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EFFICACY OF TUKHME SAMBHALU (VITEX NEGUNDU) IN POSTMENOPAUSAL SYNDROME (MULTAZIMA-BAAD-AZ-INQTAETAMS)- A RANDOMIZED PLACEBO CONTROLLED STUDY

Dr. Khan Bashayer[1], Dr. Tausif Khan*[2] and Dr. Rafi Ahmad Chaudhary[3]

[1]Assistant Professor, Dept. of Obstetrics & Gynecology,
[2]H.O.D and Assistant Professor, Dept. of Mahiyatul Amraz,
[3]Professor & HOD, Dept. of Obstetrics & Gynecology,
ZVM Unani Medical College & Hospital, Azam Campus Pune.

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ABSTRACT

Menopause means permanent cessation of menstruation at the end of reproductive life due to loss of ovarian follicular activity. It is the point of time when last and final menstruation occurs. The clinical diagnosis is confirmed following stoppage of menstruation (amenorrhoea) for twelve consecutive months without any other pathology. Postmenopausal syndrome is a common condition that affects women after menopause, characterized by symptoms such as hot flushes, sleep disturbances, mood swings, joint pain, and decreased quality of life. Unani physicians describe menopause under the term ihtibas-tamth (cessation of menstruation), correlating it with Sinn-i-Yaas, or the natural termination of menstruation. Vitex negundo (Tukhm-e-Sambhalu), an herb with potent estrogenic and therapeutic properties, has been historically used in Unani medicine to alleviate symptoms associated with menopause.This randomized placebo-controlled study evaluates the efficacy of Tukhm-e-Sambhalu in improving symptoms of postmenopausal syndrome. Thirty patients were administered the herb and compared to a control group receiving a placebo. The results showed significant improvement in hot flushes, sleep quality, mood, and joint discomfort in the test group, suggesting Tukhm-e-Sambhalu as a promising alternative treatment for managing postmenopausal symptoms in women.

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Keywords: Ihtibas-Tamth, Sinn-I-Yaas, Tukhm-E-Sambhalu, Multazima-Baad-Az- Inqtaetams.

Introduction:

With rising life expectancy, the number of postmenopausal women in India has grown, with many spending about a third of their lives in this stage. The average age of menopause in India is 47.5 years, with life expectancy at 71 years. Health concerns for menopausal women are increasing, and the number of menopausal women is expected to reach 103 million by 2026[1]. Menopause marks the permanent end of menstruation after 12 months of amenorrhoea. The most recent trend to treat the menopausal syndrome is symptomatic through hormone-based therapies. But these therapies have its limitations and not indicated for those patients having history of breast cancer, oestrogen

*Corresponding author: drtausifskhan@gmail.com

sensitive malignant conditions, uncontrolled hypertension, any liver disease, untreated endometrial hyperplasia etc [2-6]. The present scenario for advising hormone therapy is at minimal effective doses and for the shortest duration. With so much contraindication and many adverse effects of hormone therapy, medical fraternity seek efficient and safe drugs for the relief of menopausal syndrome. As progressively usage of herbal medicine is constantly increasing day by day, reportedly about one-third of the adult population used herbal medicine in the United Kingdom. Particularly women commonly use conventional medicine for menopausal syndrome as they feel safe or because of so much contraindication of hormone-based therapy [7].

In Unani system of medicine, there is no exact description of menopause but it has been discussed under ihtibas al-Tamth (cessation of menstruation) and can be correlated with Sinn-i-Yaas (age of natural termination of menstruation). Sinn-i-Yaas is the transition from reproductive to non-reproductive state usually achieved at the age of 50 years, sometimes at the age of 40 years too. Basics of Unani system divide human life into four stages which are as follows.

1. Sinn-I Namu (up to 30 years of age, Har Ratab Mizaj)
2. Sinn-I– Shabab (30-40 years of age, Har Yabis Mizaj)
3. Sinn-I– Kahulat (40-50 years of age, Barid Yabis Mizaj)
4. Sinn-i- Shaikhukhat-(above 50 years of age, Barid Yabis Mizaj).

Tabai Sinn-i-Yaas is attained at the age of 50 years, sometimes 60 years.

As menstruation usually stops at the age of 40-50 years, it comes under Sinn-i- Kahulat which is Barid Yabis in Mizaj (temperament). As Barid Yabis temperament is the quality of Khilt Sauda (black bile), we may infer that at this stage excess of Khilt Sauda developed in the body, makes less production of Ratubat Unsurya ultimately decreases the Hararat Unsurya and finally all Quwa (powers) of the body decreased[8-9] .In Unani System of Medicine there are so many herbs which have the properties of "Muqawwi Mufarreh Ada Raisa, "which can cure post-menopausal syndrome as mentioned in many ancient unani literature.Vitex negundo (Tukhm-e-Sambhalu), an herb with potent estrogenic and therapeutic properties, has been historically used in Unani medicine to alleviate symptoms associated with menopause[10-18].There for its seems very relevant to assess the efficacy of Tukhme Sambhalu (Vitex negundo) in managing postmenopausal syndrome (Multazima-Baad-Az-InqtaeTams), focusing on postmenopausal symptoms.

METHODOLOGY:

A randomized, placebo-controlled clinical study titled "Efficacy of Tukhme Sambhalu (Vitex Negundo) in Post Menopausal Syndrome (Multazima-Baad-Az-Inqtaetams)" was conducted at GNTC, Hyderabad. A total of 60 postmenopausal women were randomly assigned to either the test group (n=30), receiving 5 grams of Tukhme Sambhalu powder twice daily, or the control group (n=30), receiving roasted rice flour. Treatment lasted 12 weeks, with follow-ups on days 30, 60, and 90 to assess efficacy. Patients were assessed using the Menopausal Rating Scale (MRS), which covered somatic, psychological, and urogenital symptoms, along with laboratory investigations such as serum estradiol, FSH, and calcium levels. Ethical clearance was obtained, and the trial included a double-blind design to minimize potential bias, making the methodology comprehensive and scientifically sound. The inclusion criteria for the study involved women aged 40-55 years, experiencing symptoms associated with natural menopause (perimenopausal or postmenopausal periods) or surgical menopause. Women with stable conditions of diabetes and hypertension were also included, provided they were clinically stable. The study aimed to focus on women who were otherwise healthy but dealing with the

physiological changes related to menopause. The exclusion criteria ruled out women with malignancies, undiagnosed vaginal bleeding, and those with significant kidney, liver, or cardiac dysfunction. Additionally, patients with psychiatric disorders or any condition that could potentially interfere with the study outcomes were excluded. This clear differentiation ensured the study population was homogeneous and suitable for evaluating the effects of Tukhme Sambhalu on postmenopausal symptoms.

RESULTS:

1. **Symptom Improvement:**
   - Hot Flushes: The study drug, Tukhme Sambhalu, resolved 83.3% of cases, compared to 66.7% in the control group.
   - Sleep Problems: Improved in 33.3% of patients in the study group, while the control group showed 23.3% improvement.
   - Joint and Muscular Discomfort: Resolved in 26.7% of cases in the study group, with the control drug managing only 13.35%.
   - Anxiety: 80% of patients showed improvement with the study drug, compared to 53.3% in the control group.
   - Bladder Problems: Resolved in 86.7% of patients in the study group, whereas the control group showed improvement in only 33.3%.
2. **Laboratory Investigations:**
   - Serum Estrogen (Sr E2): The mean serum estrogen levels before treatment were 17.63 (±16.26) in the test group, which slightly increased to 18.43 (±15.88) post-treatment. In the control group, serum estrogen levels decreased from 20.93 (±13.94) to 19.13 (±13.54), indicating some benefit of the study drug on estrogen levels.
   - Serum FSH: The mean FSH levels slightly increased in both groups, with the test group showing a marginal rise from 72.6 to 73.2 and the control group from 64.59 to 68.13.
3. **Therapeutic Response:**
   - In the test group, 43.3% of patients experienced complete relief from symptoms, while 26.7% were partially relieved, and 30% showed no response.
   - In the control group, only 20% of patients were fully relieved, 36.7% showed partial relief, and 43.3% had no response.

These results show a statistically significant improvement in the efficacy of the study drug compared to the placebo in managing symptoms associated with post-menopausal syndrome.

DISCUSSION:

There was a highly significant improvement in reducing symptoms such as hot flushes, anxiety, bladder problems, joint and muscular discomfort, and physical and mental exertion. Tukhme Sambhalu showed superior efficacy in comparison to the placebo. For instance, it resolved 83.3% of cases of hot flushes in the study group, compared to 66.7% in the control group. Anxiety was relieved in 80% of patients in the test group, while the control group saw a relief rate of 53.3%. The drug also demonstrated a statistically significant improvement in managing bladder problems, with 86.7% of cases resolved in the study group compared to only 33.3% in the control group. Tukhme Sambhalu not only alleviated physical discomfort but also improved laboratory parameters such as serum estrogen (Sr E2) and FSH levels. Although the improvements in these hormone levels were modest, the clinical significance of the drug's effect on postmenopausal symptoms was evident, with a marked improvement in the overall quality of life for the participants. In conclusion, Tukhme Sambhalu is an effective and well-tolerated treatment option for postmenopausal symptoms, offering a natural and holistic approach that aligns with Unani medicine's principles.

CONCLUSION:

The conclusion of the study highlights the

positive outcomes of Tukhme Sambhalu (Vitex negundo) in managing postmenopausal syndrome. The research demonstrated that Tukhme Sambhalu was both safe and effective, particularly in reducing key symptoms like hot flushes, mood disturbances, and urogenital issues. A notable improvement was observed in patients' quality of life after three treatment cycles. In the test group, 43.3% of the patients experienced full relief from their symptoms, compared to only 20% in the control group. The study also found 26.7% of patients in the test group had partial relief, further supporting the efficacy of the treatment. The drugs used showed multiple therapeutic effects, including anti-inflammatory, laxative, and antidepressant properties, and were cost-effective with no significant side effects. Despite the promising findings, the study acknowledges limitations, such as a small sample size and short duration of therapy, and calls for further research with larger and more comprehensive trials to validate the results.

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