



## The multifaceted nature of access to compounded progesterone: A cross-sectional study from Australia



M. Joy Spark<sup>a,\*</sup>, Jon Willis<sup>b</sup>, Graeme Byrne<sup>c</sup>, Teresa Iacono<sup>d</sup>

<sup>a</sup> School of Pharmacy and Applied Science, La Trobe Institute of Molecular Science, PO Box 199, Bendigo 3552, Victoria, Australia

<sup>b</sup> Aboriginal & Torres Strait Islander Studies Unit, University of Queensland, Brisbane, Queensland, Australia

<sup>c</sup> School of Engineering and Mathematical Science, La Trobe University, PO Box 199, Bendigo 3552, Victoria, Australia

<sup>d</sup> La Trobe Rural Health School, La Trobe University, PO Box 199, Bendigo 3552, Victoria, Australia

### ARTICLE INFO

#### Article history:

Received 9 July 2013

Received in revised form 7 October 2013

Accepted 22 October 2013

#### Keywords:

Progesterone  
Access to medication  
Questionnaire  
Women's perspective  
Australia

### ABSTRACT

**Objective:** To explore the influences on accessibility of compounded progesterone therapy for Australian women.

**Study design:** A cross-sectional survey of a stratified sample of Australian women who use progesterone only products using the 'Perspectives on Progesterone' questionnaire.

**Main outcome measures:** Principle components analysis (PCA) to determine components of access to progesterone treatment and multi-way analysis of variance to compare groups.

**Results:** Women using compounded progesterone were likely to have made at least one lifestyle adaptation (73%), and to have tried and stopped using at least one complementary and alternative medicine therapy (63%) or conventional hormone therapy (41%). PCA revealed six components of access to progesterone treatment: *affordable, values natural treatments and is concerned about other treatments, conventionally available, perceived knowledge, values information gathered from a variety of sources, and rural & disadvantaged*.

The multifaceted nature of progesterone use illustrates that there are multiple aspects to use of non-conventional medicines. Women looking for non-conventional treatment are neither stupid nor uninformed, their understandings, based on experience and research, need to be addressed by health professionals while assessing their condition prior to discussing the risks and benefits of non-conventional medicines.

**Conclusion:** Access to compounded progesterone is multifaceted, and many of the women who use it have tried other treatments first. Despite the clinical ambivalence towards progesterone as an alternative for women who may have tried and rejected other treatments, including conventional hormone therapy, the women described in this paper are using it.

© 2013 Elsevier Ireland Ltd. All rights reserved.

### 1. Introduction

Access to compounded progesterone (P<sub>4</sub>) is restricted in Australia because there are few proprietary products and, outside of pregnancy support, it is not conventional treatment. As a prescription medicine the conventional entry point would be recommendation from a prescribing doctor. A doctor's first medicine choice for a medical condition is influenced by many factors, including treatment efficacy and marketing from pharmaceutical companies [1]. The P<sub>4</sub> proprietary products on the market in

Australia have limited distribution and are not marketed to general practitioners. Hence, P<sub>4</sub> is unlikely to be the first medication prescribed for symptomatic midlife women, limiting availability and therefore access.

Midlife women have been reported to use a range of strategies to improve health and minimise the symptoms associated with menopause. Menopause is perceived as natural and using conventional hormone therapy (CHT) as unnatural [2] which could explain why women have been found to use complementary and alternative medicine (CAM) therapies, including exercise and vitamins, to improve general health or to treat menopausal symptoms, either as a therapeutic alternative to [3], or in combination with, CHT [4]. Midlife women reportedly use informal and formal sources of information, both within and away from clinical encounters, and experiential and analytical reasoning to evaluate medicines, construct an understanding of risk, or learn about menopause, and keep searching for information until they find answers to their

\* Corresponding author at: School of Pharmacy and Applied Science, La Trobe Institute of Molecular Science, La Trobe University, PO Box 199, Bendigo 3552, Victoria, Australia. Tel.: +61 3 5444 7551; fax: +61 3 5444 7878.

E-mail addresses: [j.spark@latrobe.edu.au](mailto:j.spark@latrobe.edu.au) (M.J. Spark), [j.willis2@uq.edu.au](mailto:j.willis2@uq.edu.au) (J. Willis), [g.byrne@latrobe.edu.au](mailto:g.byrne@latrobe.edu.au) (G. Byrne), [t.iacono@latrobe.edu.au](mailto:t.iacono@latrobe.edu.au) (T. Iacono).

questions [5–8]. Information may be obtained from health professionals; printed health information, such as internet posts, books or pamphlets and family or friends; with doctors reported as the most important source of information associated with initiating CHT [8,9,10].

We can assume that the same processes are used by women who are using non-conventional therapy. One alternative treatment to CHT for symptomatic midlife women is P<sub>4</sub>, the progestational hormone (progesterone) native to the human body. Following exogenous administration, P<sub>4</sub> has many effects in the body that progestins (synthetic progestogens) do not have and a different safety profile [11]. Laypeople are likely to refer to P<sub>4</sub> as natural and to hold the misconception that the exogenously administered hormone is not manmade [9]. Exogenous P<sub>4</sub>, along with other steroid hormones used in CHT, is chemically synthesised from naturally occurring plant steroids [12]. Despite being a powerful steroid hormone, P<sub>4</sub> has been grouped with CAM therapies or with yam cream, which is ineffective [12], by authors reporting on treatments for menopausal symptoms [13,14]. P<sub>4</sub> has been advocated, based on clinical experience, for the treatment of a range of symptoms associated with hormone imbalance [15–17]. A small observational cohort study found that P<sub>4</sub> monotherapy alleviated mood symptoms more effectively than P<sub>4</sub> in conjunction with oestrogen [18]. Others have claimed that the efficacy of P<sub>4</sub> treatment is unsubstantiated, especially when administered transdermally [19]. Two recent systematic reviews of P<sub>4</sub> use by mid-life women suggested that it may have a place in therapy, but the authors have called for well designed clinical trials to confirm this [20,21].

Unfortunately although we suspect there are a number of women in the community using P<sub>4</sub> no prevalence studies have been done to determine how many women are using it. We anticipate that there a reasonable number of Australian women using P<sub>4</sub> compounded by pharmacies affiliated with PCCA. A small qualitative study investigating women's experience of P<sub>4</sub> found that there were few prescribing doctors for P<sub>4</sub>, limited lay information and higher cost than CHT [22]. Cost is only one aspect of affordability which is a complex issue. Most people have been found to continue using prescribed medicines despite the cost [1]. They do a cost/benefit analysis for their medicines and find the money to pay for them when the perceived benefit outweighs the cost [23]. Symptom relief and perceptions of safety and naturalness have been found to be associated with acceptance of P<sub>4</sub> by Australian women [24].

P<sub>4</sub> is not conventional treatment [14] so it is unlikely that the family doctor will prescribe P<sub>4</sub> or refer women to a specialist who does. So what contributes to P<sub>4</sub> being accessed by women? This paper reports on the influences that contribute to Australian women accessing P<sub>4</sub> treatment.

## 2. Methods

In a cross-sectional survey women were asked about their perceptions and experience of treatment with P<sub>4</sub> using the 'Perspectives on Progesterone' questionnaire [24]. The questionnaire had required modification following the pilot study [25], validity of the revised questionnaire was confirmed using cognitive interviewing [26]. Ethics approval was obtained from the La Trobe University Faculty Human Ethics Committee.

Questionnaires were distributed to women who use P<sub>4</sub> only products, between March and December 2009, using a random sample, stratified by state, of pharmacies that compound P<sub>4</sub>. To reduce selection bias, pharmacy staff were asked to include a questionnaire pack with every P<sub>4</sub> only product dispensed irrespective of use. Return of a questionnaire to the university in the reply paid envelope provided was taken as implied consent.

Data were entered into SPSS version 18, variables were screened for accuracy of data entry, and the assumptions of multivariate

analysis were assessed. Analyses included: descriptive statistics, chi-squared tests, Wilcoxon Signed Rank Test, odds ratios, factor analysis and analysis of variance (ANOVA).

To determine the components associated with access to P<sub>4</sub> treatment, a principle components analysis (PCA) was performed using 39 non-dichotomous items. Initially an oblique rotation was conducted, but as correlations between components did not exceed 0.15, an orthogonal (varimax) rotation was used to aid interpretation. Prior to PCA, the suitability of data for PCA was assessed. Two cases were identified as outliers due to excessive Mahalanobis distances ( $p < 0.001$ ) and deleted. Items that did not correlate with other items ( $r < 0.3$ ) or had a measure of sampling adequacy (MSA) of less than 0.6 were deleted [27]. A Kaiser–Meyer–Olkin (KMO) value of 0.71 ( $> 0.6$ ) and statistically significant Bartlett's Test of Sphericity ( $p < 0.001$ ) supported the factorability of the correlation matrix [28]. PCA revealed nine components with eigenvalues greater than 1. Inspection of the screeplot for discontinuity suggested six components and was supported by Parallel Analysis [28]. Items with loadings of less than 0.45 were removed from the analysis.

Resulting factor scores were used to compare access to P<sub>4</sub> treatment with regard to demographic characteristics, other treatment and doctors using a univariate multi-way ANOVA. Multivariate analysis (MANOVA) was considered, but MANOVA has reduced power when dependant variables are uncorrelated [28].

## 3. Results

Questionnaires were distributed by 47 pharmacies and 363 useable questionnaires returned [24]. Respondents reported using P<sub>4</sub> to treat a many conditions including; menopause related symptoms (70%), hormone imbalance (64%), pre-menstrual syndrome (19%), period irregularities (19%), osteoporosis (14%) or migraine (10%). Just over half were using P<sub>4</sub> alone, with 39% reporting treating their symptoms with other hormones as well as P<sub>4</sub>. Demographics of respondents are summarised in Table 1. Most respondents (84%) had had their P<sub>4</sub> levels measured. Income may not provide an accurate measure of disposable income, so respondents were asked a range of questions that were expected to reflect discretionary spending by women. Affirmative responses to these questions were counted to form a discretionary spending index (DSI), range 0–7.

Responses were obtained from women living in most Australian states and territories. More doctors and pharmacies were located in major cities than would be expected from where respondents lived (Table 2). The distance between a respondent's home and her prescribing doctor or dispensing pharmacy, both severely skewed, were compared using the Wilcoxon Signed Rank Test. The median distance to the pharmacy ( $Md = 23$  km,  $IQR = 6–96$  km) was significantly further than the median distance to the doctor ( $Md = 13$  km,  $IQR = 2–29$  km),  $z = -6.62$ ,  $p < 0.001$  (two-tailed) with a medium effect size  $r = 0.36$ . It has been reported that few people travel more than 20 miles (31.6 km) to the pharmacy of their choice to have their medicine dispensed [30], whereas 40% of respondents obtained their P<sub>4</sub> prescriptions at pharmacies more than 31.6 km from home.

The doctor prescribing P<sub>4</sub> had not been seen by 45% ( $n = 165$ ) of respondents prior to commencing P<sub>4</sub>. Odds ratios (OR) were calculated for the likelihood of prescribing doctors being chosen because they prescribe P<sub>4</sub> (Table 3). Women seeking P<sub>4</sub> treatment were more likely to be choosing doctors known to prescribe P<sub>4</sub> (OR 7.7). Prescribing doctors not seen prior to using P<sub>4</sub> were also less likely to be the doctor respondents used for general health concerns (OR 0.17) and more likely to be measuring P<sub>4</sub> levels (OR 3.2).

Other treatments had been tried, or were being used in conjunction with P<sub>4</sub>, by respondents to treat their condition. These were divided into lifestyle adaptations (exercise, changes to diet,

Download English Version:

<https://daneshyari.com/en/article/1917228>

Download Persian Version:

<https://daneshyari.com/article/1917228>

[Daneshyari.com](https://daneshyari.com)