

A COMPARATIVE STUDY OF KLIMAKT-HEEL® AND FEMOLENE ULTRA IN THE MANAGEMENT OF TYPICAL CLIMACTERIC SYMPTOMS

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ABSTRACT

The climacteric is described as the physiological cessation of menses due to a decrease in ovarian function. Typically, women between the ages of 44 and 57 years old are symptomatically affected by it. During this stage of life, a woman may experience what is referred to as 'typical climacteric symptoms' of varying intensity, including vasomotor reactions, increased perspiration, sleeping problems, mood changes, headaches, joint pains and urogenital problems.

The aim of this study was to determine the effectiveness of Femolene Ultra (phytotherapeutic preparation) and Klimakt-Heel® (homeopathic preparation) in the treatment of typical climacteric symptoms.

Thirty female volunteers between the ages of 44 and 57 years suffering from climacteric symptoms were recruited and asked to complete the Patient Profile and Case History Form and to sign a Patient Information and Consent Form. These participants were randomly placed in two groups of fifteen. One group received Femolene Ultra and the other received Klimakt-Heel® for a period of 12 weeks. The trial was blinded as neither the researcher nor the participant was aware of which treatment was being administered. Blood samples were taken to ascertain the 17β oestradiol levels before and after the 12-week period. The Kupperman Menopause Index (KMI) was used as a self-report measure and completed at four-weekly intervals. For statistical purposes, the Wilcoxon Signed Rank Test, from the class of non-parametric distribution-free tests, was used.

Both products served to decrease the typical climacteric symptoms significantly within the 12-week period. Femolene Ultra decreased the average Kupperman Menopause Index (KMI) score by 63% (26.2 to 16.4) and Klimakt-Heel® decreased the average score by 54% (28.4 to 15.28), although more participants in the Klimakt-Heel® group experienced amelioration of climacteric symptoms. The results are not conclusive, but they do provide an interesting base-line on which further research can be built.

OPSOMMING

Die oorgangseleefyd word beskryf as die fisiologiese einde van menstruasie weens verminderde eierstokfunksie. Oor die algemeen gesproke sal alle vroulike persone tussen die ouderdomme van 44 en 57 daardeur geraak word. Gedurende hierdie tydperk mag hulle ervaar waarna verwys word as 'tipiese simptome van die oorgangseleefyd' insluitend vasomotoriese reaksies, vermeerderde sweet, slaapprobleme, gemoedsveranderinge, hoofpyne, gewrigspyne en urogenitale probleme.

Die doel van die studie was om vas te stel hoe doeltreffend Femolene Ultra (phytotherapeutiese preparaat) and Klimakt-Heel® (homeopadiese preparaat) is vir die behandeling van tipiese oorgangsimptome.

Dertig vroulike vrywilligers tussen die ouderdomme 44 en 57 jaar wat aan die simptome van die oorgangseleefyd gely het het die pasiëntprofiel en -gevallegeskiedenis voltooi en het 'n pasiëntinligtings- en toestemmingsvorm geteken. Hierdie deelnemers is lukraak in twee verskillende groepe van vyftien geplaas. Een groep het Femolene Ultra vir 'n tydperk van 12 weke ontvang en die ander groep het Klimakt-Heel® vir dieselfde tydperk ontvang. Bloedmonsters is geneem om die 17 β oestradiolvlakke voor en na die 12-weekperiode vas te stel. Die Kupperman Menopause Indeks is as 'n selfrapportmaatreël gebruik en met vier-weeklikse intervalle voltooi. Statisties is die Wilcoxon rangsomtoets van die klas van nie-parametriese verspreidingsvrye toetse gebruik.

Albei produkte het bewys dat dit die tipiese simptome van die oorgangseleefyd betekenisvol tydens die 12-weekperiode verminder het. Femolene Ultra het die gemiddelde Kupperman Menopause Indekstelling met 63% verminder en Klimakt-Heel® het die gemiddelde telling met 54% verminder, alhoewel meer deelnemers in die Klimakt-Heel®-groep 'n verbetering in die simptome van die oorgangseleefyd ervaar het. Die resultate is nie afdoende nie maar dit verskaf tog 'n interessante basis waarop verdere navorsing gegrond kan word.

INTRODUCTION

Menopause is defined as the cessation of menstruation in the human female (Dorland & Newman 1994). It is established when menses have not occurred for one year and may be naturally, artificially or prematurely induced. The climacteric or peri-menopause is the transitional phase between the reproductive stage and menopause and is defined as the syndrome of endocrine, somatic and psychological changes occurring at the termination of the reproductive period in the female (Gupta & Kenney 1998).

There is an ideological dispute as to whether the climacteric is a natural event that should not be interfered with, or an endocrine deficiency disease that requires intervention (O'Connor 2001). Although

menopause is a natural and universal event of the human female cycle, like birth, adolescence and death, it is different for each individual, and can be a difficult time with erratic hormone levels causing multiple physical and psychological symptoms (O'Connor 2001).

Problem statement

Symptoms attributed to the climacteric are common among almost all middle-aged women, and non-users of Hormone Replacement Therapy (HRT) may present with a wide range of troublesome, ongoing symptoms during this time (Gupta & Kenney 1998). Due to the risks involved with HRT (O'Connor 2002), many women seek relief by using complementary and alternative treatments. Limited research has been conducted to demonstrate the efficacy of such treatments.

Natural menopause

Menopause occurs naturally when the ovaries age and their response to follicle stimulating hormone (FSH) and luteinising hormone (LH) decreases. This initially leads to a shorter follicular phase within the menstrual cycle, which in turn results in shorter menstrual cycles. In addition, there are fewer ovulations, a decrease in progesterone production and further irregularities in the cycle. Eventually the ovarian follicle fails to react to FSH and LH completely and ceases to produce oestrogen, resulting in a significant decrease in the circulating levels of oestrogen and progesterone. As a result, the circulating levels of FSH and LH rise substantially, as there is no positive oestrogen feedback. The biological diagnosis of menopause is reached when there is an elevation of serum FSH greater than 40 IU/l and decreased blood oestrogen levels of less than 80 pica-mol/l (Gupta & Kenney 1998).

Climacteric symptoms

There are a number of symptoms, varying in severity from woman to woman, that occur during the climacteric. These may include the following:

- Vasomotor flushes
- Loss of elasticity in the skin
- Urinary difficulties, particularly nocturia
- Vaginal dryness, low libido, dyspareunia and other sexual difficulties
- Mild hirsutism
- Menstrual irregularities
- Increase in frequency of vaginal and urinary infections
- Osteoporosis
- Increased incidence of arterial disease
- Psychosocial problems (depression, irritability)
- Anxiety, insomnia, inability to concentrate, memory loss and nervousness
- Intermittent dizziness and paresthesias, palpitations and tachycardia
- Gastrointestinal changes such as constipation, diarrhoea, nausea and weight gain
- Arthralgia, myalgia and cold extremities
- Formication
- Headaches
- Fatigue (Gupta & Kenney 1998; O'Connor, 2002).

Conventional treatment

Hormone Replacement Therapy

Most of the symptoms of the climacteric are related to the decrease in circulating oestrogens, and the administration of oestrogens has been the conventional treatment (Goldberg 1999). Oestrogen replacement therapy has been controversial, as it has been shown to increase certain cancers. By administering progesterone with the oestrogen, the risk has been reduced, but it is debatable whether the progesterone eliminates some of the protective effects of oestrogen against cardiovascular disease (Vander, Sherman & Luciano 1994).

Recent results from the Women's Health Initiative (WHI) study by the United States National Institutes of Health showed that the use of combination hormonal replacement therapy (HRT) is even more controversial (Ramasamy 2002).

Results from the Million Women Study in Britain, which was discontinued at the beginning of August 2003, showed that:

- Combination hormonal therapy may fuel a dangerous, more aggressive and deadlier breast cancer
- HRT poses the greatest risk of myocardial infarction during the first year of use
- HRT does not retard the advance of atherosclerosis in women who already have the condition.

The benefits revealed by the study were that there were significant reductions in hip fractures and colorectal cancer. HRT remains a suitable treatment for severe osteopaenia and osteoporosis; however, it is contra-indicated in women who smoke, are obese, have hypertension, have a history of thromboembolic disease or oestrogen-dependent neoplasia, are intolerant to oestrogen therapy, have liver disease or undiagnosed abnormal vaginal bleeding (O'Connor 2002).

Alternative treatments

Due to the risks involved with HRT, many women seek relief by using alternative treatments, such as homeopathy and phytotherapy. Although there is a misconception that herbal medicine is tantamount to homeopathy, there are important differences between the two therapies. Phytotherapy uses medications made from plant and herbal materials (Goldberg 2002) and, in the case of the treatment of menopausal symptoms, this entails the administration of phyto-oestrogens, which stimulate the oestrogen receptors (Faloon 2002).

Femolene Ultra

The phytotherapeutic product used in the study was Femolene Ultra (Kenza Health 2002). The ingredients of the product include:

- *Soya isoflavones*, which has oestrogenic activity as well as an oestradiol-blocking effect
- *Black cohosh*, which has been found to alleviate vasomotor flushes, depression, anxiety and vaginal atrophy (Faloon 2002)
- *Mexican wild yam*, which has been found to mimic progesterone (Goldberg 1999)
- *Dong quai*, which is an oestrogen-balancing agent (Scott & Scott 1998)
- *Chasteberry*, which does not contain hormones or hormone-like substances but rather exerts its progesterone-mimicking and oestrogen-balancing effects through the stimulation of the pituitary gland (Shepherd 1999; Briffa 2002)
- *Ginkgo biloba*, which reduces the vasomotor effects of menopause by regulating the tone and elasticity of the blood vessels (Shepherd 1999)
- *St John's wort*, which is valued for its mild sedative and analgesic properties
- *Folic acid*, which is essential for DNA synthesis, while a deficiency causes impairment in mitosis (Shepherd 1999)
- *Biotin*, which plays an important role in the biosynthesis of fatty acids, nucleic acids and certain amino acids (Dorland & Newman, 1994).
- *Magnesium*, which is an essential catalyst for food metabolism and is a co-factor in the formation of RNA and DNA
- *Zinc*, which exerts positive effects on the production of various sex and thyroid hormones (Shepherd 1999).

Homeopathy

Homeopathy is a therapeutic method that clinically applies the Law of Similars ('let likes be cured by likes'). Homeopathy uses medicinal substances in small doses that have undergone the pharmaceutical process of 'potentisation' (Jouanny 1993).



Klimakt-Heel®

Klimakt-Heel® is a combination of homeopathic remedies that has been proved effective in the treatment of the hormonal manifestations of endocrine deficiency. It does not act as a hormone replacement, but rather as a stimulant that biologically stimulates the ovaries, hypothalamus and pituitary gland (Reckeweg 2000).

The individual remedies of Klimakt-Heel® include: *Sanguinaria canadensis D3*, *Sepia succus D4*, *Sulphur D4*, *Ignatia amara D4*, *Cedron-simarumba ferroginea D4*, *Stannum metallicum D1* and *Lachesis muta D12*.

Aim

The purpose of the study was to compare the effectiveness of a homeopathic product (Klimakt-Heel®) and a phytotherapeutic product (Femolene Ultra) in the management of typical climacteric symptoms. A comparison of the two products was drawn on the basis of their action on subjective symptoms, as indicated on the KMI, and on the objective effects on plasma β oestradiol. The University of Johannesburg’s Ethics Committee approved the study and participants were invited to take part in the study through advertisements in the newspaper, on campus and in health stores.

RESEARCH DESIGN

Research design, population and sampling

Thirty climacteric females were recruited to participate in this quantitative, double-blind experimental study, without a control. The target population was women presenting with typical climacteric symptoms, living in Gauteng. The non-probability, purposive sampling method was utilised to select participants.

Method

Each prospective participant completed a Patient Profile in order to select the participants who would meet the entry criteria necessary for participation. The criteria for inclusion were as follows:

- Females between the ages of 44 and 57 years
- Peri-menopausal or menopausal with climacteric symptoms
- The use of HRT was not permitted
- Menopause was natural and not artificially or surgically induced.

A Patient Information and Consent Form was read by the volunteer and the researcher answered any queries. If the participant approved of the research and agreed to participate, the consent form was signed and she was included in the study.

Sampling

Each woman was allocated a remedy reference number, which placed them into one of the two treatment groups. The participants with ‘Remedy Reference One’ received Klimakt-Heel® (Group One) and those with ‘Remedy Reference Two’ received Femolene Ultra® (Group Two). At this stage, however, neither the participant nor the researcher knew which medicine was allocated to which reference. On completion of the trial, the remedy reference code was revealed to both the researcher and the participants.

At the first consultation, the participant completed the KMI and blood was drawn to obtain a baseline of the plasma 17β -oestradiol levels. The participant received a four-week supply of her medicine, to be taken according to the recommended doses. Those in Group One took one tablet of Klimakt-Heel® three times daily, whilst those in Group Two took one tablet of Femolene Ultra twice daily. At week four, the participant completed the KMI and received another four-week supply of the trial treatment. The same process occurred at week eight. At week twelve, the end of the trial, the participants filled in

TABLE 1
Kupperman scores and severity

KMI TOTAL SCORE	SEVERITY
> 35	Severe
20–35	Moderate
15–19	Mild
< 15	Favourable therapeutic result

the KMI and had blood drawn again to measure plasma 17β -oestradiol levels.

Kupperman Menopause Index (KMI)

This questionnaire was used as the subjective portion of the study. It allowed for the participants to give a score according to the subjective symptoms experienced. The KMI consists of ten typical menopausal symptoms: vasomotor flushes, perspiration, sleeping problems, nervousness, depressive moods, vertigo, concentration problems, joint pain, headaches and palpitations. The participants graded the severity of their symptoms on a scale from zero (not present) to three (severe) for each symptom. The total scores grade the severity of typical menopausal symptoms (Table 1).

The KMI was completed four times throughout the study – at four-weekly intervals. To eliminate the potential for bias, the participant answered a new index every time.

Statistical analysis

Data analysis was done using the Statistical Package for Social Sciences (SPSS). Statistical analysis was used to compare the relative differences between the two treatments. As the distribution was not normal, non-parametric tests were used, specifically the Wilcoxon Signed Rank Test. This test was used to compare the median of a column of numbers against a hypothetical median, as per the KMI. The p-value was set at 0.05.

Reliability and validity

The KMI has been used widely in studies of climacteric symptoms (Ander 1998). The original index, derived in the 1950s, omitted certain key climacteric measures. The modified version, used in this study, has included these parameters. A comparative review of rating scales in menopause by Heinemann and colleagues (2004) illustrated good criterion-oriented validity.

RESULTS

The KMI scores at each time interval for Femolene Ultra and Klimakt-Heel® were analysed statistically. At the commencement of the trial, the scores for the index were as follows for the two groups (Table 2).

TABLE 2
Results at the commencement of the trial

	FEMOLENE ULTRA	KLIMART-HEEL®
Average KMI score	26.2	28.4

TABLE 3
Femolene Ultra and Klimakt-Heel® results from the first to the fourth week

TREATMENT	TIME	AVERAGE KMI SCORE	P-VALUE
Femolene Ultra	Week 1	26.2	
Femolene Ultra	Week 4	17.2	0.03
Klimakt-Heel®	Week 1	28.4	
Klimakt-Heel®	Week 4	23.7	0.18

As can be seen from Table 2 above, the results for the KMI were similar with regard to baseline menopausal symptoms that were experienced subjectively.

Results at week 4

From the fourth week, the change in the severity of the symptoms from the previous week was evaluated in the Femolene Ultra and Klimakt-Heel® groups. The average KMI score decreased by 8.28 for the former, whilst the score for the latter decreased by 4.7, as shown in Table 3.

The results of the Femolene Ultra and Klimakt-Heel® groups showed that the symptoms improved in the first four weeks. Statistically, however, the null hypothesis was rejected only for the former group, as the p-value was below 0.05, at $p = 0.03$. In this first phase, the participants on Femolene Ultra experienced an average decrease of 32% in their subjective experience of their symptoms.

Results at week 8

The results from Week 8 are listed in Table 4. There was a continued improvement in the subjective symptoms reported in both groups. Although no statistically significant difference was experienced at this point in the study, the KMI of the Femolene Ultra group decreased by 4.58, compared to a decrease of 5.71 in the Klimakt-Heel® group.

Results at the conclusion of the trial

A comparison of the respective remedies from Week 8 to Week 12 is shown in Table 5. The average KMI decreased by 4.58 in the Femolene Ultra group, compared to a decrease of 5.71 in the Klimakt-Heel® group; however, a statistically significant difference was not noted for either treatment during this time.

A comparison between the two groups at the commencement and conclusion of the trial is given in Table 6. The results obtained from the KMI indicate that there was a statistically

significant difference in the subjective experience of menopausal symptoms in both groups from the commencement to the end of the trial.

At week 12 of the trial, the results showed that there was an improvement in symptoms in both the Femolene Ultra and Klimakt-Heel® groups. When comparing the two groups from week 8 to week 12 statistically, the null hypothesis could not be rejected for either, as the p-value for the latter was 0.08 and the p-value for the former was 0.12. Hence, even though the Femolene Ultra group showed more improvement, both groups experienced a statistically significant decrease. Both groups started the trial in the 'moderate' group and ended in the 'favourable therapeutic result' category of the KMI.

Oestrogen blood test

Two sets of blood were taken, one before the study and one at the end of the study. Seven millimetres of blood were drawn into an SST tube and sent to the pathology laboratory (Du Buisson, Bruinette and Kramer Incorporated) for analysis using the chemiluminescence test with Centaur apparatus. The blood analyses formed the objective component of the study. The plasma 17β oestradiol was measured in pica-mol per litre (pmol/l). A value of 136 pmol/l is indicative of menopause and a value of less than 37 pmol/l indicates that the oestradiol is undetectable. The results obtained from the blood tests showed no statistical significance or change in pattern for either group.

Additional comments

The findings of the trial are in keeping with the dynamics experienced in general with regard to herbal and homeopathic medicines, namely, that phytotherapeutic medicines act relatively quickly, but that the patient subsequently appears to develop a tolerance to the medication. Homeopathic medicines may take longer to create changes, but show noteworthy improvements later. Management principles for the climacteric could be to commence treatment with a regimen of both herbal and homeopathic medicines, as the herbs allow a quick response and the homeopathic remedy will sustain the improvement of the symptoms. It may also be beneficial to discontinue the herbal medicine to avoid tolerance.

It is important to note that only the symptoms experienced subjectively improved and that there was no statistically significant difference in the plasma 17β oestradiol levels of the participants. A limitation of the study was that it did not include a placebo group in order to measure the psychosomatic effect that may be attributed to the increased awareness of and attention paid by the participants on the trial.

Furthermore, it is noteworthy that the participants were assigned to either product and that no individualisation was made in order to 'match' the person to a particular remedy, as is so often done in homeopathic practice.

CONCLUSION

Both groups of menopausal women started the trial in the 'moderate' severity group and improved to the 'favourable

TABLE 4
Femolene Ultra and Klimakt-Heel® results from week 4 to week 8

TREATMENT	TIME	AVERAGE KMI SCORE	P-VALUE
Femolene Ultra	Week 4	17.92	
Femolene Ultra	Week 8	14.38	0.37
Klimakt-Heel®	Week 4	23.7	
Klimakt-Heel®	Week 8	18.82	0.1

TABLE 5
Femolene Ultra and Klimakt-Heel® results from week 8 to week 12

TREATMENT	TIME	AVERAGE KMI SCORE	P-VALUE
Femolene Ultra	Week 8	14.38	
Femolene Ultra	Week 12	9.8	0.12
Klimakt-Heel®	Week 8	18.82	
Klimakt-Heel®	Week 12	13.11	0.08

TABLE 6
Comparison between Femolene Ultra and Klimakt-Heel® at commencement and conclusion of the trial

	FEMOLENE ULTRA		KLIMAKT-HEEL®	
	COMMENCEMENT	CONCLUSION	COMMENCEMENT	CONCLUSION
Average score	26.2	9.83	28.4	13.12
Change in score	16.4		15.28	
Percentage change in score	63%		54%	
P-value:	0.00		0.00	



therapeutic result' group according to their responses on the KMI. Whilst the phytotherapeutically-treated group experienced a statistically significant decrease in symptoms within the first four weeks, the homeopathically-treated group experienced the decline in the last four weeks. Both groups had a statistically significant decline at twelve weeks when compared with their initial data.

Even though there were favourable results in this study, it would be incorrect to assume that long-term use of Femolene Ultra, Klimakt-Heel® and/or other similar products would be as favourable. It remains questionable as to whether phyto-oestrogens or other natural products are harmless and can be used indefinitely. Therefore more extensive research will need to be conducted to determine whether ongoing treatment is safe, harmless and effective.

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