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Botanical dietary supplement use in peri- and postmenopausal women

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ABSTRACT

Objective: To determine use of botanical dietary supplements (BDS) in women between the ages of 40 and 60 years at the University of Illinois at Chicago (UIC) clinics, including information about commonly used BDS, the reason for use, information resources used, and the overall perception of safety and efficacy of BDS.

Design: Five hundred female outpatients at UIC clinics were interviewed by healthcare practitioners using a botanical/drug history questionnaire. Respondents were 46.8% African American, 39.6% Caucasian, 11.7% Hispanic, and 1.5% Asian, with a mean age of 50.34 years.

Results: BDS were used by 79% of respondents (n = 395), of which 36.5% used BDS daily. Of the positive respondents, 51.7% used one or two BDS, whereas 48.4% used three or more. Commonly used botanicals included soy (42%), green tea (34.68%), chamomile (20.76%), gingko (20.51%), ginseng (17.97%), Echinacea (15.44%), and St. John's wort (7.34%). Black cohosh, garlic, red clover, kava, valerian, evening primrose, and ephedra were used by less than 15% of respondents. Efficacy ratings were high for BDS, and 68% claimed to have no side effects. Only 3% of respondents obtained BDS information from healthcare professionals, and 70% of respondents were not informing their physician of BDS use.

Conclusions: A high percentage of women at UIC clinics were using multiple BDS. The respondents believed that these products were both safe and effective for the treatment of common ailments. Concomitant BDS use with prescription and over-the-counter medications was commonplace, often without a physician's knowledge. Consumer education about the possible benefits and risks associated with BDS use is urgently needed.

Key Words: Menopause – Botanical dietary supplements – Efficacy – Safety – Information.

According to statistics from the World Health Organization, the average life span of a woman living in most countries is approximately 80 years.[1] Therefore, the vast majority of women will reach menopause, either naturally or surgically. Between 55% and 75% of these women will experience vasomotor symptoms (hot flashes) or other symptoms, such as depression, mood swings, sleep disorders, vaginal dryness, and joint pain.[2] Approximately 25% to 30% of women will seek treatment from their healthcare providers for the sequelae of menopause,[2] and, for many, hormone replacement therapy (HRT) will be recommended as the first-line treatment for menopausal symptoms.[3]

Numerous studies have demonstrated the acute and chronic benefits of HRT, including the relief of menopausal symptoms[2,3] and possible reductions in the risk of cardiovascular disease, osteoporosis, and Alzheimer's disease.[4,5] However, a significant number of women never seek treatment or will refuse or discontinue HRT because of the perceived risks,[6] medical contraindications, or a general reluctance to use "un-

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natural" exogenous hormones.[7,8] Thus, many women are now turning to botanicals to manage their menopausal symptoms.

The University of Illinois at Chicago (UIC)/National Institutes of Health (NIH) Center for Botanical Dietary Supplements, in collaboration with the National Center for Excellence in Women's Health at UIC, conducted interviews of 500 women, between the ages of 40 and 60 years, at various UIC clinics. The goals of this investigation were to determine what botanical dietary supplements (BDS) women of this age group were using, why they were using these products, where they obtained BDS information, whether they used BDS with prescription or over-the-counter (OTC) medications, their perceptions of adverse effects and efficacy, and whether women were informing their healthcare providers about their use of BDS. The widespread use of botanicals by women, particularly products containing "phytoestrogens" for treatment of menopausal symptoms, may pose health risks because many botanical extracts have not been uniformly standardized. Therefore, the collection and analysis of information on the use of botanical dietary supplements by this group of women is beneficial, not only from an informational standpoint but to determine what BDS products women in this age group are using and any related safety concerns.

METHODS

This investigation was performed in collaboration with the UIC/NIH Center for Botanical Dietary Supplements Research on Women's Health and the UIC Center for Excellence in Women's Health. At numerous clinics throughout the UIC Medical Center, 500 women were interviewed through outpatient questionnaires and drug histories. To be eligible, women had to be between 40 and 60 years of age and had to consent in writing to the interview. More than 700 women were eligible, and the participation rate was 75%. Women who reported no bleeding for at least a 12-month period were classified as postmenopausal. Women who reported irregular menstrual bleeding and/or irregularities in cycle length were classified as perimenopausal. The questionnaire (Appendix I) was developed based on a modification of an American Dietetics Association and American Pharmaceutical Association working group report on dietary supplements, "*A Healthcare Professional's Guide to Evaluating Dietary Supplements*,"[9] in combination with a clinical drug history information questionnaire used by UIC clinics. The protocols for this study were reviewed and approved in accordance with the Institutional Review Board at UIC. Using a standardized questionnaire, one registered pharmacist, two clinical pharmacy students, and a registered clinical dietitian conducted all interviews with participants. No patient identifiers, except age and ethnicity, were maintained with the data. All interviews were monitored to ensure that questions and answers were interpreted similarly. When questions arose, all four interviewers discussed the data, and a consensus was reached.

Data from the questionnaire were transferred in coded form for entry into Excel spreadsheets. The spreadsheets from different coders were made consistent and combined into a single master database designed specifically for this application. The data were rechecked manually for coding errors and cleaned. BDS substances were recoded from values into variables. Statistical analysis of the data was performed using the SAS program (SAS Institute Inc., Cary, NC, USA). Statistics were performed by Dr. J. Scott Parrot, president of the National Institute of Social Science Information, Hinsdale, IL. Descriptive statistics identified the number of BDS used, number of BDS products used, sources of information, and other study variables. Statistical analysis primarily assessed the responses of BDS users. The Student's t test was used for comparison when appropriate, and a P value less than 0.05 represented a significant difference. Means testing and risk analyses were also performed. The means were calculated for data concerning treatment versus prevention of disease. The means were compared using a two-tailed t test, with $P < 0.05$ indicating significance. A risk analysis was performed on data for prescription drug use, OTC medication use, and BDS use. To get a critical sample size, it was necessary to compare all BDS users to non-BDS users, specifically when looking at the relationship between prescription drug and OTC medication use and BDS. We reported relative risk with 95% CI.

Analysis of the data in the database was performed to answer a series of specific questions regarding the use of BDS among the respondents sampled: How prevalent is BDS use in this group of women? What are the demographics (age and ethnicity) of the 500 respondents who use BDS? Why do respondents use BDS? Where do respondents get their information on BDS, and do they tell their healthcare provider about their BDS use? Do these women use BDS in combination with other drugs, and are BDS users any more likely to be taking OTC or prescription medicines? How often and at what dose do respondents use BDS? What methods do respondents use to take BDS? How effective do

TABLE 1. *Ethnic composition of all respondents and botanical dietary supplement users*

Race	All respondents (%)	BDS users (%)
African American	46.8	45.5
White	39.6	40.9
Asian	1.5	1.8
Hispanic	11.7	11.3
Other	0.4	0.5

BDS, botanical dietary supplement.

respondents believe BDS to be? Do respondents perceive any adverse effects from BDS use?

RESULTS

Demographic data

The results were based on responses from 500 women, between the ages of 40 and 60 years, from UIC clinics. The mean age of all respondents was 50.34 years (median, 50 years). The mean age of BDS users was 50.22 years (median, 50 years). Of the respondents who claimed to use BDS, 45.5% were African American, 40.9% were Caucasian, 11.3% were Hispanic, and 1.8% were Asian (Table 1). Of the 500 respondents, 395 women (79%) indicated that they used BDS, 20.6% indicated that they did not use BDS. (The two percentages do not total 100% because two respondents did not answer this question.)

Many respondents indicated that they used more than one BDS. A total of 900 BDS uses were recorded from 395 respondents in the study, with the number of BDS used per respondent ranging from 1 to 11. The mean number of BDS taken was 2.86, with a median of 2. Of the 395 women claiming to use BDS, 379 gave information on the number of BDS that they currently used, and 16 women did not respond to the question. Of the 379 respondents, 29.3% claimed the use of only one BDS, 22.4% were using two supplements, 21.6% were using three supplements, and 26.8% were using four or more BDS; some were using as many as 11 supplements.

The study sought to distinguish whether respondents used BDS to prevent or treat disease. Only 24.2% of respondents claimed to use BDS to prevent disease, whereas 68.3% used botanicals to treat symptoms or disease states. The mean number of times respondents indicated that they took a BDS to treat a disease was 1.373. The mean number of times respondents indicated they took a BDS to prevent disease was 0.717. Comparing means using a two-tailed t test, the means were found to be significantly different ($P < 0.001$). Thus, women of this age group from UIC clinics were more likely to use BDS to treat disease than to prevent disease.

TABLE 2. *Commonly used botanicals by peri- and postmenopausal women*

BDS	Number of times used by any respondent	Percent relative to respondents using any BDS	Percent of all respondents
Soy	166	42.03	33.20
Green tea	137	34.68	27.40
Other herbals	92	23.29	18.40
Chamomile	82	20.76	16.40
Gingko	81	20.51	16.20
Ginseng	71	17.97	14.20
Echinacea	61	15.44	12.20
St. John's wort	29	7.34	5.80
Black cohosh	13	3.29	2.60
Garlic	12	3.04	2.40
Red clover	7	1.77	1.40
Kava	6	1.52	1.20
Valerian	4	1.01	0.80
Evening primrose	4	1.01	0.80
Ephedra	1	0.25	0.20

BDS, botanical dietary supplement.

Specific BDS use data

The data depicting the most commonly used botanicals by respondents are shown in Table 2. BDS in the form of teas were very popular for specific supplements, such as green tea and chamomile. Other supplements were taken in various dosage forms, such as tablets, capsules, or liquids. Interestingly, most women who claimed to use soy products did not in general use a typical "soy supplement" in a capsule or tablet, but instead were incorporating soy-containing food products, such as soy milk, tofu, and health bars containing soy, into their diet. Of the BDS users, 42% were using soy products, and 35% were using green tea, primarily because they thought that both had health benefits. Again, the respondents claimed to be ingesting green tea for health benefits, but only 10% could verbalize about specific health benefits. Thus, for the most commonly used botanicals, green tea and soy, most women recognized that there are health benefits associated with use but did not understand the benefits fully enough to verbalize them.

Approximately 21% of respondents used chamomile tea, with most women claiming to use this botanical to help them relax or to treat insomnia. Approximately 20.5% of BDS users were taking some form of Ginkgo biloba supplement, primarily to treat age-associated memory problems. Interestingly, approximately 18% of BDS users were ingesting some form of ginseng (type not specified), primarily to treat fatigue. It was

clear during the interviews and the following data analyses that the respondents felt stressed and fatigued and were looking for BDS to help them relax and to treat insomnia, and others to improve physical and mental performance. Many of these same women were using ginseng products during the day to help them overcome the lack of sleep and stress encountered on a day-to-day basis. Whether any of the respondents were suffering from ginseng-induced insomnia could not be ascertained.

Approximately 15% of respondents claimed to use Echinacea-containing products for the treatment of cough and colds. Interestingly, although the median age in this investigation was 50 years, only 3.29% of women used black cohosh products, and only 1.77% used red clover products, even though these products are widely promoted for treatment of menopausal symptoms. It was not clear whether women were using soy products for menopausal symptoms instead of black cohosh or red clover, or if they were just not as familiar with these products as they were with soy.

Frequency of BDS use

Respondents were asked how often they used BDS, and the responses were coded to data entry as the following: daily, weekly, bi/tri-weekly, monthly, bi/tri-monthly, or as needed/seasonal. Approximately 37% of respondents claimed to use BDS on a daily basis, 14% on a weekly basis, and 18% as needed or seasonally. Respondents were also asked whether they took BDS in combination with food, a beverage, other medications, or alone (with nothing else). Most respondents (52.76%) took BDS alone (without food or other medications), and only 0.79% of respondents took BDS at the same time as they took their other medications. When asked about the dosage form in which they used BDS, most women claimed to use teas 49.7% of the time and tablets or capsules 45.3% of the time. Other dosage forms, such as liquids and oils (3.0% and 2.0%, respectively), were not as popular. Interestingly, when asked for the specific dose of the BDS, not one respondent was able to state, with any degree of accuracy, the dose of the BDS she was using.

Perceived efficacy of BDS

Respondents were asked to rate the perceived effectiveness of BDS, according to their own experience, on a scale of 0 to 5, with 0 being not effective and 5 being very effective. Some of the most commonly used BDS obtained high efficacy ratings from BDS users. For example, chamomile and red clover ranked above 4, while ginseng, Echinacea, and green tea ranked above 3.5. High efficacy ratings were claimed for black cohosh (3.8), red clover (4.25), garlic (3.9), kava (4.7), evening primrose (4.5), and valerian (5.0); however, St. John's wort rated only 2.5.

TABLE 3. *Cross tabulation: correlation between BDS and Rx medicine use*

		Rx use		
		No	Yes	Respondents (*n*)
BDS use	No	24	17	41
	Yes	134	260	394
Total		158	277	435

BDS, botanical dietary supplement; Rx, prescription.

TABLE 4. *Cross tabulation: Chi-square tests*[a]

	Value	df	Asymp. sig. (2-sided)
Pearson Chi-square	9.658	1	.002

df, degree of freedom; Asymp. sig., asymptotic significance.
[a]Valid cases, $n = 435$.

TABLE 5. *Cross tabulation: risk estimate, Rx and BDS use*[a]

	Value	95% CI	
		Lower	Upper
Odds ratio for BDS use (no/yes)	2.739	1.422	5.275
For cohort taking Rx = no	1.721	1.285	2.305
For cohort taking Rx = yes	0.628	0.434	0.910

BDS, botanical dietary supplement; Rx, prescription medication.
[a]Valid cases, $n = 435$.

Perceived adverse reactions

The questionnaire also addressed issues of adverse reactions to BDS. The respondents were asked to describe any adverse reactions or side effects they may have experienced from using BDS. Only 10.72% of the respondents indicated that they had experienced adverse reactions but could not or did not elaborate on the details of the reaction. Approximately 68% of respondents said they did not experience any adverse effects from using BDS. However, 21.4% claimed they were unsure whether they had experienced an adverse reaction because of BDS use and, as a consequence, could not answer the question.

Concomitant BDS use with other medications

The study also sought to determine whether BDS users were more likely to use prescription drugs and OTC medications in conjunction with BDS. A cross tabulations calculation of BDS use and prescription medicine use is presented in Tables 3, 4, and 5. A relative risk

TABLE 6. *Cross tabulation: BDS and OTC use*

		OTC use		
		No	Yes	Respondents (*n*)
BDS use	No	24	16	40
	Yes	132	263	395
Total		156	279	435

BDS, botanical dietary supplement; OTC, over-the-counter medication.

TABLE 7. *Cross tabulation: Chi-square tests*[a]

	Value	df	Asymp. sign. (2-sided)
Pearson Chi-square	11.158	1	0.001

df, degree of freedom; Asymp. sig., asymptotic significance.
[a]Valid cases, $n = 435$.

TABLE 8. *Cross tabulation: risk estimate*[a]

	Value	95% CI	
		Lower	Upper
Odds ratio for BDS use (no/yes)	2.989	1.535	5.819
For cohort taking OTC = no	1.795	1.345	2.397
For cohort taking OTC = yes	0.601	0.408	0.884

BDS, botanical dietary supplement; OTC, over-the-counter medication.
[a]Valid cases, $n = 435$.

analysis of the data showed that respondents who were not taking prescription medications were 1.721 times more likely to *not* take a BDS than respondents who were taking prescription medicine. The conclusion drawn from these data indicates that respondents who were taking prescription medicines were more likely to also use BDS.

A cross tabs calculation of BDS use and OTC medicine use is presented in Tables 6, 7, and 8. The χ^2 statistic allowed us to reject the null hypothesis that BDS use and OTC medicine use are independent. In short, BDS use and OTC medicine uses did not seem to be independent. A relative risk analysis of the data showed that respondents who were *not* taking OTC medications were 1.75 times more likely *not* to take a BDS than respondents who were taking any OTC medications. Thus, the study concludes that respondents who were taking OTC medications were more likely to also take BDS.

Information resources for BDS

One of the more disturbing findings of the study was that most respondents were using less than reliable resources for BDS information. Reliance on word of mouth from friends and family or media resources for their information on BDS is still commonplace. Information from the media ranked 55.5%, with information from friends and family ranking 32.5%. Unfortunately, only 3.8% of respondents claimed that they received information and recommendations for the use of BDS from healthcare providers, such as physicians, pharmacists, dietitians, or nurses. Considering the significant amount of clinical data now available for the assessment of the safety and efficacy of BDS, it is important that healthcare providers educate themselves about BDS and take the time to address these issues with their patients.

Furthermore, when respondents were asked whether they informed their physician of their BDS use, approximately 70% reported that they did not. Considering that most respondents were using more than one BDS in combination with prescription drugs and OTC medications, women from UIC clinics may be at risk for adverse effects. Patients taking prescription medications may also be at a higher risk for a serious herb-drug interaction if they do not confide in their physicians about dietary supplement use. This is especially true for women using prescription medications in conjunction with St. John's wort, kava, valerian, and ephedra.[10-13]

DISCUSSION

This investigation has several limitations, including the patient profile and selection bias. Because the study had a very limited patient profile, in that it consisted of only women 40 to 60 years of age from UIC clinics and was geographically limited to the metropolitan Chicago area, our findings may not be generalizable to the entire US population. In addition, because these women were already seeking healthcare services from UIC clinics, they might have been more inclined to use all types of medications, including BDS. In fact, one published investigation has reported that clinic respondents have higher prescription medication use than nonclinic respondents.[14] In addition, women in the 40- to 60-year-old age group may have more healthcare problems and, therefore, may also be more inclined to seek out more alternative and complementary treatments than younger women. Irrespective of these limitations, the data suggest that women still significantly underreport the use of BDS alone or in conjunction with other medications. Although other studies have suggested that women reported herbal use (BDS) to a healthcare professional much more frequently than our study suggests,[14,15] we specifically asked women about their use of soy and green tea. Although most women were using soy and green tea for health benefits, the products were viewed as food and, thus, would not normally be included as part of an herbal

survey. Therefore, specific questions with regard to the use of soy or botanical teas may have increased the number of "BDS user" respondents. However, this information is important if women are incorporating large amounts of either soy or green tea into their diets. Ingestion of large doses of green tea may antagonize the effects of anticoagulants, such as warfarin,[16,17] Furthermore, soy products should be avoided in patients taking monoamine oxidase inhibitors because of the tyramine content, and the ingestion of some medications in conjunction with soy protein products may require a dose adjustment.[18,19]

CONCLUSIONS

The primary goal of this investigation was to determine the use of BDS by peri- and postmenopausal women at UIC clinics, as this type of assessment is not routinely performed as part of the drug history. The results of the investigation demonstrate that a questionnaire specially addressing BDS (including soy and green tea) use in conjunction with a drug history is valid and worthy of use in any clinical setting in which time is limited. Our data indicate that a high percentage of peri- and postmenopausal women use BDS, and it is prudent to include questions on BDS use in drug histories. Women should be encouraged to discuss all BDS use with their healthcare providers, particularly in cases of chronic disease and concomitant prescription medication use.

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Appendix I.

Appendix I. *Botanical dietary supplement (BDS) usage in women*

Race/Ethnicity _____ **Age** _____ **yrs** **Subject I.D.** _____

Q1: **What** BDS do you use?	Q2: **Why** do you take each BDS?		Q3: **Who** recommended each BDS?						Q4: **How** do you take each BDS?				Q5: **Amount** you take of each BDS?			Q6: Do you think each BDS is **effective?**		Q7: Does your healthcare provider know you take these?		
Name and brand (if known)	Prevent Disease	Treat Disease	Healthcare provider	Label-claim	Media	Family	Friend	Other	W/food	W/bev	W/other meds	Other	Amount	× per day	× per wk	Any adverse effects?	1 2 3 4 5 least most	Yes	No	Unsure
Teas:																				
Oil/Extract:																				
Pills:																				
Liquid:																				
Others:																				
Medications:																				
Rx:																				
OTC:																				

Appendix I (continued).

Appendix I. *Botanical dietary supplement (BDS) usage in women*

Race/Ethnicity _____ **Age** _____ **yrs** **Subject I.D.** _____

Q8: What **soy products** do you eat or drink?		Q9: **Why** do you use **soy products?**		Q10: **Who** recommended the **soy products** you use?						Q11: Do you think the **soy products** you take are **effective?**	
Type	Brand	Prevent disease/sx	Treat disease/sx	Other	Friend	Family	Media	Label-claim	Healthcare provider	Any adverse effects?	least 1 2 3 4 5 most
Soy milk											
Soy burgers											
Soy creamer											
Soy nuts											
Soy flour											
Soy pro powder											
Performace drinks											
Performance bars											
Tempeh											
Textured soy											
Tofu											
Tofu dogs											
Tofu burgers											
Others											