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Beliefs about bioidentical hormone therapy: A cross-sectional survey of pharmacists

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ABSTRACT

Objective: The aim of this study was to assess pharmacists' beliefs about bioidentical hormone therapy (BHT) and to identify factors influencing these beliefs.
Study design: This was a cross-sectional survey of pharmacists. An email invitation to participate in the online survey was sent to a random sample of 2000 pharmacists in Alberta. The survey was accessible for a six-week period from May to July, 2011. A 54-item questionnaire was used to capture knowledge and beliefs about, and confidence in BHT. Summary statistics and multivariate regression were used for analyses.
Results: Overall, 401 pharmacists completed the survey (response rate 20%). Respondents were mainly female (64%), above 30 years of age (81%) and in practice for more than 10 years (63%). Only 35% of respondents correctly classified BHT as including both compounding and commercial products. In regards to beliefs, 68% of respondents agreed that BHT is as effective as non-bioidentical hormones for vasomotor symptoms, while 60% agreed BHT had equal risk. Beliefs on estriol, progesterone, and saliva testing however, were more diverse with many "do not know" responses (40%). In multivariate analysis, pharmacists who worked in pharmacies that compounded BHT were more likely to believe in BHT safety ($p < 0.001$), and have greater confidence with BHT ($p < 0.001$).
Conclusions: Results from this survey indicated that pharmacists had varying beliefs on BHT. In addition, beliefs on the safety of BHT were associated with pharmacists' practice, specifically working in a pharmacy that compounds BHT. This study helps identify areas for targeted education.

1. Introduction

The use of hormone therapy (HT) declined dramatically after the publication of the initial results of the Women's Health Initiative (WHI) in 2002 [1–3]. In North America, this trend continues a decade later [4,5]. As a result of the outcomes of the WHI and safety concerns expressed in the lay press, health care providers and women have become more conservative with the use of HT, including a shift to the use of perceived safer alternatives such as bioidentical hormone therapy (BHT). Recent promotion by the media and celebrity endorsements has caused even more confusion on the role of BHT [6,7].

A great deal of controversy exists surrounding the term "bioidentical hormones". A recent proposed definition is "*chemical substances that are identical in molecular structure to human hormones*" [8]. In the context of HT, these would include any product containing estradiol, estrone, estriol, progesterone or testosterone. The term is sometimes used to refer to compounded formulations, however, many commercially available, Health Canada/FDA-approved HT products also contain bioidentical hormones [6,9]. BHT is also promoted as being natural, however this is misleading as natural refers to the source, not the chemical structure [10]. In fact, bioidentical hormones cannot be considered truly natural, as plant-derived estrogens are synthesized to produce hormones identical to the human body [11].

Advocates promote BHT as being safer and more effective than conventional HT. As these products are identical to endogenous hormones, advocates claim that BHT has better affinity to human receptors, and therefore produces natural biological results with fewer adverse outcomes [12]. However, published studies indicating BHT with better outcomes and fewer risks are lacking [6,7,9,11,12]. Current position statements from professional organizations such as the North American Menopause Society (NAMS), and the Endocrine Society recommend that the benefits and risks should apply equally to all HT [9,13].

Compounded BHT formulations, which are available from compounding pharmacies, can be made for a variety of administration routes including capsules, topical gels and creams [6]. Compounded preparations include the use of estriol, the least potent of the estrogens, often in combination with estradiol (Bi-Est) or both estradiol

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and estrone (Tri-Est). Estriol is not commercially available in North America. Proponents of estriol promote it as less risk of breast cancer compared to other estrogens; however, there is a lack of good quality evidence to support this claim [11,14]. Transdermal progesterone cream is another commonly compounded HT. Transdermal progesterone cream may help relieve vasomotor symptoms [15], however, should not be used for endometrial protection during estrogen therapy [9]. Salivary hormone levels are also sometimes used to guide individualization of compounded BHT products and adjust therapy [12]. The role of salivary hormone testing in this setting remains unclear [16].

Due to the highly publicized claims about BHT, women may be receiving misleading information about the benefits and risks of BHT [17,18]. With the lack of evidence on the safety and efficacy of BHT, health care providers may provide information to patients based on their own personal beliefs and experiences with BHT. The information provided may affect patients' perceptions and treatment decisions about hormone therapy [19]. There is limited information available on the beliefs of health care professionals, including pharmacists regarding BHT and the factors influencing these beliefs. Identifying these beliefs can help us understand the type of information currently communicated to patients about BHT and its role in clinical practice. The primary objective of this study was to assess beliefs of pharmacists on the safety and efficacy of BHT and identify factors influencing these beliefs.

2. Methods

2.1. Study design and participants

This was a cross-sectional web-based survey targeting practicing pharmacists in Alberta, Canada. Inclusion criteria included pharmacists on the clinical registry of the Alberta College of Pharmacists who agreed to participate in practice-based research and were willing to complete an online survey. The study was approved by the University of Alberta Health Research Ethics Board.

2.2. Research procedures

An email invitation to participate in the web-based survey was sent to a random sample of pharmacists who met the inclusion criteria. The list was generated by the Alberta College of Pharmacists through a random number generator and sent to the study investigators. The online survey was accessible for a six-week period from May to July, 2011 with email reminders sent each week to non-responders. In an attempt to increase the response rate, an incentive (iPod Touch) in the form of a draw was offered for interested participants. The survey was administered by Academic Information and Communication Technologies (AICT) at the University of Alberta.

2.3. Survey instrument

2.3.1. Questionnaire format

The 54-item online self-administered questionnaire was developed by the study team containing primarily quantitative components (close-ended and Likert scale questions). All survey questions were investigator initiated as a review of the literature failed to identify any published surveys on BHT. The survey contained 4 sections: (1) demographics and practice related questions, (2) knowledge on BHT, (3) beliefs about BHT, and (4) confidence level and learning needs. Knowledge on BHT definition was measured on a 3-item subscale that participants rated "true/agree", "false/disagree", or "do not know/not sure". Beliefs and confidence were measured using a 4-point multi-item Likert subscales anchored as "strongly disagree" to "strongly agree". A "do not know" response choice was also provided. An open-ended question was included at the end of the questionnaire for pharmacists to share their practice experiences with BHT. For the purposes of the survey, non-bioidentical hormones were classified as HT products that contained estrogen or progestin that are not identical in structure to the human body (e.g. synthetic or animal sources).

2.3.2. Validity and reliability of questionnaire

The initial questionnaire was assessed for content validity by a small sample of experts ($n = 2$) and then used in a pilot study of community pharmacists in Edmonton ($n = 95$). The questionnaire was then revised and peer-reviewed by a cohort of 11 pharmacists for face validity and comprehensibility using cognitive semi-structured interviews [20]. For test–retest reliability, the survey was resent to a random sample of 60 pharmacists two weeks after initial survey completion, with 8 pharmacists completing the survey a second time. Internal consistency of different constructs (knowledge, beliefs and confidence) was measured using the Cronbach's alpha coefficient [21]. All sections demonstrated acceptable to excellent internal consistency with Cronbach's alpha values ranging from >0.7 to >0.9. Further evidence of the tool reliability over time was provided by a test re-test reliability coefficient of 0.70.

2.4. Sample size

Approximately 4200 pharmacists are registered on the clinical register in Alberta and the majority have agreed to be contacted for research purposes. Assuming a 95% confidence interval with a 5% margin of error, and a proportional variable of interest we needed 352 subjects in our study [22]. We inflated the numbers to a sample size of 400 to account for partial completion of surveys. Based on previous experience, response rates for online surveys with pharmacists are often low (i.e. less than 20%) [23–25] therefore, the survey was sent to 2000 pharmacists to achieve a sample size of 400.

2.5. Statistical analysis

Summary statistics were used to describe the extracted data and characterize the cohort. Multivariate logistic regression was used to examine factors associated with knowledge and multiple linear regression for variables associated with beliefs and confidence. One logistic regression model and 10 multiple linear regression models were conducted using purposeful selection methods. All "do not know" responses were excluded from the multivariate analyses. Several variables were collapsed or combined into new variables to be used as dependent measures in the analyses. Items measuring knowledge on BHT definition were combined creating a new dichotomous variable with two response categories: "good knowledge" and "poor knowledge". Good knowledge was defined as correctly answering all of the questions (total 6 out of 6 maximum score), while poor knowledge defined as incorrectly answering any of these questions (<6 score). For subscales measuring beliefs and confidence, items were combined and divided by the total number of items for subscale total scores, creating eight continuous dependent variables. These variables were: (1) beliefs about BHT efficacy in vasomotor symptoms, (2) beliefs about BHT efficacy in osteoporosis, (3) beliefs about BHT risks, (4) beliefs about estriol efficacy, (5) beliefs about estriol risks, (6) beliefs about progesterone risks and efficacy, (7) beliefs about saliva testing, and (8) confidence in recommending and providing patient education about BHT. $p < 0.05$ was considered statistically significant. All analyses were conducted with SPSS18 (SPSS Inc., Chicago, IL).