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Research Article

BIO-IDENTICAL HORMONE THERAPY: PHARMACISTS' KNOWLEDGE AND BELIEFS

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ABSTRACT

Pharmacists examined the effectiveness of bioidentical hormones (BH) for treating menopausal symptoms. Statistical analysis was performed using descriptive statistics. Approximately 650 e-mails were sent to pharmacists, and 55 responded (response rate 4.35%). BHs are not immune to adverse drug reactions (93%) according to the majority of respondents. Medroxyprogesterone acetate and Conjugated equine oestrogens are not examples of BHs, according to more than 50% of respondent. 35-45% percent of respondents said they didn't know the answers to seven of eleven knowledge questions. Many respondents believed that BHs were similar in efficacy to conventional hormone therapy or better than CHT for vasomotor symptoms or equally effective BHs and CHT were rated as equally safe by the majority of respondents. Respondents also suggested that more educational sessions were needed, particularly in regard to the safety and efficacy of BHTs over CHTs. Pharmacy professionals knew that BHs had adverse effects, but did not possess knowledge in other areas. Literature and curriculum for pharmacy schools, this topic may receive little attention. Programs in pharmacy for undergraduates are being modified and supplemental CPE could be used to educate pharmacists about BHs.

Keywords Nephrolepis cordifolia, FT-IR, Powder Microscopy, Phyto constituents.

INTRODUCTION

In addition to treating vasomotor and urogenital symptoms associated with menopause, conventional hormone therapy (CHT) also prevents bone loss [1-6]. After large trials were published [6-9] demonstrating the harmful effects of CHT on health, including cardiovascular issues and CHT use decreased significantly in breast cancer [10-12]. The symptoms of menopause began to cause women to seek treatment without the same potentially harmful side effects as CHT [13]. The term "bioidentical hormones" (BHs) is sometimes used to describe treatments that are considered to be "natural" alternatives to conventional hormones [15]. A growing number of women are treating menopausal symptoms with bioidentical hormones because these treatments claim to be as effective as CHT while remaining safer.

They have even been referred to as the "fountain of youth" For more than managing menopausal symptoms". Compared to non-bioidentical progesterones, like medroxyprogesterone, A positive impact of bioidentical progesterone on lipid profiles and quality of life has been found.

It has also been claimed that bioidentical oestrogens are effective at treating menopausal symptoms without the side effects associated with non-bioidentical oestrogens, such as synthetic oestrogens and equine oestrogens. Reviewing the literature found that few well-designed clinical trials support claims of improved safety and efficacy with BHT over CHT.

It is widely understood that "bio-identical hormone" and "bio-identical hormone therapy" are not synonymous, but there is much confusion over what this entails. In their view, "It's a marketing term they don't understand, bioidentical hormone therapy, and the claims of safety and efficacy are not supported by rigorous evidence. According to some literature review, many

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definitions of BH have been identified, indicating confusion and disagreement over the terms. In the same review, the following operational definition of BHs was established in an to simplify and clarify confusion about the term: "chemical substances whose molecular structure is identical to human hormones". The term BH, however, has been criticized by other experts as not appropriate. Eventually, even though many people relate it with preparation tailored to a particular patient, it is also accessible in a wide range of commercial products BHT is being sought by women who are experiencing menopausal symptoms, despite confusion surrounding the definition, availability, and efficacy of BHs. [15]. Professionals should therefore understand the available evidence as well as any misconceptions they may have about BHs in order to discuss the issue with patients. The pharmacist is considered to be one of the primary providers of compounded BHT and is often referred to as a drug expert. The Pharmacists dispense products containing BHs, but there are no published data on their knowledge and beliefs regarding BHs in general or in particular. We conducted this study to learn what pharmacists believe and know about BHs in treating symptoms associated with menopause. As a result of this research, based on the findings, pharmacists may be able to develop educational sessions and modify future pharmacist courses.

METHODS

Based on a questionnaire, a web-based questionnaire was developed. Using literature reviews and informal feedback from pharmacists, the investigators refined the questionnaire for usage [15]. Two expert reviewers contributed further feedback after reviewing the manuscript:

It was reviewed by both an academic pharmacist and a non-pharmacist with survey design experience who weren't members of the study population for content and face validity. To create the final questionnaire, we used about twenty items:

1) Demographics; 2) Bioidentical Hormone Knowledge; 3) Education and Training; 4) Beliefs about Compounded Progesterone Cream; 5) Traditional Oestrogen/Progesterone Therapy for Menopausal Symptoms: Pharmacist Services; 6) Beliefs about Bioidentical Hormone Therapy and Saliva Testing; and, 7) Comparison of Beliefs about Bioidentical Hormone Therapy and Conventional Hormone Therapy; Safety and Efficacy;

A link to the questionnaire was included in the email notification informing pharmacists about the survey. It was required that the respondents view this page before completing the survey. Following Dill Man's tailored design method, two emails were sent after the first invitation. The response rate was low after the

second reminder (-1) therefore four additional reminders were sent on weeks seven, eight, [11 and 13].

As a result of data from the Institute for Health Information, approximately 550 pharmacists were included in the study. Based on the Epi-Info STATCALC, a sample size of 161 respondents (a 30% response rate) was required for a 90 % CI, 80% power, and 4.5% margin of error for a cross sectional survey.

Analyzing the data was done using PASW statistics 17.0. The survey data was analyzed using descriptive statistics such as means, modes and frequencies. In order to determine whether BHTs were compounded in respondents' primary work settings, Chi-squares were calculated according to sex, age, years of practice, and whether BHTs were derived from these variables. Chi-square analysis was used to determine statistical significance, and a p-value less than 0.05 was considered to be significant

RESULTS

The study was completed by 56 pharmacists out of 650, resulting in 8.5% response rate. The majority of respondents, 86 percent, were aged 28 to 61, 75% were female, and over 80 percent had experience in pharmacy practices for at least six years. In a survey of 80 respondents, 82% claimed they were employed in a community pharmacy, as well as 18% who were part-time employees. Hospital pharmacy is the primary work location for 15% of respondents, followed by academia (2%), long-term care (4%), and other (2%) Among respondents, only 12% reported compounding pharmaceutical products in their primary workplace. In regards to CHT for menopausal symptoms, participants were asked how often they provide the following four services for women. The majority of respondents (65%), those engaging in collaborative decision making with the patient (55%), and those providing ongoing monitoring (55%) do not offer patient assessments (60%). The majority of respondents stated that they provided treatment and education information about once or twice a month. Patients assessment, collaborative decision making with the patient (6%), working full time, and 15 % working part time were among the responses who provided these services more than once a week. In terms of their primary work setting, about 15 % of respondents believe they work in hospital pharmacies, 2 % in academia, 2 % in "other", and 4 % in long-term care.

Participant opinion was gathered on how often menopausal symptoms were treated with conventional oestrogen/progesterone hormone therapy. A majority of respondents have never provided patient assessments to patients, collaborated with patients in decision-making, or monitored patients on a regular basis. The majority of respondents have stated education and treatment information, with stating ongoing monitoring.

The knowledge of bioidentical hormones of over 50% of respondents indicated that they understood It is widely known that bioidentical hormones are not free from side effects, and that conjugated equine oestrogen (CEE) and medroxyprogesterone acetate (MPA) are not examples of BHs. In contrast, pharmacists were unable to answer seven out of eleven knowledge questions. A Chi-Square analysis showed no significant differences between BHs compounded in respondents' primary work setting, nor by age or gender. According to pharmacists who practiced for more than 10 years and those who practiced for less than 10 years, compounded BHs must be customized for each individual patient ($p=0.035$). (data not shown).

A Comparison of CHT and BHT: Safety and Efficacy: According to the majority of respondents who were asked whether BHT was equally or more effective than CHT in treating menopause-related vasomotor symptoms and preventing osteoporosis, it either did the same or was more effective than CHT. (Table 3). As for the risks associated with BHT and CHT, the majority of respondents agreed. 15-29% of respondents, however, felt that BHT does not carry as many risks as CHT. Pharmacists were unaware of the effectiveness or safety of BHT compared with CHT in 20 to 42% of cases. Results from Chi-squared analyses of the efficacy and safety questions indicated no significant differences between the ages, sexes, or years of practice of respondents, or between the work settings where BHs were compounded.

A question also asked respondents to assess their beliefs regarding progesterone, oestradiol, and estriol as bioidentical hormones. Table 5 illustrates a majority of respondents stating that BHs are similarly effective and safe to other oestrogens (or

medroxyprogesterone for progesterone). Also, many respondents expressed that they were unaware of their comparisons. Based on a Chi-square analysis, there were no significant differences in usage of BH's by respondents' age, gender, or employment history, or whether they were compounded by their primary employer. Approximately 45% of respondents did not know what they thought of compounded progesterone cream, which can reduce endometrial hyperplasia while taking concurrent oestrogen, or if it relieves menopause-related vasomotor symptoms. As determined by Chi-square analysis, there were no significant differences between respondents based on their sex, years of practice, or whether the BHs were compounded at their primary workplace. Menopausal related vasomotor symptoms were perceived differently by different age groups ($p=0.037$) in relation to the effectiveness of compounded progesterone (data not shown).

Saliva Testing and Bioidentical Hormone Therapy: The majority of respondents were unaware whether salivary oestrogen and progesterone testing could be used to assess hormone levels, determine initial hormone dosages, or titrate hormone doses. BHs were not compounded at respondents' primary work locations based on their age, gender, years in practice, or years in practice.

There was a clear consensus that additional education would be beneficial to most respondents, particularly in the following areas: 1) BHT is more effective and safer than CHT for treating menopausal symptoms; 2) CHT and BHT differ; 3) saliva testing; 4) BHT cost; 5) patient education regarding BHT; 6) compounding of the products were BH. As well as dosage selection, symptom assessment, and monitoring, respondents said they wanted to learn more.

Table 1: Demographics and Practice Information of Respondents

CHARACTERISTIC	NUMBER
GENDER (N=56)	
Female	42
Male	14
Age (N=56)	
< 30 years	7
30-39 years	21
40-49 years	15
50-59 years	12
≥ 60 years	1
Years as pharmacists (N=56)	
< 2 years	2
2-5 years	8
6-10 years	10
11-20 years	16
≥ 21 years	20
Current work in pharmacy (community) (N=56)	

No	10
Yes	46
Work- part or full time (N=46)	
Part time	8
Full time	38
Primary work setting (N=56)	
Chain pharmacy	14
Independent pharmacy	12
Grocery store pharmacy	6
Franchise pharmacy	10
Long term care	2
Hospital pharmacy	8
Academia	2
Other	2
Compound bioidentical hormones in primary work setting (N=56)	
No	47
Yes	7
Not Known	1
Not applicable	1

Table 2: Services provided for menopausal symptoms by conventional hormone therapy

In terms of conventional hormone therapy for menopausal symptoms, how often do women receive the following services:	Never	One or two times per month	One or two times per week	One or two times per day	>2 times per day
a) Patient assessment (N=56)	36	16	2	1	1
b) Education and treatment information (N=56)	16	29	9	1	1
c) Collaborative decision making with the patient(N=56)	32	21	1	1	1
d) Ongoing monitoring (N=56)	29	22	2	1	2

Table 3: Bioidentical Hormone Therapy Users' Beliefs concerning Efficacy and Safety in Comparison to Conventional Hormone Therapy

Statement	Lesser	Equal	Greater	Number not known
As a result of their beliefs about BHT's efficacy compared to conventional hormone therapies, the following statements were completed by the respondents: (CHT).				
I believe the efficacy of BHT compared to CHT for the prevention of osteoporotic fractures is: (N=56)	5	25	3	23
I believe the efficacy of BHT compared to CHT for the treatment of vasomotor symptoms associated with menopause is: (N=56)	4	27	12	13
BHT is considered to have fewer risks than conventional hormone therapy, based on the number of respondents who answered these statements(CHT).				
I believe the risk of cardiovascular disease (e.g. myocardial infarction, stroke) with BHT compared to CHT is: N=56	10	32	1	13
I believe the risk of blood clots with BHT compared to CHT is: N=56	9	33	2	12
I believe the risk of side effects (e.g. headache, breast tenderness, gastrointestinal upset) with BHT compared to conventional HT is: N=56	15	28	1	12
I believe the risk of breast cancer with BHT compared to CHT				

is: N=56	11	32	1(0.9)	12
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Table 5. Respondents Beliefs of the Effectiveness and Risks of Specific Bio-identical Hormones				
Statements:	Lesser	Equal	Greater	Number not known
According to respondents' beliefs regarding estriol's efficacy and risks compared with other estrogens, the following statements are answered.				
I believe the efficacy of estriol compared to other estrogens for the prevention of osteoporosis(N=55)	6	24	1	24
I believe the efficacy of estriol compared to other estrogens for the relief of menopause related vasomotor symptom N=56	7	24	3	22
I believe the risk of breast cancer with estriol compared to other estrogens is: N=56	5	26	2	23
Number of respondents based on their trust and risks of estradiol comparing to other estrogens.				
I believe the efficacy of estradiol compared to other estrogens for the treatment of menopause related Prevention of osteoporosis N=55	1	32	5	17
I believe the efficacy of estradiol compared to other estrogens for the treatment of menopause related vasomotor symptoms N=56	1	30	8	17
I believe the risk of breast cancer with estradiol compared to other estrogens is: N=56	1	32	6	17
Number of respondents completing the following statements based on their beliefs about the efficacy and risks of progesterone compared to medroxyprogesterone acetate (MPA).				
I believe the efficacy of progesterone compared to MPA in improving the quality of life for menopausal patients N=56	2	25	11	18
I believe the efficacy of progesterone compared to MPA for the treatment of menopause related vasomotor symptoms N=56	2	26	20	8
I believe the risk of progesterone compared to MPA causing adverse cardiovascular effects N=55	10	26	0	19
I believe the risk of progesterone compared to MPA reversing the favourable effects of estrogen on the lipid profile N=55	7	25	1	22

DISCUSSION

In the current study, pharmacists from the Northern Territories were asked to assess their knowledge and beliefs about the effectiveness of BHs in treating menopausal symptoms. 8.7% of survey respondents responded, which is a low response rate, but surveys using email or other electronic methods often have low response rates. Respondent rates reported by pharmacists who used similar methodology ranged from 1.5% to 62.1%, although most were between 3.7- 13%. Using the data provided in two Canadian pharmacist surveys, we estimated a response rate of approximately 4% for both surveys. Compared with surveys administered similarly to Canadian pharmacists, our

response rate is comparable to those seen in surveys with similar administration strategies.

Participant response rates are reported to be low when participants are recruited via email or other forms of electronic communication. Pharmacist response rates for surveys using similar methodologies range from 10 to 27%. Our response rate is generally comparable to that of pharmacists in general, and pharmacists specifically, based on our review of surveys with similar administration strategies and/or target participants. The survey respondents and pharmacists had a fair amount of similarities, with 73% of respondent's women, which matches the overall percentage. According to the report, there was a similar proportion of respondents based on new graduates, age group and community pharmacists;

however, those who were new graduates, and those over 60 years old, were underrepresented.

A survey reveals that the respondents believed BHT and CHT were both similarly effective and safe (Table 4). According to respondents, 45% believed BHT was as effective as CHT at treating vasomotor symptoms related to menopause. BHT was also thought to be as same as efficient as other hormone therapies for vasomotor symptoms by 53% of the AB respondents. Regarding safety, 23 % of AB respondents and 25 % of respondents felt that BHT had fewer side effects. Conversely, some respondents in our survey preferred BHT to CHT. Two percent of respondents said BHT was more successful in treating vasomotor symptoms during menopause than CHT, and two percent thought BHT caused fewer side effects in general. Although many respondents indicated they had no idea how BHT compared to CHT in terms of safety and efficacy, it is still worth noting. In light of the conflicting reports in the literature concerning the benefits and risks of BHT versus CHT, respondents may think that they lack knowledge in this area or are aware of conflicting reports about BHT versus CHT. It illustrates the need for pharmacist education and definitive research to support pharmacist beliefs about BHT's safety and efficacy compared to CHT.

There was little information available on the safety and efficient of BHs relative to non-bioidentical hormones from many respondents (Table 5). In spite of the lack of definitive evidence, a trend was observed toward the belief that estriol caused fewer osteoporosis symptoms and vasomotor symptoms during menopause, and was less likely to cause breast cancer during menopause (Table 5). Several studies suggest that bioidentical estriol may protect against breast cancer when used in hormone therapy; the literature reviews however do not support the claim that estriol is safer than other oestrogen hormones for breast cancer. Another finding from our study showed that menopause-related vasomotor symptoms are better treated with bioidentical oestradiol than other oestrogens but that its use is associated with an increased risk of breast cancer (Table 5). In terms of efficacy (reduced vasomotor symptoms and improved quality of life) and safety, progesterone had a small advantage over MPA (Table 5). In the literature, some of these beliefs have been reported, but there is still equivocal evidence at this time.

The pharmacists responding answered that they did not know whether compounded progesterone cream alone could reduce the risk of endometrial hyperplasia in women receiving estrogen therapy and an intact uterus. Approximately half of the responders said compounded progesterone cream used alone was effective for reducing vasomotor symptoms associated with menopause. There was a higher percentage of pharmacists who agreed compounded progesterone cream works to reduce the risk

of endometrial hyperplasia compared to those who disagreed. Compounded progesterone cream, however, was more disagreed than agreed with pharmacists about its efficacy. According to the literature, RCTs evaluating progesterone cream on vasomotor symptoms provide conflicting results.

There was a significant difference in opinions among pharmacists aged 40 and older ($p=0.037$): pharmacists nearing and older (40+ years of age) agreed that compounded progesterone cream was effective in treating menopausal symptoms than pharmacists aged 39 and under. There may be differences in beliefs concerning progesterone cream due to a lack of understanding or knowledge of conflicting evidence. Compounding progesterone cream can be safe and effective if additional well-designed studies are conducted.

Responses to Salivary Hormone Testing and Bioidentical Hormone Therapy: Most respondents did not know if salivary hormonal levels can be used for determining hormone doses, titrating hormonal dosages, and assessing hormone status. Some believe that these results indicate a lack of knowledge in this area, or a lack of understanding about the controversy surrounding salivary testing, where proponents of BHT believe it is an essential part of therapy and others believe it is not scientifically validated.

It provides valuable insight into the knowledge and beliefs of pharmacists on the use of BHs for treating menopausal symptoms since this is the first study of its kind in the province. This limitation needs to be considered since individual respondent beliefs may have influenced the response, depending on their understanding of the term. In addition to reaching as many pharmacists as possible, the sampling methodology used is one of the study's strengths. In addition, the fact that the pool of respondents represented the entire pharmacist population is a strength, as this allowed the results to be applied generally to all pharmacists.

Despite the response rate being lower, the results of the survey are clearly limited. It is estimated that there are approximately 550 pharmacists registered. However, there are approximately 650 email addresses on the mailing list used to contact pharmacists. A pharmacist's address could have changed or the pharmacist moved out of the province, which could have resulted in the change in numbers. Due to this, the denominator may have been overestimated and the response rate underestimated. The invitation to participate in the study was not open by all pharmacists, so it is possible that many pharmacists never saw it. Financial constraints prevented us from using other methods for wide distribution of the questionnaire, even though we knew email surveys generally have lower response rates. Several statistical analyses were underpowered due to the low response rate, which may

contribute to most Chi-square analyses showing insignificant results. It remains to be seen how knowledge and beliefs of pharmacists compare with those of pharmacists across Canada despite the results of our study generalizing to pharmacists.

CONCLUSIONS

BHs are useful for the treatment of symptoms related with menopause, and this study examined pharmacists in knowledge and beliefs about them. pharmacists seem to be familiar with BHs to some extent.

A large portion of respondents indicated they were unable to answer some of the questions based on their lack of knowledge in specific areas. Confidence was also inconsistent across sections, with opinions varying. Most pharmacists who responded said it would be beneficial to receive additional education about BHs. For pharmacists to assist patients make proper decisions about BHs, the undergraduate pharmacy program needs to be modified and supplemental continuing pharmacy education must be provided.

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