

## Role of Winopause – A Multi-Herbal Product in the Treatment of Menopausal Syndrome

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### ABSTRACT

*In this study, Winopause has been found to be highly effective in the treatment of menopausal syndrome. There was significant response in hot flushes, irritability, insomnia, palpitation, pruritus vulvae and social interaction parameters. This response of Winopause could be due to the presence of phytoestrogens in the formulations. The drug was found to be effective and safe and no adverse effect was observed in any patient.*

**Keywords:** Menopause, Winopause, Asoka, phytoestrogens, herbs

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### 1. INTRODUCTION

The menopause is identified by the end of menstruation and hence of reproductive life. It normally occurs between the ages of 40 and 57 years in western countries but is normally seen earlier in Indian subcontinent [1]. Women may experience a number of symptoms during menopause with symptoms such as hot flushes and sweats occurring more commonly than others [2]. A number of factors contribute to the experience of menopause, which includes

falling estrogen levels and lifestyle changes. Sometimes the effect of life events at the time of the menopause can also influence the onset of menopause although their relative importance is uncertain [3]. Some women may have serious symptoms of menopause which may affect her day to day activities. These symptoms in most of cases may last for the whole of their life; however, some may experience them only during the transition phase. Role of hormone replacement therapy (HRT) in the treatment of menopause has been

extensively studied and most of the trial reports have shown the efficacy of HRT over placebo. While most women respond successfully to estrogen and progesterone therapy [4, 5], the effect of HRT on the risk of stroke is still under debate. Estrogen is well known for its effect in treating hot flushes, sweating and sleeplessness but its role in treating depression is still uncertain [6, 7]. There is proof to show that estrogens can increase the risk of endometrial cancer but its exact role in breast cancer is still not clear. These effects of estrogen are seen only when it is administered alone; however, the role of addition of progestogens may avoid the risk of endometrial cancer but at the same time the beneficial effects of hormone replacement therapy may affect lipid profile [8].

Herbal medicine has such an extraordinary influence on every walks of our life that numerous alternative medicine therapies have been prescribed by physicians to their patients. This includes Herbal therapy, Unani and Ayurveda. Approximately 25 percent of all prescription drugs are derived from various herbs. Since menopause is a serious issue and HRTs are the only options available, patients have been looking for safer and effective remedies for the alleviation of their suffering. Many herbal preparations are available in the market but none of them has been clinically proven for safety and efficacy. Therefore, we decided to conduct a study to evaluate the efficacy and safety of Winopause, a poly herbal formulation, marketed by Matxin Labs.

Winopause, a multiherbal researched product which contains *Saraca asoka* 150 mg, *Asparagus racemosus* 100 mg, *Hibiscus rosa sinensis* 50 mg, *Eclipta alba* 50 mg and *Glycyrrhiza glabra* 25 mg, is used in the treatment of various symptoms of menopause. *Saraca asoka* and *asparagus racemosus* provide a rich source of plant oestrogens that regulate the hormonal imbalance and thus help in relieving symptoms during menopause. *Saraca indica*, also popularly known as the Asoka tree, is a rich natural source of phytoestrogens and helps in relieving the symptoms of menopause. Satavari contains active markers like shatavarin I–IV, these saponins are rich sources of phytoestrogens. They help in nourishing the genital tract of a woman and help in alleviating the symptoms of menopause. Hibiscus and Bhringaraj have been used to alleviate the symptoms of hot flushes [9].

With this information about the difficulties faced by menopausal women and the side effects of HRT, we decided to conduct a well-planned study to evaluate the efficacy and safety of Winopause, a poly herbal formulation marketed by Matxin Labs.

## 2. MATERIALS AND METHODS

Fifty female patients were selected for this double blind placebo controlled trial; 35 of them had natural menopause and 15 underwent total abdominal hysterectomy with BSO, and were suffering from surgical menopause. At

the randomization visit, a detailed medical history was obtained. Those patients who had satisfied the inclusion criterion were included in the study. Patients who were on HRT, steroids, hormonal therapy and other herbal supplements and were not ready to give informed consent were excluded from the study. The patients were asked to visit the clinic every month for a period of 16 weeks and were randomly divided into 25 in each group and received either the placebo or the active drug at the dose of one tablet twice daily for 16 weeks. They were asked to visit

the investigating research assistant every 15 days for any adverse effect. The research assistant, who regularly monitored the symptoms of the patients and distributed Winopause/placebo according to the randomization chart, was completely unaware of the drugs administered to patients to avoid any bias during evaluation of patients. During each visit, every patient underwent physical and gynecological examination. Blood test, ECG and the hormonal levels were estimated only initially and at end of 16 weeks of study (Tables I–III).

**Table I:** Symptoms of Menopause in Patients at the Time of Inclusion in the Study.

Symptoms	Severe	Moderate	Mild
Hot Flashes	45	4	1
Depression	10	35	5
Insomnia	40	8	2
Excessive Sweating	48	2	-
Irritability	38	10	2
Social Interaction	25	15	10
Pruritus Valvae	30	15	5

### 3. RESULTS

About 46 patients successfully completed the study and no adverse response was reported in any patient. After the study period of four months, the data was evaluated by a statistician. Four patients (three from placebo and one from the Winopause group) dropped out. There was no statistically significant difference between both the groups in terms of

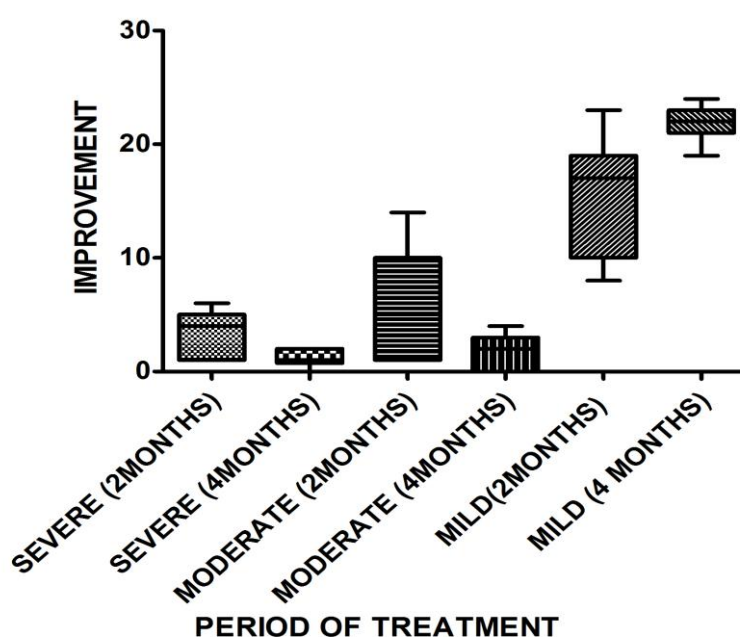
signs and symptoms at the time of initiation of the study. There was statistically significant reduction of symptoms like hot flushes, depression, insomnia and irritability in the Winopause treated group. Almost all the patients in the Winopause treated group recovered from pruritus valvae, and social interactions. All of them had a sense of wellbeing.

**Table II:** Response of Patients after 2 and 4 Months of Treatment with Winopause.

Symptoms	Severe		Moderate		Mild	
	2 Months	4 Months	2 Months	4 Months	2 Months	4 Months
Hot Flashes	6	1	4	2	15	22
Depression	1	-	14	3	10	22
Insomnia	5	1	8	3	12	20
Excessive Sweating	3	1	5	1	17	23
Irritability	3	1	2	1	20	23
Social Interaction	1	-	2	1	22	24
Pruritus Valvae	5	3	10	1	10	21

**Table III:** Response of Patients after 2 and 4 Months of Treatment with Placebo.

Symptoms	Severe		Moderate		Mild	
	2 Months	4 Months	2 Months	4 Months	2 Months	4 Months
Hot Flashes	19	17	5	6	1	2
Depression	12	10	10	8	3	7
Insomnia	15	12	8	10	2	3
Excessive Sweating	18	17	7	7	-	1
Irritability	19	18	5	6	1	1
Social Interaction	12	10	8	9	5	6
Pruritus Valvae	20	20	5	4	-	1



*Fig. 1: Effect of Winopause Treatment on Menopausal Symptoms.*

In the placebo treated group, there was no significant change in the signs and symptoms of any of the parameters. Although some reduction was observed in symptoms like social interaction and insomnia, there was no major change in the hormonal profile in the patients before and after treatment.

#### 4. DISCUSSION

The increase in life expectancy and more and more awareness of women towards menopause have compelled scientists to look for an alternative to HRT. Although HRT has been found to be extensively prescribed by the attending physicians, women are demanding a safer alternative to HRT [10]. Several herbs have been used by ancient physicians since long to relieve the symptoms of menopause. Herbs like Asoka and Satavari, have been used

for this purpose. These herbs are found to contain actives which are similar to estrogens but without any side effects of synthetic estrogens. The problem with the menopause lies in the symptoms like those of vasomotor instability, such as hot flushes, sweating, dizziness, and paraesthesiae; those of emotional instability, which include fatigue, depression, and sometimes reduction in sexual responsiveness; and local symptoms such as atrophy of the genitalia, atrophic vaginitis, which is associated with reduction of tissue glycogen. Other medical menopausal consequences may arise through an increased prevalence of hypertension and a reduced density of bones. The main fundamental theory of treating menopause lies in elevating the estrogen level so that the symptoms are reduced [11]; however, the major problem lies not in relieving the symptoms but associate

side effects like thromboembolism, hypertension, obesity, liver disease and carcinoma of the female genital tract [12]. Scientists have shown an association between the use of exogenous estrogen and an increased risk of endometrial carcinoma and it should also be remembered that estrogen therapy can alter many biochemical tests, including, for example, several thyroid function tests.

Menopause can be physiological as part of natural ageing or can be brought on surgically when the ovaries are removed in a woman. In both cases, the reducing levels of estrogens bring a number of unpleasant symptoms. A disciplined and systematic approach is required to help ease the symptoms of menopause. Lifestyle changes like cessation of smoking, diet and exercise are as much important as medical management [13]. Phytoestrogens are a class of compounds derived from plant sources and have been studied extensively. These compounds bind to estrogenic receptors and produce the same effect as natural or synthetic estrogen [14]. Phytoestrogens are known to strengthen bones and heart, control weight, lessen hot flashes, improve sleep, boost energy, increase sex drive and make the skin glow naturally.

In the present study, we observed a highly significant reduction in the mean score for vasomotor symptoms like hot flushes, excessive sweating, palpitation, urogenital symptoms like dry vagina and pruritis valvae

and other psychosomatic symptoms in the Winopause treated group. This alleviation of symptoms could be due to the presence of phytoestrogens in Winopause. Therefore, it could be concluded that Winopause is a safe and effective multi-herbal product and it can be safely prescribed in women suffering from menopausal syndrome.

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### REFERENCES

1. Aylward, M., Maddock, J., Rees, P. *British Medical Journal*. 1976. 1. 220.
2. Beard, R. *Modern Geriatrics*. 1977. 6. 18–22p.
3. Coope, J., Thomson, J. M., Poller, L. *British Medical Journal*. 1975. 4. 139–143p.
4. Daw, E. *Current Medical Research Opinion*. 1974. 2. 256–259. General Practitioner Research Group (1977). *The Practitioner*. 218, 573–579p.
5. Gomez, G. *Clinical Trials Journal*. 1977. 14. 2. 65–70p.
6. Illich, I. *Medical Nemesis*. London: Calder & Boyars. 1975.
7. Inman, W. H. W., Vessey, M. P. *British Medical Journal*. 1968. 2. 193–199p.

8. McKinlay, S., Jeffreys, M., Thompson B. *Journal of Biosocial Science*. 1972. 4. 161–173p.
9. Anderson J. J. B. *Nutrition Research Review*. 1999. 12. 75.
10. Studd, J. *Prescribers' Journal*. 1976. 16. 51–58p.
11. Vessey, M. P., Doll, R. *British Medical Journal*. 1969. 2. 651p.
12. Markiewicz, Gary J. *Journal of Steroid, Biochemical Molecular Biology*. 1993. 45. 399–405p.
13. Knight D. C., Eden J. A. *Obstetrics & Gynecology*. 1996. 87. 897–904p.
14. Ewies, Aywan A. A. *Up to Date in Obstetrics & Gynecological Surgery*. 2002. 57(5). 306–313p.