

Management of Distress During Climacteric Years by Homeopathic Therapy

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Abstract

Objectives: The purpose of this study was to ascertain the usefulness of homeopathic therapy in the management of distressing symptoms encountered during climacteric years in women (primary objective) and also the changes brought about in the levels of follicle-stimulating hormone (FSH) and lipid profile in these women after homeopathic treatment (secondary objective).

Materials and methods: An open, multicenter, prospective, observational study was carried out to ascertain the usefulness of homeopathic treatment in distress during climacteric years (DDCY). Patients were enrolled from the general outpatient department of the six Institutes/Units of Central Council for Research in Homoeopathy (CCRH) and were required to complete a follow-up period of 1 year as per the protocol designed by the CCRH. A uniform questionnaire assessing 15 predefined symptoms of menopause was adopted, with assessment of each symptom at every visit. Levels of serum FSH and lipid profile were monitored at entry and at completion. Effect size of the study was also calculated. CARA Software was used for repertorization of the presenting symptoms of menopause along with the characteristic attributes of each patient to arrive at a simillimum. The selected medicine was prescribed in a single dose as per the homeopathic principles. The assessment of the results was made through statistical analysis using the Wilcoxon signed rank test on Statistical Package for Social Sciences (SPSS) comparing symptom score at entry and completion of 1 year of treatment and *t* test for analyzing improvement in laboratory findings.

Results: Homeopathic therapy was found to be useful in relieving menopausal distressing symptoms such as hot flashes, night sweats, anxiety, palpitation, depression, insomnia, and so on. Influence on serum levels of FSH, high-density lipoprotein, and low-density lipoprotein was not significant but serum levels of cholesterol, triglycerides, and very-low-density lipoprotein decreased significantly. Effect size of the study was found to be large. The medicines found to be most frequently indicated and useful were *Sepia*, *Lachesis*, *Calcarea carb.*, *Lycopodium*, and *Sulphur*.

Conclusions: This study proves the usefulness of homeopathic medicines in relieving DDCY.

Introduction

CIMACTERIC IS THE PHASE in the aging of women marking the transition from the reproductive phase to the nonreproductive state. This phase incorporates the perimenopause by extending for a longer variable period before and after the perimenopause.¹

The time of menopause is determined genetically and occurs at a median age of 51 years.²

By the year 2025, the World Health Organization estimates that 1.1 billion women will be aged 50 or over.³ A total of 130 million Indian women are expected to live beyond the menopause into old age by 2015.⁴

According to a survey, overall, 44% of postmenopausal women reported having ever used hormone replacement therapy (HRT).⁵ The most frequently cited primary use for HRT was symptom relief, particularly hot flashes (HF), with 70% of women stating that this was a reason for taking the therapy.⁶

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Since the publication of results of a study on risks and benefits of estrogen plus progestin in healthy postmenopausal women indicated that overall health risks exceed benefits,⁷ it has led women to seek alternatives. In 2008, conventional HRT use over age 50 had dropped to 11.8%, compared to 22% in the year 2000.⁸

Menopausal symptoms have been treated with homeopathic medicines for more than one and a half centuries.⁹ Homeopathy is based on the principle of "Similia," first stated by Hippocrates and propounded into a therapeutic system by Samuel Hahnemann in the late 18th century.¹⁰ Homeopathic medicines are prepared as per the directions of the Homoeopathic Pharmacopoeia of India,¹¹ and 12.7% of the Indian population prefers homeopathic therapy.¹²

A pilot study on homeopathic treatment of hot flashes was carried out on 31 patients. Overall, at least 73% of patients reported improvement in both severity and frequency of symptoms, with a reasonable agreement between doctor- and patient-assessed outcomes.¹³

In another prospective observational study on 45 patients with breast cancer, 38 had hot flashes. Other symptoms such as mood disturbances, joint pains, fatigue, sleeplessness, and so on were also present in these patients. Significant improvement was seen in HF, and quality of life also showed an improvement.¹⁴

The observational study on treatment of hot flashes with homeopathy in 438 patients revealed a significant reduction ($p < 0.001$) in the frequency of HF and in daily discomfort they cause.¹⁵

An audit report of a National Health Service community menopause clinic through homeopathic intervention suggested that the greatest response was in those who reported headaches, vasomotor symptoms, emotional/psychologic symptoms, and tiredness/fatigue as their primary symptoms.¹⁶

Randomized clinical trials (RCTs) on homeopathy for menopausal symptoms¹⁷ and estrogen withdrawal symptoms¹⁸ in breast cancer survivors did not show the statistically significant results as the primary outcome measure for homeopathy over placebo.

The study was undertaken by the Central Council for Research in Homoeopathy (CCRH), with the primary objective to ascertain the role of homeopathic therapy in the management of distress during climacteric years (DDCY) with regard to improvement in symptom complex and the secondary objectives to assess the effect on the level of the serum follicle-stimulating hormone (FSH) and the changes in lipid profile.

Materials and Methods

An open prospective observational study was undertaken by the CCRH at six centers from October 2005 to September 2009 (including a follow-up period of 1 year) as per the protocol. Female patients between the ages of 40 and 55 years and with changes in menstrual pattern or with cessation of menstruation for at least 1 year were screened from the general outpatient department of the institutes/units. Of the screened cases, patients who fulfilled the inclusion criteria (i.e., cessation of menstruation for at least 1 year with FSH level >40 mIU/mL) or women in the perimenopausal period with serum FSH ranging between 10 and 40 mIU/mL

on the second day of menstrual cycle, after submission of informed written consent were enrolled in the study. The patients who had an artificial menopause and were on HRT, had a history of breast or reproductive organ cancer, uncontrolled hypertension, diabetes mellitus, chronic renal failure, and severe psychiatric disturbance based on the history, relevant investigations, or physical examination were excluded. Two hundred and ninety three (293) women were studied from October 2005 to September 2009 including a follow-up period of 1 year. A flow chart the inflow of patients is given below (Fig. 1). The study protocol was in accordance with the Helsinki declaration on human experimentation¹⁹ and Guidelines of Good Clinical Practice.²⁰ Clearance was obtained from the Institutional Ethical Committee of the Council.

As the study was done at six centers, a uniform questionnaire "Distress During Climacteric Years Symptom Scale" (DDCYSS) was devised by the Council to remove the bias of the investigator for assessing the individual symptoms. (Table 1).

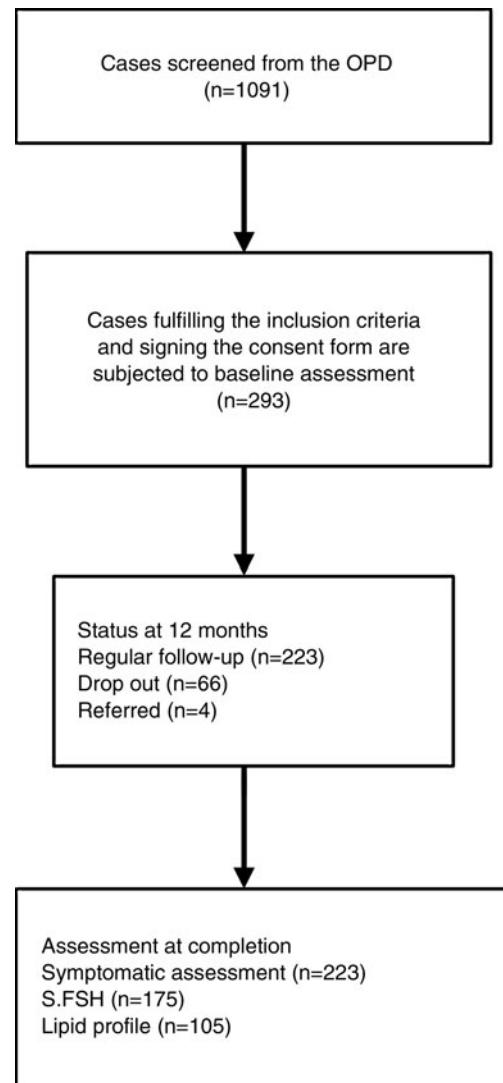


FIG. 1. Flow chart depicting inflow of patients. OPD, outpatient department; S.FSH, serum-follicle-stimulating hormone.

At entry, an objective assessment of 15 predefined symptoms of menopause was done on DDCYSS. Each symptom in DDCYSS was quantified considering its frequency, duration, and intensity by attributing scores 0–4. Depending upon the baseline symptom score, the intensity of the distress was classified into *mild* (4–11), *moderate* (12–24), and *severe* (25–36). Also, every patient was subjected to per vagina and/or per speculum examination as required at the baseline.

Following a detailed homeopathic consultation with assessment of signs and symptoms, each patient was treated with an individualized homeopathic medicine after repertorization on CARA Software²¹ in final consultation with *Materia Medica*. The selected medicine was given in single dose in 30 C potency.

After the first visit, follow-up was done every week for a month, then every 2 weeks for 3 months (if required maybe

early with the consultation of a gynecologist), and then monthly for 8 months. Evaluation of symptoms was done as per DDCYSS at every follow-up and per vaginal/per speculum examination was done at the third, sixth, ninth, and twelfth month. Serum FSH and lipid profile assessment was done at entry and on completion of 1 year. The patients were followed up for a period of 1 year.

Medicine was repeated, first in the same potency and subsequently in higher potencies only when the patient did not improve further.

Investigators were allowed to change the medicine only twice after reviewing the case. In case the patient did not improve even after changing the medicine twice, the case was to be declared as a treatment failure.

The data were analyzed statistically by using the Wilcoxon signed rank test on SPSS for analyzing the score and *t* test

TABLE 1. DISTRESS DURING CLIMACTERIC YEARS SYMPTOM SCALE (DDCYSS) DEVELOPED BY THE CENTRAL COUNCIL FOR RESEARCH IN HOMOEOPATHY

S. no.	Symptoms	Symptom score			
		0	1	2	3
1	Hot flashes	Not at all	1–2 Times/24 hrs	3–5 Times/24 hrs	>5 Times/24 hrs
2	Night sweats	Not at all	1–2 Times/24 hrs	3–5 Times/24 hrs	>5 Times/24 hrs
3.	Mood swings				
	a) Anxiety psychic (irritability)	Not at all	Worrying about minor matters	Apprehensive attitude apparent in speech	Fear and anxiety expressed without questioning
	b) Depression	Not at all	Feelings expressed on questioning	Expresses nonverbally through facial expression	Expresses in verbal and nonverbal communication
		0	1	2	
4.	Palpitation	Not at all	2 to 3 Times/week	>3 Times/week	
5.	Pruritus vulvae	Not at all	Present but not disturbing work	Present and disturbing work	
6	Dysuria	Not at all	Tolerable	Intolerable	
7.	Sexual desire (change from previous)	Not at all	Decreased	Increased	
8.	Poor memory	Not at all	Occasional	Disturbing routine work	
		0	1	2	
9.	Stress incontinence	Not at all	Symptom revealed on enquiry	Symptom expressed spontaneously	
10.	Dyspareunia if observed	Not at all	Symptom revealed on enquiry	Symptom expressed spontaneously	
11	Vaginal dryness on p/s examination	Not at all	Symptom revealed on enquiry	Symptom expressed spontaneously	
12	Vaginal discharge	Not at all	Symptom revealed on enquiry	Symptom expressed spontaneously	
13	Insomnia	Not at all	Occasional	Disturbing routine work	
		0	1	2	
14	Are work and activities affected (lack of concentration)?	Not at all	Thoughts & feelings of incapacity, fatigue related to activities	Loss of interest in work and activity	Decrease in actual time spent in working
Total symptom score	Intensity of the disease:				Stopped activities because of present illness
	Mild [4–11],				
	Moderate [12–24],				
	Severe [25–36]				

S. no., serial number; p/s, per speculum.

for analyzing improvement in laboratory findings, as per protocol. On completion of a 1-year period of treatment, the outcome was assessed by using the following formula:

$$\% \text{ improvement} = \frac{(\text{Score at entry} - \text{Score at completion})}{\text{Score at entry}} \times 100$$

Accordingly, improvement indices were formulated as marked improvement (75% or more improvement in symptoms score from baseline score), moderate improvement (50% to <75% improvement in symptoms score from baseline score), mild improvement (25% to <50% improvement in symptoms score from baseline score), and not significant improvement (<25% improvement in symptoms score from baseline score).

The value of Cohen's d and the effect-size correlation, r_{YX} , were calculated by using the means and standard deviations of two groups (before and after treatment) by applying the following formula:

$$\text{Cohen's } d = M_1 - M_2 / \sigma_{\text{pooled}}$$

where $\sigma_{\text{pooled}} = \sqrt{(\sigma_1^2 + \sigma_2^2)/2}$.

Results

Of 1091 women screened, only 293 qualified for the inclusion criteria. Of these 293 patients, 223 patients regularly followed up for symptomatic assessment for 1 year, 66 dropped out, and 4 were referred. One hundred and seventy-five (175) patients were investigated for FSH both at entry and completion, and 105 patients were investigated for dyslipidemia before and after treatment. The data pertaining to symptom score and medicines found useful were analyzed and conclusions drawn thereupon (Tables 2 and 3). The mean score at the end of the study was reduced to 3.30 from 14.10 at baseline, which was statistically significant ($p=0.0001$).

TABLE 3. MEDICINES FOUND USEFUL FOR IMPROVEMENT IN STATUS

Medicine	No. of cases prescribed	Marked improvement in no. of cases	Moderate improvement in no. of cases	Mild improvement in no. of cases
<i>Sepia</i>	53	37	14	2
<i>Pulsatilla</i>	27	15	9	3
<i>Lachesis</i>	24	13	6	5
<i>Sulphur</i>	27	17	8	2
<i>Calcarea carb.</i>	25	19	4	2
<i>Lycopodium</i>	17	14	1	2
<i>Natrum mur.</i>	9	4	5	0
<i>Arsenic alb.</i>	4	3	1	0
<i>Phosphorus</i>	4	2	1	1
<i>Ferrum met.</i>	4	4	0	0
<i>Kali carb.</i>	3	3	0	0
<i>Silicea</i>	2	2	0	0
<i>Sabina</i>	1	1	0	0
<i>Graphites</i>	2	1	1	0
<i>Crotalus horridus</i>	3	2	1	0
<i>Belladonna</i>	1	1	0	0
<i>Amyl nit.</i>	1	1	0	0
<i>Merc. sol.</i>	1	1	0	0
<i>Glonoina</i>	1	1	0	0
<i>Causticum</i>	1	0	1	0
<i>Nux vom.</i>	1	1	0	0
<i>Mag. carb.</i>	1	1	0	0
<i>Zinc. met.</i>	1	0	1	0
<i>Psorinum</i>	4	4	0	0
<i>China</i>	1	1	0	0
<i>Nitric acid</i>	2	2	0	0
<i>Syphillinum</i>	2	0	2	0
<i>Coccus</i>	1	1	0	0
<i>Total</i>	223	151	55	17

TABLE 2. COMPARISON OF THE SYMPTOM SCORE AT BASELINE AND AT END BY USING WILCOXON SIGNED RANK TEST

Symptoms	Symptom present in no. of cases before treatment (%)	No. of cases after treatment (%)	Mean score at baseline (SD) (n)	Mean score at end (SD) (n)	Z- value*	p-Value*
Hot flashes	205 (91.93%)	54 (24.22%)	1.90 (0.84) (n=205)	1.24 (0.47) (n=54)	12.13	0.0001
Night sweats	189 (84.75%)	46 (20.63%)	1.89 (0.84) (n=189)	1.15 (0.42) (n=46)	11.66	0.0001
Anxiety	195 (87.44%)	45 (20.18%)	1.79 (0.78) (n=195)	1.22 (0.42) (n=45)	11.90	0.0001
Depression	162 (72.65%)	35 (15.70%)	1.66 (0.78) (n=162)	1.17 (0.45) (n=35)	10.02	0.0001
Palpitation	152 (68.16%)	26 (11.66%)	1.31 (0.46) (n=152)	1.04 (0.20) (n=26)	10.84	0.0001
Pruritis vulvae	88 (39.46%)	14 (6.28%)	1.20 (0.41) (n=88)	1.00 (0.00) (n=14)	8.28	0.0001
Dysuria	70 (31.39%)	10 (4.48%)	1.16 (0.37) (n=70)	1.30 (0.48) (n=10)	7.39	0.0001
Sexual desire (change from previous)	117 (52.47%)	72 (32.29%)	1.56 (0.50) (n=117)	1.46 (0.50) (n=72)	6.43	0.0001
Poor memory	180 (80.72%)	119 (53.36%)	1.40 (0.49) (n=180)	1.18 (0.38) (n=119)	9.21	0.0001
Stress incontinence	119 (53.36%)	51 (22.87%)	1.30 (0.46) (n=119)	1.06 (0.24) (n=51)	8.57	0.0001
Dyspareunia	52 (23.32%)	19 (8.52%)	1.19 (0.40) (n=52)	1.11 (0.32) (n=19)	5.51	0.0001
Vaginal dryness	55 (24.66%)	13 (5.83%)	1.13 (0.34) (n=55)	1.08 (0.28) (n=13)	6.33	0.0001
Discharge per vagina	94 (42.15%)	13 (5.83%)	1.32 (0.47) (n=94)	1.15 (0.38) (n=13)	8.44	0.0001
Insomnia	152 (68.16%)	44 (19.73%)	1.30 (0.46) (n=152)	1.09 (0.29) (n=44)	10.51	0.0001
Work & activities affected	185 (82.96%)	60 (26.91%)	1.92 (0.88) (n=185)	1.23 (0.46) (n=60)	11.55	0.0001
Total score	223 (100.00%)	223 (100.00%)	14.1 (4.79) (n=223)	303 (2.92) (n=223)	12.96	0.0001

* $p < 0.05$ is considered significant.

SD, standard deviation.

The level of FSH was reduced in 98 of 175 patients, which was not statistically significant ($p=0.86$). Statistically significant results were seen in serum levels of cholesterol ($p=0.033$), triglycerides ($p=0.022$), and very low density lipoprotein (VLDL) ($p=0.006$). However, HDL and LDL values did not show statistically significant results. The degree of improvement in 223 patients was as follows: *marked* = 151, *moderate* = 55, and *mild* = 17.

The medicines found indicated were *Sepia*, *Lachesis*, *Sulphur*, *Pulsatilla*, *Nat.mur.*, *Lycopodium*, *Calc. carb.*, *Arsenic alb.*, *Phosphorus*, *Ferrum met.*, *Kali carb.*, *Silicea*, *Sabina*, *Graphites*, *Crotalus hor.*, *Belladonna*, *Amyl nit.*, *Merc. sol.*, *Glonoina*, *Castricum*, *Nux. vom.*, *Mag. carb.*, *Zinc. met.*, *Psorinum*, *China*, *Nitric acid*, *Syphillinum*, and *Coccus*.

Besides the objectives, it was found that cervicitis, cervical erosion, cervical polyp, cystocele and rectocele also improved in 37 patients after treatment.

The value of Cohen's d and the effect size correlation, r_{YX} , worked out to be: Cohen's $d=2.7226193$ and effect size $r=0.8059230$ ($r=0.8059230$, which suggested a large effect size of the study).

Discussion

The mean menopausal age of the sample population was 46.66 years. This corroborates with the results of a demographic study conducted on the onset of menopause on 129 women in the Haridwar district of Uttarakhand, India, in which it was found to be 46.82 years.²²

The DDCYSS was useful in quantifying the individual symptoms and the total distress. It was easy to fill out and quick to assess.

Homeopathic treatment was found to be effective in HF,^{13–15} vasomotor symptoms, emotional/psychologic symptoms, and fatigue.¹⁶

It was observed that the medicines found frequently indicated and useful were *Sepia*, *Lachesis*, *Sulphur*, *Pulsatilla*, *Nat.mur.* and *Lycopodium*.¹⁵

Sepia, *Sulphur*, *Lachesis*, and *Pulsatilla* have been successfully used by homeopathic practitioners for the treatment of menopausal distress symptoms.^{23–25}

Amyl nit., *Graphites*, *Psorinum*, *Lachesis*, *Sepia*, and *Sulphur* are also mentioned as first-grade medicines under the rubric "menopause" in the Synthesis Repertory.²⁶

Influence on serum levels of FSH, HDL, and LDL was not significant, but serum levels of cholesterol, triglycerides, and VLDL decreased significantly.

The effect size of the study was also found to be large.

Apart from the primary objective, it was found that cervicitis, cervical erosion, cervical polyp, cystocele, and rectocele were also improved. This is again a reconfirmation of the holistic tenet of homeopathy where a holistically selected *simillimum* not only relieves the primary complaint of the patient but at the same time takes care of other problems as well.

In the present-day scenario with the HRT scare, women are looking forward to safer and effective treatment options. This study reconfirms the scope of homeopathy for effective management of menopausal complaints.

Conclusions

The results of the study imply that homeopathic medicines prescribed on the basis of totality of symptoms act holisti-

cally in relieving symptoms of menopause. Further RCTs can be conducted to validate these results.

Acknowledgments

We thank consultant gynecologists Dr. Sonia Kaushal, RRI(H), Shimla; Dr. Kiran Singh, CRU(H), Ranchi; Dr. Renu Awane, CRI(H), Noida; Dr. Susheela, CRU(H), Chennai; Dr. Jayanti, CRI(H), Kottayam; and Dr. Shankar Devi, CRU(H), Puducherry for their guidance and monitoring of study throughout. We also thank Dr. Paromita Goswami, Senior Research Fellow (H), CCRH, for her help in compiling the data. We thank Dr. D. Sahu, Scientist D, National Institute of Medical Statistics, ICMR and Mr. Arvind Kumar, Statistical Assistant, CCRH, for analyzing the data statistically. We thank all Programme Officers of the study at different institutes and units for their administrative help.

Disclosure Statement

No competing financial interests exist.

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