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Research Article

Efficacy of *Sumbul ut Teeb* (*Nardostachys jatamansi* Linn) on Vasomotor Symptoms in Post Menopausal Women - An Open Observational Study

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Abstract

Background: Hot flushes and night sweats are the most prevalent symptoms in menopause with 85% of incidence. Hormone therapy is the most effective treatment for alleviating menopausal vasomotor symptoms. Many women are reluctant to take this treatment due to side effects and concerns about safety. Women and healthcare providers are looking for alternative. Clinical evidence indicates number of complementary and alternative therapies may be effective in alleviating menopausal vasomotor symptoms. Hence this study was conducted to evaluate the efficacy of *Sumbul ut teeb* in vasomotor symptoms of postmenopausal women.

Methodology: An open observation study entitle "Efficacy of *Sumbul ut teeb* in vasomotor symptoms of postmenopausal women was carried out in the OPD, Dept of OBG, NIUM, Bangalore during the year of 2016 - 17. Total 30 post menopausal women of 45 - 55 years were included. Informed consent was taken and test drug *Sumbul ut teeb* 3 gm was given daily in three divided doses for 2 months. Follow up was done at every fortnight assess the response of the drug by using hot flushes rating scale.

Results: Results were analyzed statistically by using student test and paired proportion test. Significant effect was observed in both subjective and objective parameters. Out of 30 patients 24 were relieved, 4 were partially relieved and only 2 patients go no response. It is indicate that the test drug was found effective and the management of vasomotor symptoms in post menopausal women with p value < 0.001**.

Interpretation and Conclusion: On observation the results and properties of test drug it can be concluded that the test drug *Sumbul ut teeb* show promising effect in treating vasomotor symptom in post menopausal women without any side effects.

Keywords: *Post Menopausal Syndrome, Vasomotor Symptoms, Hot Flushes, Night Sweats, Sumbul ut teeb; Hot Flushes Rating Scale*

Background and Objective

Menarche and menopause are the turning point in the life of a woman. Menopause is a stage of life not a disease. It is a major physiological change in woman's life and leads to serious health problems in developing countries. Menopause is defined as the permanent cessation of menses. Natural menopause is recognized after 12 months of amenorrhoea that is not associated with a pathologic cause [1].

Post menopausal women have to face a lot of problems both physical as well as psychological [2]. In health system women of reproductive age group are given more importance, but the post menopausal women are neglected. Menopause is an important stage within the continuum of health in women's life has gained a lot of attention since the last century. Menopause currently affects the lives of millions of women globally and will be an issue of increasing concern as the population ages over the few decades. The majority of women in the age group 45 - 54 years experience menopausal symptoms, although not all experience these as troublesome [3]. During menopause Mizaj of the women changes more towards burudat. Menstruation may get ceased due to liver disease and obesity as the blood vessels becomes narrow and production of blood in liver gets decreased, which leads to galbahe burudat in the body [4]. Cause of Ehtebase tams at this age may be burudate rehm or ghalbae burudat or increased viscosity of blood [4,5]. Various symptoms like weakness, frequency of micturation, sue hazm etc are caused due to ghalbae burudat [6]. Ehtebase tams also leads to complications such as depression, palpitations, hysteria, anorexia, increased thirst, headache, indigestion, anxiety, fatigue, dysuria, backache etc [7].

Vasomotor symptoms (VMS), hot flushes and night sweats (HF/NS) are often considered the cardinal symptoms of menopause, affecting more than three - quarters of midlife women. Symptoms typically last 5 to 7 years, although some women continue to experience symptoms for longer than 10 or 15 years VMS generally last from 1 - 5 minutes with a small percentage of women reporting a time longer than six minutes [8,9]. The prevalence of menopausal vasomotor symptoms in women varies according to country and ethnic origin. Worldwide, it is estimated that they are experienced by 50% - 85% of women over 45 years. [10]. Vasomotor symptoms (VMS) Hot flushes and night sweats occur due to decline in ovarian function and are the cardinal symptoms of menopause [11]. Vasomotor hot flushes are complained by approximately three out of four menopausal women. VMS contribute to the women's discomfort, inconvenience and distress. For a significant number of women, vasomotor symptoms may impact negatively on quality of life and warrant the need for treatment [12].

Although a number of other treatments are available, their efficacy and safety have not been fully substantiated. Given the problems associated with long-term HRT use, an effective treatment that can alleviate symptoms would be highly desirable to take during this period of hormonal change [13]. Unani physicians documented number of single as well as compound formulations for relieving menopausal symptoms. Among these *Sumbul-ut-teeb* (*N. jatamansi* DC) has long been used by its properties such as Musakkin (Analgesic), Mufarih, Munavim (Sedative), Muqawi Qulb Dimagh wa Asab, Muqawi Bah. (Tonic of heart, brain and nerves) etc [14-16]. Pharmacological studies also reported its antioxidant activity [17], hepato and renal protective properties [18]. This drug also contains phytooestrogenes [19]. This drug also possess Emmenogague, Antispasmodic, Stomachic, Diuretic, Depressant of CNS, Tonic, Deobstruent, Laxative, Aromatic adjunct, Antiseptic, Anti-arrhythmic and Hypotensive [20]. It helps in relieving VMS in post menopausal women. However till date no clinical validation and documentation regarding its use in VMS is available. With this background in consideration the study was planned to find out the effective and safe treatment for vasomotor symptoms in post menopausal women and thereby improving health related quality of life.

Methodology

The present study entitled "Efficacy of *Sumbul-ut-teeb* (*Nardostachys jatamansi* DC) in vasomotor symptoms of post menopausal women - An Open Observational study" was carried out on 30 patients between the age group of 45 - 55 years at NIUM Hospital, Bangalore during the year of 2016 - 17. Initially 62 Post menopausal women with vasomotor symptoms were assessed for eligibility, among them 10 patients denied to participate in study, 52 patients were accepted for enrollment and investigated. Out of 52, 22 patients were excluded due to various reasons like DM, HTN and carcinoma and remaining 30 patients were enrolled in the study and assessed for subjective and objective parameters. Eligible patients were allocated to test group. This study was designed as an Open Observational Study. Before trial Ethical clearance was obtained. Information regarding the study was given to the patients and formal consent was taken before starting the trial. Thorough clinical assessment of symptoms such as hot flushes and night sweats was done. Hot Flush Rating Scale was used to

assess the severity of VMS before and after trial. Orally Test drug *Sumbul-ut-teeb* 3 grams powder in three divided doses was given for two months. Follow up was done at every fortnight from base line (visit 1) to after trial (visit 6) for the assessment of improvement in subjective and objective parameters. Safety profile was done before and after trial. The results were analyzed statistically by using student "t test and paired proportion test.

Results

Assessment of subjective parameters at different study points

Hot flushes

Paired proportionate test was used to assess the response of the test drug. Results were assessed on the basis of improvement in vasomotor symptoms like hot flushes and night sweats. The severity of Hot flushes were categorized into mild (+), moderate (++) and severe (+++) degree. Before trial 30 (100%) were found in severe category and no patients were found in moderate and mild categories. After trial 27(90%) were found in mild category, 1 (3.3%) was found in moderate category and 2 (6.7%) were found in severe category with the improvement of 93.3% with P value < 0.001* (Figure 1).

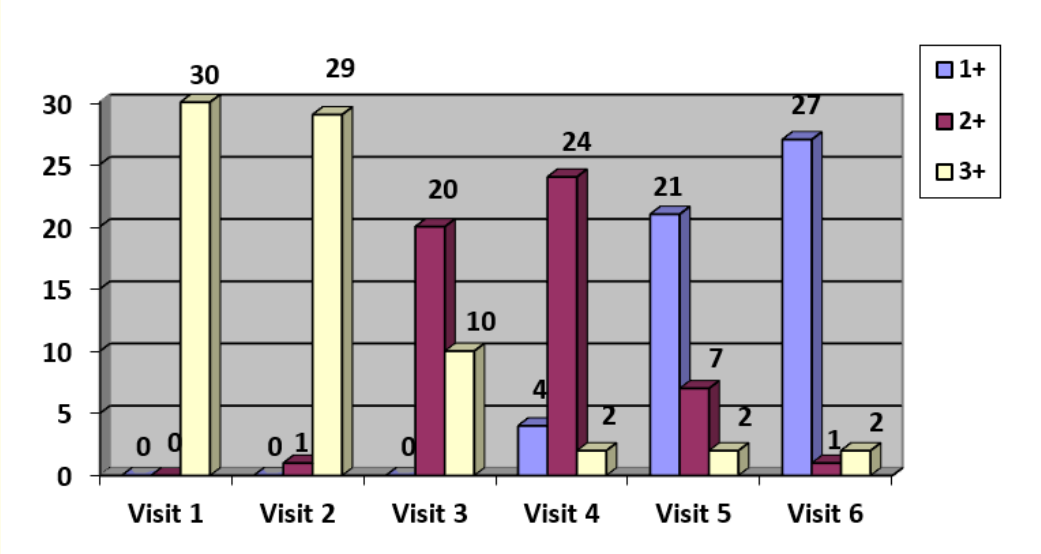

Figure 1: *Hot flushes: Assessment at different study points.*

Night sweats

The severity of Night sweats were also categorized into mild (+), moderate (++) and severe (+++) degree. Before trial 18 (60%) were found in severe category followed by 10 (33.3%) in moderate category, 2(6.7%) in mild category. After trial 1(3.3%) was found in severe category, no patients in moderate category, 29 (96.6%) in mild category were found with the improvement of 89.9% with *P* value < 0.001** (Figure 2).

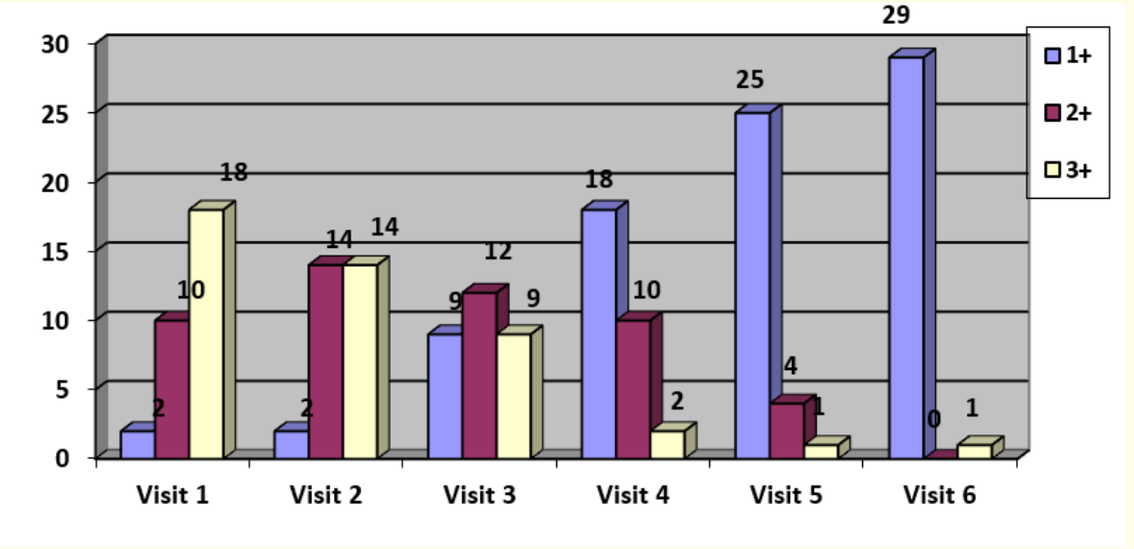

Figure 2: *Night sweats: Assessment at different study points.*

Assessment of objective parameter at different study point

Assessment of the results was done on the basis of improvement in objective parameter. Follow up was done at every fortnight for the assessment of efficacy of test drug by using student t test and paired proportionate test.

HF/NS frequency score assessment

Inter group improvement was observed in HF/NS freq score from visit 1 (Baseline) to visit 6 (After trial). In visit 1 the mean score was 51.20 ± 10.17 and in visit 6 the mean SD was 4.50 ± 4.99. In was observed that visit 2 onwards the mean difference was found significant *P* value was < 0.001** (Figure 3).

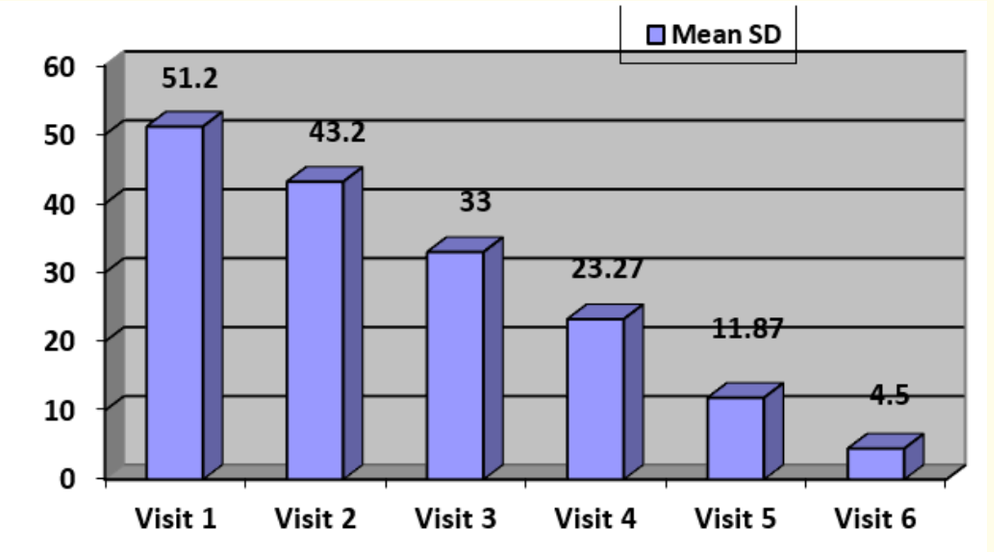

Figure 3: *HS/NS freq score - Assessment at different study points.*

HF/NS rating score assessment

For inter group comparison the mean difference between V1 and subsequent visits was found highly significant with *P* value of < 0.001**. At visit 1 the mean SD was 8.91 ± 0.68 and in visit 6 it was 1.82 ± 1.45. This indicates that the test drug significantly improves HF and NS. From this it can be inferred that test drug *Sumbul ut teeb* was found effective in improving HF/NS rating score from second visit onwards with *P* vale < 0.001** (Figure 4).

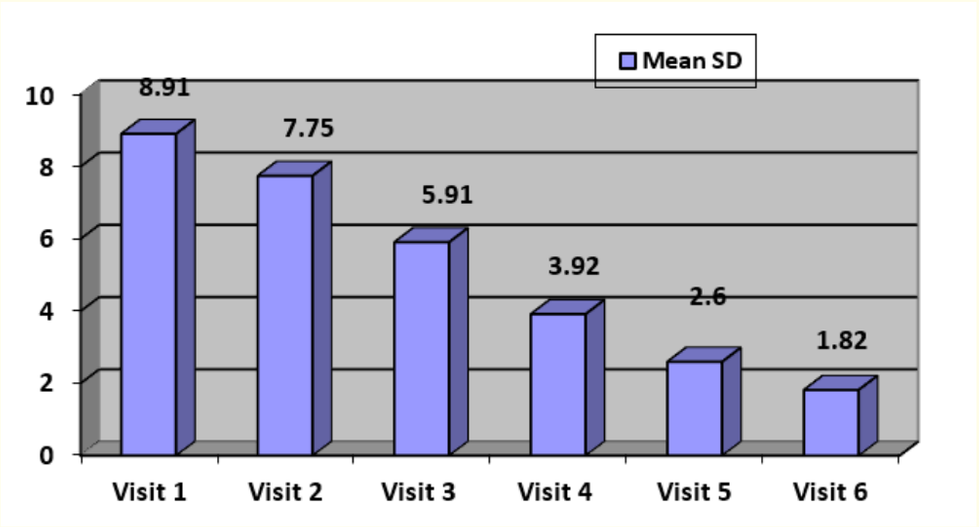

Figure 4: *HS/NS rating score –Assessement at differetn study point.*

Therapeutic outcome

Assessment of efficacy of test drug was done before and after trial. Results were analyzed on the basis of three categories i.e. relieved, partially relieved and no response. It revealed that out of 30 patients 24 (80%) were relieved, 4(13.3%) patients were partially relieved and no response was seen in 2 (6.7%) patients (Figure 5).

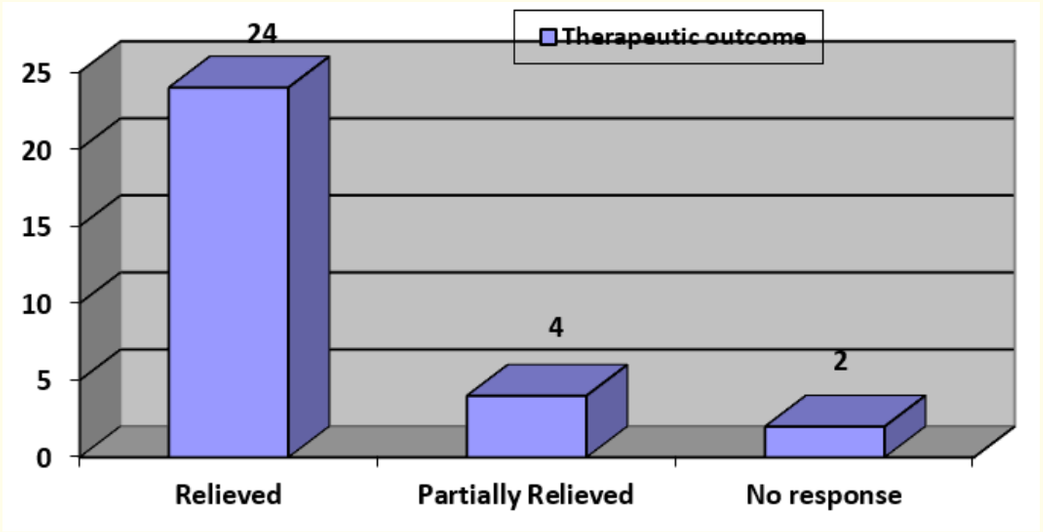

Figure 5: *Therapeutic outcomes.*

Discussion

In the present study out of 30 patients the age of the participants ranged from 45 - 55 years and the highest prevalence i.e. 23 (76.7%) of vasomotor symptoms were observed in the age group of 45 - 50 followed by 7 (23.3%) in the age group of 51 - 55 years. This is almost similar to the studies done by Avanie pal., *et al*. [21] 40 - 50 years (80%) and Arpita Mandals., *et al*. [22] 45 - 50 years (46.2%). In the current study the mean age was 48.73 ± 3.10 which was similar to the study by Sharma [23] and sing and Kim YH., *et al*. [24] were also reported the mean age was 48.29%. In another study by Madhu Kumar., *et al*. [25] reported the mean age of the patients was 57 years. The diversity in attainment of menopause may be due to regional, community variation, genetic, environmental variations and nutritional factors. In this study it was also observed maximum patients i.e. 15 (50%) were of less than 30 years of married life and 13 (43.3%) patients had 30 - 35 years of married life and 2 (6.7%) had more than 35 years of married life.

The most of the patients 28(93.3%) in this study were found housewives. It means that housewives experienced more severity of symptoms than that of other women. Studies by Monika Satpathy [26] and Donald Crhistian., *et al*. [27] also showed housewives were more prone to develop symptoms as compared to other 83% and 73.5% respectively. This can be explained that lack of physical activity leads to accumulation of excess waste material in the body causes obesity and excess perception of symptoms. Another explanation is may be due to work load or tension or worries. To live with the partner has got some positive implications on the perception of symptoms as social factors do play.

Kuppuswamy's scale was used to assess the socioeconomic status of the patients. In the present study, majority of patients i.e. 23(76.7%) belongs to lower middle class followed by 7(23.3%) upper lower class. Socio economic and financial status is an important factor that affects the Health and QoL. Poor socio economical status is also associated with higher chances of getting menopausal symptoms. This is substantiated by the study conducted by Donald Christian., *et al*. [27] reported Poor socio-economic conditions predisposes higher rates of menopausal complains i.e. 86(58.5%) as evident by a study conducted by Sharma [23] which showed higher proportion of depressive symptoms.

Mizaj of the patient is an important factor to assess the condition of the body; a particular mizaj is inclined towards age and a specific type of disease. In our study highest number i.e.16 (53.3%) patients were of balghami mizaj followed by Damvi 8 (26.7%), Safravi 4 (13.3%) and Saudavi 2 (6.7%). This finding confirms the writings of ancient unani scholars that the vasomotor symptoms are more commonly seen in balghami Mizaj women. Dominance of khilt balgham and dam are cause of appearance of vasomotor symptoms like hot flushes and night sweats.

Overweight and obesity are the significant factors which contribute to higher perception of symptoms. Higher BMI was positively related to more severe hot flushes among post menopausal women. The mean BMI in this study was 29.27 ± 5.52 kg/m^2 and maximum number of participants i.e. 12(40%) had BMI of more than 30Kg/m^2 followed by 10 (33.3%) had BMI between 25 - 30 kg/m^2, 7 (23.3%) had BMI between 18.5 - 25 and only 1 (3.3) had BMI less than 18.5. It indicates that the greatest number of women were overweight and obese. In other studies conducted by Jaqueline Teixeira., *et al*. [28] reported the mean BMI 28.3kg/m^2. Women with higher BMI experienced severe vasomotor symptoms. According to the literature in middle aged women overweight and obesity are relevant risk factors for the development of menopausal symptoms.

It was observed that the symptoms were more prominent after 2 years of menopause. Out of 30 patients with vasomotor symptoms maximum number of i.e. 9 (30%) were found with 2 years of menopausal age followed by equal number of patients i.e. 6 (20%) were found with 1 and 3 years of menopausal age respectively, 5 (16.7%) with 4 years of menopausal age, 3 (10%) with 5 years and only one patient had 8 years of menopausal age. A study by Nisar N., *et al*. [29] reported that severity of the symptoms were more between 1 - 5 years (69.1%) of menopause. The reasons postulated for this may be because of adjustment to biological changes occurring after menopause and women perceived more symptoms than longer duration of menopause.

The test drug *Sumbul ut teeb* was effective in relieving hot flushes. Major symptoms in post menopausal women are hot flushes. It is due to circulation of the blood along with ruh towards outer parts of the body results in hot flushes. Circulation of blood with ruh carries hararat gharizia so the skin becomes red and hot and is experiences as discomfort by the women. Due to masakkin and mafarih properties of the drug it produces a feeling of wellbeing n the body, while counter the discomfort and gives relief from hot flushes. Moreover, the test drug contains pharmacological activities such as analgesic anti inflammatory, CNS depressant, antioxidant, sedative and tranquilizer properties, which are also helpful in relieving in the symptoms [30]. The drug also contain active ingredient i.e. Jatamansone which is mainly known as stress modulators, which in turn may be responsible for anti anxiolytic and sedative effects. Other ingredients such as flavonoids and polyphenols have anti stress and antioxidant activities which are helpful in reduction of oxidative stress in the body, hence it relieves vasomotor symptoms sin post menopausal women.

Night sweats occur due to the action of harahrate gharizia on the morbid material which accumulates in the body due to cessation of menstruation. In menopausal women when hararte gharizia act upon these morbid material then tabiyat adopt other means of dissolution of waste. They are converted into vapours which are experience in the form of sweat. The test drug has munaqqi action hence excreted morbid material from the body. Due to its muqavi jijar property it processed the food more towards akhlate salh (good quality) and decreased the production of waste, hence sweating was relieved [31-34].

Conclusion

By the observation of the results of the study, it can be concluded that the vasomotor symptoms i.e. hot flushes and night sweats in post menopausal women were controlled by test drug i.e. *Sumbul ut teeb*. Further large scale studies on large sample size with longer duration are recommended for long term effect of test drug, so that the drug can be used as an alternative to HRT for vasomotor symptoms in post menopausal women.

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