THE EFFICACY OF LACHESIS 30CH IN THE TREATMENT OF MENOPAUSAL SYMPTOMS

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Abstract

Menopause is defined as the physiological cessation of menses due to decreased ovarian function and is established when the menses have not occurred for a year, usually occurring at a median age of 50.8 years. The period around the menopause is a time of transition that can contribute to both emotional and physical symptoms. The purpose of the study was to determine the efficacy of the homoeopathically prepared remedy *Lachesis* in the treatment of the symptoms of the menopause in women whose symptoms match the symptom picture of *Lachesis*. Thirty female volunteers between the ages of sixty and sixty years were recruited from the Johannesburg and Potchefstroom areas. This was a single-blind study and the participants did not know if they were in the control or experimental group. The participants were required to complete an *Abbreviated Kupperman Index* on a weekly basis throughout the four week trial period. The Experimental group experienced a 58.27% overall decrease in average Kupperman score, compared to 28.65% of the Control group. The P-value of the total response of the trial is 0.2110, therefore there is not a significant statistical difference between the two groups over the total trial period. Although there was not a statistically significant difference for the total response between the two groups there was statistically significant differences between the two groups for the following individual symptoms: profuse sweating, depressive moods and the inability to concentrate.
INTRODUCTION

Menopause is defined as the physiological cessation of menses due to decreased ovarian function and is established when the menses have not occurred for a year, usually occurring at a median age of 50.8 years. The period around the menopause is a time of transition that can contribute to both emotional and physical symptoms which includes vasomotor symptoms, sleeping problems, mood changes, headaches, joint pains and genitourinary problems. Many women seek medical assistance to palliate these symptoms and to seek explanation and reassurance (Berkow et al., 1999; Curtis and Fraser, 1991; Haslett et al., 1999). Alternative treatments like homoeopathy are often sought by women looking for symptomatic relief without the risks and potential side-effects of hormone replacement therapy (Col and Komaroff, 2004; Kronenberg and Fugh-Bermann, 2002). More scientific research is needed to establish the efficacy of the use of homoeopathy in the treatment of menopausal symptoms.

The purpose of this study was to determine the efficacy of the homoeopathically prepared remedy Lachesis in the treatment of the symptoms of the menopause in women whose symptoms match the symptom picture of Lachesis.

Thirty female volunteers between the ages of fifty and sixty years suffering from menopausal symptoms were recruited from the Johannesburg and Potchefstroom areas by means of an advertising campaign. The volunteers were required to complete the Suitability Criteria Questionnaire to select participants that would meet the inclusion criteria necessary for participation in the study. Participants that met the criteria of the study had to complete the Patient Information and Consent form. The participants had to complete the Symptom Questionnaire listing sixteen characteristic symptoms of Lachesis. The fifteen participants who had the highest scores (score of at least nine) on this questionnaire were put in the experimental
group and the rest of the participants were put into the control group. This was a single-blind study and the participants did not know in which group they were. At the first consultation the *Abbreviated Kupperman Index* was completed with the aid of the researcher. The participants were required to complete an *Abbreviated Kupperman Index* on a weekly basis throughout the trial period. The information from the five completed Abbreviated Kupperman Indexes was then transferred to each participant’s Main Kupperman Menopause Index to compare results.

Statistically a two-way analysis of variance with grouping factor and repeated measures over time was used. To accommodate missing values Mixed Modeling was used. The study design was accepted by the University of Johannesburg Higher Degrees Committee on the 26th of September 2006 and was cleared by the University of Johannesburg Faculty of Health Sciences Academic Ethics Committee (AEC number: 48/06).

During the four week study there was not a statistically significant difference between the two groups in the treatment of typical menopausal symptoms. In terms of percentages however *Lachesis* reduced the Abbreviated Kupperman Menopause score more significantly (58.27%) when compared to placebo (28.65%). There were also statistically significant differences between the two groups for some of the individual symptoms of the Abbreviated Kupperman Menopause Index namely: profuse sweating, depressive moods and the inability to concentrate.

More studies like this one need to be performed over longer periods of time with larger sample groups. It is also recommended that more studies like this be performed for different conditions and remedies.

**MATERIALS AND METHODS**
Recruitment and Sample

Participants were recruited from the Johannesburg and Potchefstroom areas by means of an advertising campaign. Advertisements were placed at various shopping malls, gyms, hairdressing salons, health shops and pharmacies.

The researcher informed the participants of the four-week duration of the study. The researcher requested information from the participants by completing the Suitability Criteria Questionnaire. This questionnaire was done once, at the beginning of the trail period, in order to select participants that would meet the inclusion criteria necessary for participation in the study. The inclusion criteria were as follows:

- The participants had to be female and between the ages of fifty and sixty years.
- Menopause had to be established for a year (no menstrual periods for a year).
- Menopause had to be natural and not surgically or artificially induced.

The exclusion criteria were as follows:

- The participants could not be using any other treatment for their climacteric symptoms. If the participant had been on hormone replacement therapy or any other treatment for the menopause before, she was permitted to participate in the study, provided that she had been off the therapy for at least six weeks.

Participants were excluded from the study if they had any of the following:

- A bilateral ovariotomy or total hysterectomy.
- Any irradiation, chemotherapy, drug treatment, or other process that has resulted in menopausal symptoms.
• Treatment for any chronic condition that could complicate or confound variables eg: uncontrolled hypertension or severe depression.

Methodology

Procedure
At the first consultation the research procedure was discussed with participants that met the criteria of the study. The participants had to complete the Patient Information and Consent form at the first consultation. The participants then had to complete the Symptom questionnaire listing sixteen characteristic symptoms of Lachesis. The fifteen participants out of the thirty total participants who had the highest scores (score of at least nine) on this questionnaire were put in the experimental group and the rest of the participants were put into the control group. This was a single-blind study and the participants did not know in which group they were. The participants were given a reference number. Even numbers were in the experimental group and uneven numbers in the control group. At the first consultation the Abbreviated Kupperman Index was completed with the aid of the researcher. The participants were required to complete an Abbreviated Kupperman Menopause Index on a weekly basis throughout the trial period of one month and therefore completed the Abbreviated Kupperman Menopause Index a total of five times. To ensure credibility of data and to prevent bias the importance of not referring to previous indexes were stressed to the participants at the beginning of the trial.

Remedy administration
Medication was dispensed in a liquid form. The participants were provided with enough medication for the full four weeks of the trial. Participants received medication according to their reference number. Participants had to take ten drops twice daily of the medication provided and were provided with a checklist to encourage compliance. Participants were informed to stop medication if symptoms got worse and contact the researcher for further instructions.
**Tools utilized**

**Kupperman Menopause Index**

The Kupperman Menopause Index was used with minor alterations. The abbreviated Kupperman Menopause Index was completed five times throughout the study (Artemi, 2004; Penny, 2004). The index was completed once before the treatment and then four times at weekly intervals until the four-week trail was completed. The information from the completed Abbreviated Kupperman Menopause Indexes was then transferred to each participant’s Main Kupperman Menopause Index to compare results. The index consists of eleven typical climacteric/menopausal symptoms, as listed below:

- Hot flushes: severity
- Hot flushes: frequency
- Profuse perspiration
- Sleeping problems
- Nervousness/irritability
- Depressive moods
- Feelings of vertigo
- Inability of concentration
- Joint pain
- Headache
- Heart palpitations

The participants graded the severity of their symptoms as follows:

1. Severe………………3
2. Moderate………2
The numbers were recorded and then multiplied by the constant, and the resultant value was also recorded. The Kupperman Menopause Index assigns a greater significance to the “more typical” menopausal symptoms by way of this higher constant value. The resulting values for each symptom are added and a total value for the Kupperman Menopause Index is determined. The Kupperman Menopause Index thus gives an indication of the severity of the menopausal syndrome, as experienced by each individual patient. The severity of the index is categorized as follows:

1. >47…………..severe
2. 32-47…………moderate
3. 27-32…………mild
4. <27…………..favourable therapeutic result.

The index therefore allows the participant to quantitively record the way she is experiencing the typical symptoms of menopause.

**Statistics Utilised**

To compare the relative difference between the experimental and the control group statistical analysis was used. A two-way analysis of variance with grouping factor and repeated measures over time was used. To accommodate missing values Mixed Modeling was used, using MIXED Procedure of SAS. The Unstructured Covariance option of this programme was used (SAS Institute Inc. 2002).
A P-value ≤ 0.05 is considered as statistically significant; that is the test statistic is significant at a 0.05 level and less. The Null hypothesis is that there is not a significant difference in the improvement of menopausal symptoms between the two groups. Alternative hypothesis: There is a significant difference in improvement of the severity of menopausal symptoms between the two groups. The Rejection rule is: reject null hypothesis if P-value ≤ 0.05

Note:
1) Where participants withdrew from the study, results were considered missing and not scored with a zero.
2) Time periods 1 to 5 in statistical program is Week 0 to Week 4 of trial.

RESULTS

A comparison between the two groups at commencement and conclusion of the trial is given in Table 1.
Table 1. Comparison Between *Lachesis* and Control at Commencement and Conclusion of the Trial

<table>
<thead>
<tr>
<th></th>
<th>Lachesis</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Commencement</td>
<td>Conclusion</td>
</tr>
<tr>
<td>Number of participants</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>9</td>
</tr>
<tr>
<td>Average Kupperman</td>
<td>41.07</td>
<td>17.14</td>
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<tr>
<td>Index score</td>
<td>28.87</td>
<td>20.62</td>
</tr>
<tr>
<td>Change in Kupperman</td>
<td>23.93</td>
<td>8.25</td>
</tr>
<tr>
<td>Index score</td>
<td>58.27%</td>
<td>28.65%</td>
</tr>
<tr>
<td>Percentage change in</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kupperman score</td>
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<td></td>
</tr>
</tbody>
</table>

**Results of the Statistical Programme**

A two-way analysis of variance (ANOVA) with grouping factor and repeated measures over time were calculated. Mixed modeling was used to accommodate missing values. The following graph and tables will be discussed.
Graph 1. Scatterplot of Estimated Abbreviated Kupperman Menopause Index averages against Time; categorized by Group
Table 2. Results of the ANOVA

<table>
<thead>
<tr>
<th>Effect</th>
<th>Numerator (Degrees of Freedom)</th>
<th>Denominator (Degrees of Freedom)</th>
<th>F Value</th>
<th>P-Value</th>
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<td>Group</td>
<td>1</td>
<td>92</td>
<td>0.25</td>
<td>0.6183</td>
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<tr>
<td>Time</td>
<td>4</td>
<td>92</td>
<td>9.00</td>
<td>&lt;0.0001</td>
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<tr>
<td>Group*time</td>
<td>4</td>
<td>92</td>
<td>1.49</td>
<td>0.2110</td>
</tr>
</tbody>
</table>

DISCUSSION

At the conclusion of the trial, the Experimental group had an average Abbreviated Kupperman Menopause Index score of 17.14 compared to the Control group with an average score of 20.62 (Table 1.). The Control group therefore concluded the trial with a greater severity in climacteric symptoms than the Experimental group. An Abbreviated Kupperman Menopause Index score of less than twenty-seven however is considered as a “favourable therapeutic result”. The Experimental group however had an average Kupperman score of 41.07 at the commencement of the trial compared to the 28.87 of the Control group (Table 1.). The Experimental group experienced a 58.27% overall decrease in average Kupperman score, compared to 28.65% of the Control group. All this data however was statistically processed and analysed to see if there is a significant difference between the two groups.

Discussion of Statistical Program Results

A two-way analysis of variance with grouping factor and repeated measures over time were performed. To accommodate missing values mixed modeling was used. Estimated average Kuppnerman scores were calculated by the statistical program. These scores were used to create a
scatterplot of estimated Abbreviated Kupperman Menopause Index values over time categorised by group (Graph 1.).

The P-value of the total response of the trial is 0.2110. Therefore there is not a significant statistical difference between the two groups over the trial period (Table 2). Because there is no significant difference between the two groups, the statistical program automatically combined the values from both groups for the next set of calculations to see if there is a statistically significant decline in symptom severity over time. The statistical program shows that there is a statistically significant decline in symptoms for the combined groups over the following time periods:
- Commencement of trial to Week 3 (P-value 0.0271)
  - Commencement of trial to Week 4 (P-value <0.0001)
  - Week 1 to Week 3 (P-value <0.0001)
  - Week 1 to Conclusion of trial (P-value <0.0001)
  - Week 2 to Week 3 (P-value 0.0037)
  - Week 2 to Conclusion of trial (P-value <0.0001)
  - Week 3 to Conclusion of trial (P-value 0.0395)

To summarise: There is a statistically significant decrease in symptom severity as measured by the Abbreviated Menopause Index over the trial period for the combined groups, but no statistically significant difference between the two groups.

Discussion of Individual Symptom Results

The individual symptom scores of the Abbreviated Kupperman Menopause Index were statistically analysed. There are eleven different symptoms that make up the Abbreviated Kupperman Menopause Index. Not all the symptoms carry the same weight in making up the Abbreviated Kupperman Menopause Index score, but it was thought that it would be very
interesting to analyse the individual symptom scores. The symptoms that were ameliorated significantly more by *Lachesis* were profuse sweating, depressive moods and the inability to concentrate.

**CONCLUSION**

During the four week study period there was not a statistically significant difference between the two groups in the treatment of typical menopausal symptoms, namely; hot flushes severity and frequency, profuse sweating, sleeping problems, nervousness, irritability, depressive moods, feelings of vertigo, inability to concentrate, joint pains and heart palpitations. In terms of percentages however *Lachesis* reduced the Abbreviated Kupperman Menopause score more significantly (58.27%) when compared to placebo (28.65%).

Although there was not a statistically significant difference for the total response between the two groups there was statistically significant differences between the two groups for some of the individual symptoms. The symptoms that were ameliorated significantly more by *Lachesis* were profuse sweating, depressive moods and the inability to concentrate.

Possible reasons why there was not a statistically significant difference for the total response between the two groups:

- The participant’s interpretation of symptoms experienced was subjective and no objective means of measurement was used in this study.
- A larger sample size and less people stopping treatment during the study might have given different results.
- The experimental group had a much higher average Kupperman score at the beginning of the trial.
- The participants did not commence treatment the same time of the year and therefore results might have been influenced by the weather.
- The duration of the study was short.
- The statistical tests used were limited.
ACKNOWLEDGEMENTS

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AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist.

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Dr K.S. Peck
REFERENCES


