



Research Article

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Lepidium Meyeni and Pfaffia Paniculata May Improve QoL in Postmenopausal Women



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Abbreviations: HF: Hot Flashes; HT: Hormone Therapy; KI: Kupperman Index

Introduction

Menopause is a biological event associated with a cessation of women reproductive ability as a consequence of the exhaustion of the ovarian reserve. Age at menopause in the world ranges between 40-58, with an average of 51 years [1]. It also involves menopause-related complaints and disorders. Hormone changes observed in this period may cause a variety of symptoms: irregular menstrual cycle, vasomotor and psycho-emotional disorders, urogenital dysfunctions, cardiovascular diseases, lipid disorders, osteoporosis, type 2 diabetes mellitus, and mental disorders. Approximately 70% of midlife western women experience hot flashes (HF) in menopausal transition. Hot flashes in midlife women may last few months, or some years and, in certain cases, even up to 30 years [2]. Following recent medical advances and the consequent increase in life expectancy, the number of menopausal women is on a rapid rise in western countries, thus postmenopausal years constitute about one-third of women's lives [1]. Hormone therapy (HT), using oestrogen either alone or in combination with progestogens, is often recommended for the management of menopausal symptoms [3]. However, many women prefer complementary or alternative remedies such as herbal preparations or nutraceuticals, which are often perceived as natural and therefore free of adverse effects. One of the alternatives to HT is *Lepidium Meyenii* (Maca), which is an Andean plant of the brassica (mustard) family, widely spread in several South American countries. For centuries, Maca has been used successfully by native people of Peru for hormonal imbalances, menstrual irregularities and infertility [4]. Some reports suggest that Maca can be helpful in reducing discomfort caused by menopausal symptoms, including hot flashes, vaginal dryness, loss of energy, reduced libido and depression [4]. The other supplement used in this study is *Pfaffia paniculata*, a common root in South America, especially in Brazil, popularly known as Brazilian ginseng, with reported estrogen-like effects

[5]. The aim of the study was to ascertain whether this new supplement might improve the quality of life of postmenopausal women.

Material and Methods

The study involved 60 Italian women who had their last menstrual period at least one year before the study. The inclusion criteria were the presence of postmenopausal symptoms, first of all hot flashes, an age from 45 to 60, no hormonal therapy or other alternative treatment and no psychiatric treatment by the time. The outpatient women who met the above criteria were informed about the possibility of taking part in the study, and after an informed consent, they were randomly assigned to receive the supplement (200mg of Maca and 150mg of *Pfaffia Panniculata*, n=30) or placebo (n=30) for 3 months. A computerized database was used for randomization. Placebo and supplement tablets had a similar appearance. All 60 participants included in the study were instructed to record in a diary the number and the severity of hot flashes. The baseline and 3-month hot flash counts were calculated as the mean of the last 7 days before treatment and before each monthly control. Reductions from the baseline in the frequency and severity of hot flashes were the principal criteria of efficacy. The severity of hot flashes was evaluated using a score from 1 to 3: 1, mild; 2, moderate; 3, severe. Mild hot flashes were defined as a warm sensation without sweating that left the woman able to continue her daily activity. Moderate hot flashes were defined as a warm sensation with sweating that left the woman able to continue her daily activity. Severe hot flashes were defined as a hot sensation with sweating so intense that the woman had to stop her activity.

The quality-of-life was evaluated through the Kupperman Index (KI) [6], a well-validated, nonintrusive, self-report questionnaire that measures the physical and psychological

symptoms associated with menopause. This Index assesses the severity of 11 menopausal symptoms, such as: hot flashes, sweats, insomnia, nervousness, melancholia, dizziness, fatigue, arthritic pain, headache, palpitations and formication. Each symptom on the KI was rated from 0 to 3 for no, slight, moderate, and severe complaints. The symptoms were weighted as follows: hot flushes (×4), sweats (×2), insomnia (×2), nervousness (×2), and all other symptoms (×1). The highest potential score is 51. The scores obtained were interpreted as follows: 0-16 points-no menopausal symptoms, 17-25 points-mild symptoms, 26-30 points-moderate symptoms, and more than 30 points-severe symptoms. The primary outcome of the study was the changes in frequency and severity of menopausal symptoms in the group treated with this new supplement. Written informed consent was obtained from all participants; the protocol and other materials were in accord with the Helsinki Declaration of 1975 and approved by institutional review boards.

Statistical Analyses

The demographic characteristics of the study groups and the number of hot flashes and severity score are expressed as mean±SD. The Student's t test was initially used to verify the differences between the independent groups. A two-way analysis of variance with repeated measures followed by a post hoc multiple-comparison procedure was performed to verify differences in the numbers of hot flashes and other symptoms between different treatment groups and within groups over time. Statistical tests were two tailed; the significance level was set at P<0.05, and data were analyzed with SPSS software, version 17.0 (SPSS Inc, Chicago, IL).

Result

Table 1: General characteristics of the study groups at the beginning of the study.

	Supplement n. 30	Placebo n. 30	P
Age (years)	52.1±5.5	52.7±5.8	ns
Body Mass Index (Kg/m ²)	26.8±4.9	26.5±4.7	ns
Time since menopause (months)	34±25	33±26	ns

ns = not significant

Among postmenopausal women referred to our Menopause Center, sixty women were recruited who met the inclusion criteria. Three women in the control group abandoned the study, failing the appointment at the end of the study, probably thinking that the supplement didn't work; one dropped out in the

Table 5: Mean±SD of KI value in the supplement group at baseline and after 3 months.

Symptoms	Baseline N. 30	3 ^o Month N.29	P
Hot flashes	10.3±2.0	6.3±2.05	< 0.01
Night sweats	4.3±1.6	2.8±1.5	0.03
Insomnia	2.1±2.6	1.3±1.9	ns
Nervousness	4.1±1.8	1.3±1.5	< 0.01
Melancholia	1.0±1.1	0.2±0.4	0.04
Dizziness	1.0±1.1	1.1±1.1	ns

supplement group for not well precised side effects of the drug. General characteristics of postmenopausal women enrolled are reported in Table 1; there were no statistical difference in age, BMI and years from menopause between the 2 groups. In Table 2&3 are reported mean number±SD of hot flashes per day and mean±SD of hot flashes severity score per day respectively. No difference was shown at baseline between groups. Instead, in both cases, a statistically significant difference was highlighted either between groups after 3 months, either in the treated group comparing the values at the beginning and at the end of the study. In Table 4 are reported mean±SD of Kuppermann Index values in both groups. No difference was shown at baseline between groups. Instead, a statistically significant difference was highlighted either between groups after 3 months, either in the treated group comparing the values at the beginning and at the end of the study. In Table 5, baseline and 3-month value of each symptom included in the KI of the supplement group are reported. Apart for hot flashes and night sweats, a significant difference was highlighted only for nervousness, melancholia and palpitations. In the placebo group no significant difference before and after treatment for each symptom of KI.

Table 2: Mean±SD of hot flashes number per day in both groups during the study.

	Supplement n. 29	Placebo n. 27	P
BASELINE	8.1±5,8	8.9±5,6	ns
3 th MONTH	5.8±5.6	8.7±4.6	< 0.01
P	< 0.01	ns	

ns = not significant

Table 3: Mean±SD of hot flashes severity score per day in both groups during the study.

	Supplement n. 29	Placebo n. 27	P
BASELINE	2.6±0.4	2.4±0,6	ns
3 th MONTH	1.8±0.7	2.2±0.6	0.04
P	< 0.01	ns	

ns = not significant

Table 4: Mean±SD of Kuppermann Index (KI) value in both groups during the study.

	Supplement n. 29	Placebo n. 27	P
KI BASELINE	32.9±7.2	34.8±7.2	ns
KI 3 th MONTH	16.6±4.2	32.6±7.5	0.01
P	0.01	ns	

ns = not significant

Fatigue	1.9±1.1	1.0±1.1	0.06
Arthritic pain	2.6±0.4	2.0±1.1	ns
Headache	0.7±0.8	0.3±0.4	ns
Palpitation	1.2±1.1	0.2±0.4	< 0.01
Formication	1.1±1.2	0.7±0.9	ns

Discussion

The KI value indicated that *Lepidium Meyenii* plus *Pfaffia Panniculata* treatment was associated with a significant reduction in symptom scores of about 50% from baseline values. Thus, women treated with this supplement changed from the area of severe symptoms (score 32) to the area of no symptoms (score 16). The improvement of wellbeing in these women was determined not only by a significant reduction in hot flashes number and severity, but also by symptoms such as nervousness and melancholia, which suggests some effects on mood. Furthermore, experimental studies showed that Maca may improve memory impairment [7]. A border line difference was evidenced for fatigue, confirming a very recent study, in which 2 fractions of polysaccharide extracted from *Lepidium Meyenii* presented dose-dependently positive effects on the fatigue related parameters [8]. A systematic review that included four RCTs tested the effects of Maca on menopausal symptoms in healthy perimenopausal, early postmenopausal, and late postmenopausal women [4]. The review showed favorable effects of Maca on menopausal symptoms using the KI and the Green Climacteric Score; despite some limitations of methodological quality. However, it's probably that such effects may depend on plant sterols, which act as chemical trigger to produce higher level of hormones appropriate to the age and gender [4]. Furthermore, Gonzales et al. [9] reported that the glucosinolates of maca could function as antioxidants and free radical scavengers, improving fertility and sexual function in rats.

Safety has not yet been proven, although Maca has been reported to have low toxicity in both in vivo and in vitro studies [10]. The other plant extract contained in the supplement was *Pfaffia Paniculata*, that probably exerts similar effect of Maca because its main components are stigmasterol, sitosterol, allantoin, pfaffic acid, and glycosides, which are triterpenoid saponins, denominated pfaffosides A, B, C, D, E, and F [5]. These saponins are considered the main active components of the root and they have several biological properties [5]. Experimental studies have demonstrated that oral intake of *Pfaffia Paniculata* significantly increased levels of female and male sex hormones

(estradiol-17 β , progesterone and testosterone) in mice [5]. In conclusion, this is the first randomized, control study in which a new supplement has been used for the treatment of menopausal symptoms, evaluated with KI. After 3 months, a significant reduction in hot flashes and night sweats number and severity, but also a significant improvement in mood, have been shown. Phytosterols contained in both substances of the supplement might be the most important agents of efficacy, but larger studies and for a longer time of treatment are needed to ascertain the real efficacy of this new supplement.

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