supplements of some kind [1]. This distinct literature examines the prevalence of consumption (of general and of specific supplements) [1-3] and the beliefs [4] and demographic factors (race, income, education, age and gender) [2,4-11] that motivate, enable or inhibit supplementation behavior. Non-Hispanic whites tend to have increased odds of herbal supplement consumption relative to Black and Hispanic groups [12], but both Black [13] and Hispanic [14] women have increased odds of experiencing menopausal symptoms. Experiencing menopausal symptoms is also associated with supplement consumption, as demonstrated by Cardini et al. [15] Italian menopausal women who experienced severe hot flashes had an increased likelihood, relative to that of women without symptoms, of consuming comparative or alternative medicine supplements, like black cohosh, traditional Chinese herbal formulas, soy in both pill and food form, Angelica sinensis formulations, homeopathic pills, Dioscorea villosa or Trifolium pratense phytoestrogens [15]. The literature examining to the effectiveness and safety of herbal supplements in addressing these symptoms is, at times, conflicted [16], as it is with black cohosh; sold as a neutraceutical supplement to mitigate hot flashes, it is reported to safely reduce symptom severity [17,18], without adversely affecting hepatic blood flow or function [19] yet, case reports have reported an association between the supplement's use and hepatic dysfunction [20-23]. Literature pertaining to other supplements demonstrates similarly mixed findings regarding efficacy across climacteric symptoms for instance, evening primrose oil had no effect on flushing during menopause in one study [24], but, in another, its use was associated with a decrease in hot flash severity [25]. Ginseng was found to reduce vasomotor symptoms in postmenopausal women [26] more generally, it and ginko biloba are used to halt the cognitive decline that accompanies aging, which is relevant, but not exclusive, to menopausal and postmenopausal women. Teik et al. [27] found that ginko biloba improved women's executive functioning abilities the same could not be said of ginseng consumption, but the researchers posited that it was these compounds' effects on cardiovascular reactivity that improved participants' cognitive faculties. These positive studies are countered by the literature, which also finds that consuming these supplements has no effect when compared with controls [28,29]. In spite of the "conflicts" in the herbal supplement literature as a whole, women, relative to men, had an 81% increased odds of using herbal supplements (excluding eucheinicea) based on scientific indications [30]. This finding begs the question from where and what kind of information women are receiving regarding supplementation praxis.

Though we may have a sense of the motivating factors for herbal supplement use in the menopausal population, the sources that inform supplement consumption decision-making are understudied. In a sample of menopausal Italian women on mainstream Hormone Replacement Therapy (HRT) regimens, 25% used medical doctors as their source of supplement information [15]. Alternatively, among women on HRT regimens in the United Kingdom, the most prevalent sources of information were friends, followed by the Internet, their doctors and women's magazines [31]. The Internet hosts many types of sources, each with varying credibility Owens et al. [32] found that retail sites, which composed 53.1% of their supplement-centric site analytic sample, that addressed black cohosh supplement consumption, relative to nonretail sites, had an decreased likelihood of...
reporting adverse effects, highlighting the importance of consulting a healthcare provider about the use of herbal supplements and mentioning warnings. In the United States, from 2002 to 2012, herbal supplement consumption decreased 1.8% among adult women but increased 5% among the population (male and female) 65 years and older [33] trends that occur in an environment wherein the FDA does not require pre-market approval or clinical trials or research to prove the safety or efficacy of supplements [34,35]. We currently lack an understanding of where menopausal women living in the United States get their supplement information and how it relates to their ultimate supplementation choices, as well as how these women's understandings of supplement regulation impacts their supplementation decisions. We are investigating whether the preferred sources of supplement information: 1) friends, family members, co-workers, or self; 2) their healthcare provider (including doctors, pharmacists, drugstore); 3) the Internet; 4) books, newspapers, newsletters, radio, magazines, television shows or commercials; and/or 5) a health store associates with having ever consumed an herbal supplement (black cohosh, evening primrose, ginko biloba and/or ginseng). We hypothesize that specific sources of information are associated with using herbal supplements at least once—further, we assert that these relationships are moderated by whether or not women know that the FDA does not require clinical trials or research to prove supplements' safety or efficacy.

Methods

Data and sample description

Data used in this study come from the Dietary Supplements in Menopause dataset, which evaluates menopausal supplementation behavior, knowledge and attitudes. The targeted survey was conducted by the Stony Brook University Center for Survey Research. Between May 7 and July 9, 2013, 4,310 phone numbers in the contiguous United States were called; if potential respondents could not be reached, making contact was reattempted, at most, between 5 and 9 times. Those who initially refused to participate were called again to maintain the representativeness of the sample; the total sample was comprised of 403 respondents who had completed the survey, composed of 88 women from the Midwest, 80 from the Northeast, 100 from the West and 135 from the South. Inclusion criteria were: women between the ages of 55 and 75, who had ceased menstruation for at least one year. Age was established by asking year of birth if born between 1938 and 1958, the respondent was included in the study and the telephone questionnaire proceeded to the questions about menopausal status, the respondent was included in the study and the telephone questionnaire proceeded to the questions about menopausal status, and, if the respondent qualified, further questions were asked. Of those contacted, 541 were disqualified based on age and 20 because they did not meet the menopausal criteria. After all ineligible respondents were eliminated; the response rate of the survey was 10.75%. This study was institutional review board-approved consent was obtained verbally as part of the administration of the survey.

Measures

The dependent variable was an aggregate of whether any type of the listed herbal supplements had ever been consumed. The supplements asked about in the survey included the herbal supplements black cohosh, evening primrose, ginko biloba. The primary independent variables of interest were women's choices of supplement information source. Respondents were asked whether they get their information from: 1) friends, family members, co-workers, or self; 2) their healthcare provider (including doctors, pharmacists, drugstore); 3) the Internet; 4) a health store; 5) books, newspapers, newsletters, radio & magazines; and 6) television shows or commercials. (The two last information sources listed were collapsed into one variable, books, newspapers, newsletters, radio, magazines, television shows or commercials, given their shared mass media source status). Information source variables were summarized separately and then coded into the aforementioned categories for bivariate and multivariable analysis. These variables were not mutually exclusive.

Our selected covariates included dichotomized age (<65 years vs. ≥ 65 years), education (college education vs. no college education), household income level (<$55,000 vs. ≥ $55,000), race (white vs. non-white (which includes African American, Hispanic, Asian, Native American or Alaskan native, and African American and another race)) and the severity of menopause's physical (hot flashes, night sweats, joint pain, fatigue, headaches) and psychological (depression, anxiety, mood swings, difficulty concentrating, difficulty sleeping) side effects, which has been linked to supplementation behaviors [15]. In our analysis, we created a severity score based on the subjects' assessment of the intensity each of the specified symptoms; respondents were asked about the severity of each of their physical symptoms (none, moderate or severe). The severity values of each physical symptoms were weighted (=0 if none,=1 if moderate,=2 if severe) and added into a score the score was categorized into a three-level physical symptom severity variable (none=0; mild=1–5; severe=6–10). Mental health symptoms were similarly added and categorized (none=0; mild=1–5; severe=6-10). These covariates were controlled for because of their potential to confound the relationship between information sources and supplement consumption behavior. We also assessed self-perceived health status (poor vs. good-collapsed from poor and fair, and good, very good and excellent, respectively). Additionally, we examined responses to the question: “To the best of your knowledge, does the FDA require research evidence or clinical trials to demonstrate safety and efficacy?” (“No” vs. “Yes”/“Don't know”), the latter of which was collapsed from the “Yes” and “Don't know” responses.

Statistical analysis

Data analysis was performed using Stata 13.1 (Stata Corp, College Station, TX). We performed bivariate analysis examining the correlation between supplementation behavior and the following characteristics: age, education, income level, race, self-perceived health status and the severity of pregnancy's physical and psychological effects. Chi-squared tests were utilized to evaluate the correlation between the source of information and the supplement consumption dependent variable. Multivariable logistic regression was performed to examine the relationship between sources of information and supplementation behavior, controlling for covariates. To choose the most robust form of the model for stratification, we conducted Hosmer-Lemeshow and likelihood ratio tests, the latter of which compared the restricted model, controlling for healthcare provider, Internet and health store information sources, physical symptom severity, age and the FDA regulation knowledge variable, to the unrestricted model, which controlled for all the information source variables, age, education, income level, race, self-perceived health status and the severity of menopause's physical and psychological effects and the FDA regulation knowledge variable. As there was not a statistically significant difference between the restricted and unrestricted models, we chose the restricted model for further analysis. Three observations (0.01% of the sample) were dropped for refusal to
respond to the question regarding whether the FDA requires research evidence or clinical trials to demonstrate safety and efficacy. Of 400 complete remaining interviewee responses, 373 made up the final analytic sample (6.75% of the sample had missing covariates). Odds ratios and 95% confidence intervals were reported. The significance level was set at P < 0.05.

Results

We found that the greatest proportion of respondents (64.25%) got their information from medical professionals, followed by books, newspapers, newsletters, radio & magazines, television shows or commercials (39.25%), the Internet (23.75%) and health stores (13.75%). In accordance with the literature (Kelly et al., 2005), 34.25% of the population had ever consumed some form of herbal supplement. The population was largely white (88.89%), age 65 or over (56.78%) and had a household income of $50,000 or more per year (55.74%).

Bivariate analysis

Our initial bivariate analysis of independent and the dependent variables yielded significant evidence that particular sources of supplementation information correlated with one-time herbal supplement consumption. Those who consulted the Internet (p=0.02) or a health store (p=0.01) were more likely to have engaged in the consumption of herbal supplements at least once compared to those who did not use these information sources. Those who consulted a healthcare provider were less likely to have ever consumed an herbal supplement compared to those who did not consult a healthcare provider (p=0.01).

Multivariable logistic regression

The restricted model, which included healthcare provider, Internet and health store information sources, physical symptom severity variables, demonstrated that, on average, with covariates controlled, those who consulted healthcare providers about supplements had 39% reduced odds of having ever consumed an herbal supplement relative to those who did not consult this information source (OR=0.61; CI=0.38, 0.96). Those who experienced severe physical menopausal symptoms had an 83 percent increased odds of having ever taken a herbal supplement compared to those who did not. In stratifying our model by response to this question, we found that among those who responded “No” to the FDA question, the use of a healthcare provider information source, on average, yielded significantly decreased odds of having consumed an herbal supplement, compared to those who did not use this information source. Those who did not express this understanding of FDA regulation do play an intervening role in the relationship between the information source(s) consulted and the ultimate consumption of an herbal supplement at least once and that there may be a fundamental difference between those who responded “No” to the question: “To the best of your knowledge, does the FDA require research evidence or clinical trials to demonstrate safety and efficacy?” and those who did not. In stratifying our model by response to this question, we found that among those who responded “No” to the FDA question, those who experienced severe physical side effects of menopause had over 2 times the odds of having ever taken a herbal supplement compared to those who experienced mild physical menopausal symptoms, with covariates controlled (OR=2.44; CI=1.30, 4.59).

Discussion

This study is one of the first of its kind to examine the intervening role that perceived knowledge of supplement regulation plays between information sources and supplement consumption. We found that menopausal women had varied understandings of the FDA’s role in supplement regulation, in accordance with Marinac et al. [4] findings in an older adult population; our model demonstrated an increased odds of menopausal women’s consumption of herbal supplements if they responded “No”, as opposed to “Yes”/“Don’t know”, to the question: “To the best of your knowledge, does the FDA require research evidence or clinical trials to demonstrate safety and efficacy?” This finding may be explained by women’s exposure to supplement regulation information in the process of engaging in herbal supplementation behavior. Comparing different national approaches to supplement regulation, van der Sluijs et al. [15] posited that the differing national approaches to supplement regulation explain the differences in consumption between Sydney-based Australian and Bologna-based Italian menopausal women [36]; the United States differs from both countries in terms of its approach towards supplement regulation [34,35]. In our analysis of a U.S. sample, our findings support the assertion that knowledge of supplement regulation does play an intervening role in the relationship between the information source(s) consulted and the ultimate consumption of an herbal supplement at least once and that there may be a fundamental difference between those who responded “No” to the question: “To the best of your knowledge, does the FDA require research evidence or clinical trials to demonstrate safety and efficacy?” and those who did not. In stratifying our model by response to this question, we found that among those who responded “No” to the FDA question, those who experienced severe physical symptoms that differ from those who responded “No” to this question. The former group potentially believes that if supplements give the relief that is advertised, then they must be regulated, as they have “medicinal” qualities. Thus, there is a possible bi-directional relationship between the physical symptoms of menopause and survey respondents’ understandings of FDA knowledge.

Our findings regarding severe menopausal symptoms associated with herbal supplement consumption are consistent with the existing literature [15]. Racial, financial and educational variables have been consistently found to associate with supplement consumption [3,4,6,8,11], yet, in our analysis, none of these variables were significantly correlated with herbal supplement consumption in bivariate testing and, thus, were not constituent parts of our final tested model. Given the relative homogeneity of our sample, we likely lacked power to analyze our dependent variable by these demographic variables.

It is important to note that the majority of women in our sample responded “No” to the question: “To the best of your knowledge, does...
the FDA require research evidence or clinical trials to demonstrate safety and efficacy? The directionality of the relationships between information source independent variables and the herbal supplement consumption dependent variable are consistent with the extant literature [15] and appear to be more defined within the subpopulation that believes that the FDA does not require research evidence or clinical trials to demonstrate safety and efficacy. Though health store or Internet information did not rise to significance in the regression models, these information sources present an interesting avenue for future study with a larger, more diverse sample.

A limitation of this study was its cross-sectional nature, which prevents us from asserting that there is a causal relationship between information sources and ultimate behavior. We also had a relatively low survey response rate of 10.75%, which was likely due to our reliance on contacting women via landline rather than via landline and cellphone. We were not able to survey those without a landline, limiting the generalizability of this study. Our survey, by virtue of the absence of an appropriate validated survey that asks both about supplements consumed and attitudes towards the FDA's role in their regulation, is novel and, therefore, hasn't previously been validated. A limitation in terms of response to a survey question was the paucity of women who were unsure of whether the FDA requires research evidence or clinical trials to demonstrate safety and efficacy. This would have been a category of interest to include in our moderating variable but the number of women who responded thusly was too small to include as a standalone moderator category. Because of the variable's relevance within our scope of inquiry, we felt we could legitimately collapse it into the larger "Yes" response as our moderator focused on whether or not subjects had responded "No" to the question of whether the FDA requires clinical trials or proof of efficacy and safety [34,35].

Our findings also contribute to the literature regarding age and supplement consumption our model demonstrated that women in our sample who were younger than 65 years had an increased odds of having ever consumed an herbal supplement, which aligns with previous findings in an analysis of supplement consumption within 12 months prior to being surveyed [2] but counter to what the recent literature has reported with regard to age greater than 65 and the increased likelihood of supplement consumption within 12 months prior to taking the survey [33]. We posit that this association can be explained by the specific supplements of interest, which are typically used to treat menopause-related symptoms. Younger women may remember menopause-relevant herbal supplement consumption better than their older counterparts, as younger women may have experienced the menopausal and post-menopausal symptoms that associate with supplement use [15] more recently. Further, younger women may have experienced menopause in an environment greatly affected by the findings of the Women's Health Initiative [37]; published in 2002, the study of post-menopausal women found that estrogen plus progestin hormone therapy was associated with an elevated hazard of breast cancer and coronary heart disease [38-40]. Ghazal & Pal assert that, in light of these findings, for women who were either unfit candidates for hormone treatment or were unwilling to pursue this form of treatment, there exist other care options including the use of herbal supplements for the management of vasomotor symptoms [37].

Our dependent variable, the consumption of black cohosh, evening primrose, ginseng, and/or ginko biloba at least once, attempts to access the initial decision-making process associated with supplement consumption; we weren't able to assess the consistency of use as our telephone questionnaire only addressed one-time and present supplement consumption. Lastly, there is the possibility for recall bias, both in terms of what information source was consulted for supplement information and what supplements were consumed. Future, large-scale studies are needed to understand the sources from which women get supplement information and, specifically, where they get information about herbal supplements so we may better understand the nature of the communication that occurs among women and their information sources. Furthermore, we need to assess the quality of the information that is being distributed by these information sources. In the clinical setting, physicians are in a unique position through their care provider role to educate patients about supplementation and the FDA's role in the regulation of supplements [34,35]. Our analysis, which used a national sample, reveals there could be a widespread misperception of the FDA's regulatory role with regard to supplements. Further, these perceptions may play a role in supplement consumption behavior.

References


