Evaluation Of The Efficacy And Tolerability Of Micronutrient Supplementation In Treatment Of Post Menopausal Symptoms

S Pandit, S Umbardand, V Ghodake, U Vats, H Tayade, O Rathod

Citation


Abstract

Objective- To study the efficacy and tolerability of micronutrient supplementation in alleviating menopausal symptoms

Method- In this randomized pilot study, 54 postmenopausal women from the outpatient department were supplemented with either micronutrients or placebo for three months. Along with the menopausal symptoms, hemoglobin and lipid profile were assessed.

Results- Micronutrients demonstrated moderate to almost complete improvement in symptoms on the 60th and 90th day of the treatment which was better compared to placebo group. The treatment group reported better improvement in night sweats, insomnia and feeling of well-being on the 60th day and almost complete improvement in hot flushes, insomnia, tiredness and feeling of well-being which was significantly better compared to the placebo group (p<0.05) on the 90th day of treatment. No side effects were reported in the micronutrient supplement group.

Conclusion- Our findings suggest that the multiple micronutrient supplements are effective in improving postmenopausal symptoms of hot flushes, night sweats, insomnia, depression, tiredness and for improving feeling of well-being.

INTRODUCTION

Menopause, commonly known as the “change of life” for women, is a gradual physiological cessation of menses as a result of decreasing ovarian function.

About 75% of women report troublesome symptoms during menopause, but the severity and frequency of symptoms is very inconsistent. The most common symptoms are hot flushes and vaginal atrophy. Other symptoms at the onset include fatigue, irritability, insomnia, depression, night sweats, palpitation and anxiety. The duration of these symptoms is usually one year but last for more than five years in about 25-50% of women. Several hormonal products are available and growing. At the same time, use of dietary products to treat menopausal symptoms is also rising.

Earlier studies state that women with menopause suffer from osteoporosis due to estrogen deficiency. The bone fragility increases with the additional deficiency of Magnesium. Cummings SR concluded that Vitamin D substantially reduced the risk of hip fracture in post menopausal elderly women.

The balanced and appropriate multivitamin and mineral supplements containing vitamins (Vitamin A, Riboflavin, Pantothenic acid, Pyridoxine, Folic acid, Vitamin E) and minerals (chromium, copper, magnesium, selenium, silicon, zinc) are essential for the prevention or correction of disorders accompanying menopause like ageing of skin and its accessory structures, decreased bone metabolism, decreased immune function and increased risk of degenerative pathology, in particular cardiovascular system.

Antioxidants like Vitamin C acutely improve the endothelial function in postmenopausal women with established estrogen deficiency. Evidence indicates that postmenopausal women have increased plasma homocysteine level. Folic acid, Vitamin B8 and Vitamin B12 is associated with a significant reduction in plasma concentrations of homocysteine. The highest initial levels of homocysteine reduced with the low folic acid doses when given as supplementation in postmenopausal women.

All these multiple micronutrient supplements when given in combination, can effectively alleviate the menopausal symptoms. Menopausal women often suffer from common symptoms. Though there is growing need and
interest of using nutrient and other non-hormonal therapies
due to the risks of HRT, clinical evidence for efficacy of
nutrients in menopausal symptoms is limited. Pertaining to
this background, this pilot study was conducted in Indian
women.

MATERIALS AND METHODS

This randomized trial was performed to determine and
compare the effect of micronutrient supplementation with
that of placebo in reducing the menopausal symptoms.
Secondary objectives were to compare the effects of both the
treatment therapy on lipid profile and hemoglobin. Total
fifty four women with in the age group of 40-60 years
[(mean age ± SD) (48.86±7.10)] with characteristic
menopausal symptoms for at least one year were enrolled in
the study. The study was approved by Lokmanya Tilak
Hospital Ethics Committee at Sion, Mumbai and was
conducted in accordance to applicable regulatory guidelines
for clinical trials, Declaration of Helsinki, as revised in 2000.
Written informed consent was obtained from all the
participants before starting any of the study related
procedures. Women with both natural and surgical
menopause were included. Women who were on any
hormone replacement therapy (HRT); with known history of
any hypersensitivity to study drugs; who experienced serious
adverse events or hypersensitivity reaction during ongoing
treatment were excluded from the study. Subjects were
randomized and divided into two groups where group A
(N=29) received micronutrient supplementation while group
B (N=25) received placebo treatment. The micronutrient
supplement (Refer Table-1) was a non-hormonal preparation
providing a specific range of vitamins & minerals and
assumed to be effective in relieving a large number of
symptoms. Micronutrient supplementation was provided by
Meyer Organics Pvt Ltd Thane.

Primary efficacy endpoints were improvement in the
symptoms including; hot flushes, night sweats, depression,
tiredness, insomnia and feeling of well being. The secondary
endpoints were improvement in abaseline levels of total
cholesterol (TC), serum triglycerides (TG) and hemoglobin
(Hb). Physical parameters like blood pressure, pulse rate and
body weight we evaluated at each visits. Subjects received
one oral capsule daily after meal for three months. The
improvements in symptoms were graded as mild or minimal
(1-25%), moderate to good (26-50%) and almost complete
(51-75%) on the 30th, 60th and 90th day of study. The
biochemical parameters were also evaluated on the
respective visits. The study subjects were evaluated for
occurrence of any adverse events including their intensity,
action taken, outcome and causality. Micronutrient
supplementation (Menopace ® Tablets) was provided by
Meyer Organics Pvt Ltd Thane

RESULTS

Results were analyzed statistically by the Chi- Square test. P
value less than 0.05 was considered significant. The results
are presented here.

Hot Flushes: At baseline, 20 women each from active and
placebo reported presence of hot flushes. On the 90th day, 13
women (65%) in micronutrient treatment group as compared
to 3 (15%) in placebo group reported almost complete
improvement. (P=0.001) Also, 7 (35%) women in treatment
group reported moderate to good improvement compared to
11 (55%) in placebo group. 6 (30%) women in placebo
group reported minimal or no improvement in hot flushes at
the end of treatment period.

Night sweats: At baseline, 14 and 12 women reported
presence of night sweats in active and placebo group
respectively.

On 60th day 12 (85.7%) women in micronutrient treatment
group experienced moderate to good improvement in night
sweats as compared to 6 (50%) in placebo group (P=0.04).
Further, on the 90th day, 13 (93%) patients in active and 8
(67%) patients in placebo group reported moderate to almost
complete improvement in their night sweats.

Depression: On the 90th day of treatment, 10 (66.7%)
women in active group compared to only 2 (22.2%) women
in placebo group reported moderate to good improvement in
depression. (P=0.03) Overall, 14 (80%) women
experiences good to almost complete improvement in depression compared to 4 (45%) in placebo group.

Tiredness: At baseline, 18 women in active group and 19
women in placebo group reported presence of tiredness.
Improvements were comparable on the 60th day. However
on the 90th day of treatment, 7 (39%) women in
micronutrient treatment group experienced almost complete
improvement compared to only 1 woman in placebo group
(P=0.03).

Insomnia: At baseline 15/29 and 16/25 women reported
insomnia.
On the 60th day, 14 (93.3%) women reported moderate improvement compared to 10 (62%) in the placebo group (P=0.004) and at the 90th, 8 (53%) women reported almost complete improvement as compared to 1 (6.2%) in placebo group. (P=0.004) Also, 8 (50%) women experienced minimal or no improvement in insomnia till the end of therapy period.

Feeling of well-being: At baseline 16 and 14 women had reported feeling of not being well.

Of them 15 (93.8%) women in active group reported moderate to good improvement compared to 8 (57%) in placebo group on the 60th day. (P=0.01) Further, on the 90th day, all 16 (100%) reported good to almost complete improvement in feeling of well being compared to 8 (57%) in the placebo group. (P=0.02)

Anxiety: At baseline, 18 and 13 women in the active and placebo group reported anxiety, respectively. Out of them, 15 in active group and 8 in the placebo group reported moderate to good improvement at the 60th day. Furthermore, at the 90th day, all 18 (100%) women in active group compared to 10 (76%) in placebo group reported moderate to good improvement.

Safety assessment: Baseline hemoglobin, total cholesterol & serum triglyceride values did not change significantly at the end of the study. (Table 2) In addition no change was observed in physical examinations including blood pressure, pulse rate and body weight in both the study groups. (Table 3) Micronutrient supplementation was found safe and well tolerated.
Evaluation Of The Efficacy And Tolerability Of Micronutrient Supplementation In Treatment Of Post Menopausal Symptoms

Figure 3
Table 3: Change in baseline blood pressure (BP) measurement, pulse rate & weight

<table>
<thead>
<tr>
<th>Examinations</th>
<th>Study Group (N=29)</th>
<th>Control Group (N=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-treatment</td>
<td>Post-treatment</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>116.07±9.68</td>
<td>110.89±5.56</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>78.00±6.29</td>
<td>79.41±5.57</td>
</tr>
<tr>
<td>Pulse Rate</td>
<td>83.97±4.68</td>
<td>85.56±4.31</td>
</tr>
<tr>
<td>Weight</td>
<td>56.97±10.81</td>
<td>58.64±10.74</td>
</tr>
</tbody>
</table>

By Student’s t Test  P > 0.05 Not Significant

DISCUSSION

To our knowledge this is the first double-blind clinical study conducted to evaluate efficacy of micronutrient supplementation for relieving menopausal symptoms in Indian women. In this study key symptoms of menopause were quantified to assess the effectiveness of micronutrient supplementations in menopause. At the end of the treatment, subjects reported almost complete improvement in hot flushes, insomnia, tiredness, and feeling of well-being. Micronutrient supplements significantly reduced the postmenopausal symptoms and improved general well being suggesting their important role in the treatment of menopausal symptoms. Tolerability and the compliance to the study drug were found to be very good. Our study may be lacking in strong study design with respect to duration of the study and relatively less sample size, but this data may prove useful for the researchers and general population when it comes to multiple micronutrients as a safe and effective option for women.

CONCLUSION

A non-hormonal nutritional supplement which provides specific range of vitamins and minerals corrects nutritional imbalance and thereby provides relief and prevention from menopausal symptoms. Results obtained from this study supports to the evidence that long-term treatment with micronutrient supplementation could be more effective in improving symptoms related to menopause without any detrimental effects on women’s health. The regimen also appears to be a safe and effective alternative to HRT for post menopausal women. Larger studies are warranted to confirm these findings.

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References

Author Information

Suchitra Pandit
Professor, Department of Gynecology & Obstetrics, LTM Medical College and General Hospital

Shahikant Umbarand
Senior Resident, Department of Gynecology & Obstetrics, LTM Medical College and General Hospital

V. B Ghodake
Senior Resident, Department of Gynecology & Obstetrics, LTM Medical College and General Hospital

Urvashi Vats
Senior Resident, Department of Gynecology & Obstetrics, LTM Medical College and General Hospital

Himanshu Tayade
Manager, Department of Medical Services, Meyer Organics Pvt. Ltd

Onkar Rathod
Assistant Manager, Department of Medical Services, Meyer Organics Pvt. Ltd