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A Comparative Study of *Sepia Officinalis* and *Lachesis MUTUS* in the Management of Menopausal Syndrome: A Prospective Observational Study Protocol

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ABSTRACT

Menopausal syndrome is a cluster of vasomotor, psychological, urogenital, sexual and musculoskeletal complaints that appear as ovarian function declines, and it can substantially lower a woman's quality of life during mid-life. Hormone-based treatment is not suitable or acceptable for every woman, and many seek complementary options, including homoeopathy. *Sepia officinalis* and *Lachesis mutus* are two of the medicines most often considered in the homoeopathic literature for climacteric complaints, yet no structured clinical comparison of the two is available. This article presents the protocol of a prospective, observational, comparative clinical study designed to measure and compare the response of menopausal syndrome to individualised *Sepia officinalis* and *Lachesis mutus*. Sixty women aged 40–55 years attending the outpatient and inpatient departments and peripheral centres of the host institution will be enrolled by purposive sampling over twelve months. Case-taking will follow Aphorisms 83–104 of the Organon of Medicine, and the remedy will be chosen on the totality of symptoms. Symptom severity will be recorded with the Menopause Rating Scale (MRS) before treatment and at follow-up, and pre- and post-treatment scores will be examined with descriptive statistics and t-tests. The study aims to generate preliminary, clinic-based evidence on the relative usefulness of the two medicines and to support the design of larger controlled trials.

Keywords: Menopausal syndrome, Climacteric, *Sepia officinalis*, *Lachesis mutus*, Menopause Rating Scale, Homoeopathy

INTRODUCTION

Menopause is the permanent end of menstruation resulting from the loss of ovarian follicular activity. It is identified retrospectively, once a woman has had no menstrual bleeding for twelve consecutive months in the absence of any other pathological or physiological cause [1,2]. The span in which a woman moves from reproductive to non-reproductive life is called the climacteric and extends for roughly five to ten years on each side of the final menstrual period; the portion of it marked by irregular cycles is termed the perimenopause [1,2]. Natural menopause generally occurs between 45 and 55 years of age, with a mean near 50 years, and its timing appears to be largely determined by genetic factors, although smoking and severe undernutrition have been linked to an earlier onset [1,2].

The underlying change is progressive ovarian failure. Corpus luteum function falters first, so progesterone secretion falls and cycles become anovulatory and irregular. Follicular development then fails, oestrogen and inhibin levels drop, and the pituitary responds with a rebound rise in follicle-stimulating hormone (FSH) and luteinising hormone (LH) [1,2]. The consequences are wide-ranging. In the short term women report irregular bleeding, hot flushes, night sweats, sleep disturbance, anxiety, irritability and low mood. Over the medium term, urogenital atrophy and skin changes emerge, and in the long term the loss of oestrogen contributes to osteoporosis, cardiovascular disease and cognitive decline [1,3]. Because life expectancy has risen, a woman may now spend a third or more of her life in the post-menopausal state, which makes the management of symptoms and long-term health a substantial public health concern.

Conventional management centres on hormone therapy, but this is not appropriate for every woman, and concerns about adverse effects lead many to look for alternatives. Homoeopathy, founded on the principle of *similia similibus curentur*, treats the person as a whole and takes mental, emotional and physical features into account together. This approach is attractive in menopausal syndrome, where psychological and somatic complaints are closely entwined. A number of medicines are described in homoeopathic materia medica for this phase of life, including *Sepia officinalis*, *Lachesis mutus*, Graphites, *Natrum muriaticum*, *Calcarea carbonica*, *Ignatia*, *Silicea* and *Sulphur* [4–6]. Of these, *Sepia* and *Lachesis* are the two that are cited most frequently in connection with climacteric flushes and related complaints, but they present quite different constitutional pictures. Whether one performs better than the other in a defined clinical population has not been systematically examined. The present study has been designed to address this gap.

RESEARCH QUESTION, AIM AND OBJECTIVES

- ❖ **Research question:** Are *Sepia officinalis* and *Lachesis mutus* effective in the treatment of menopausal syndrome, and does either perform better than the other?
- ❖ **Aim:** To compare the effectiveness of *Lachesis mutus* and *Sepia officinalis* in the treatment of menopausal syndrome.
- ❖ **Objectives:**
 - To assess the effectiveness of *Lachesis mutus* in menopausal syndrome.
 - To assess the effectiveness of *Sepia officinalis* in menopausal syndrome.
 - To compare the effectiveness of the two medicines.

HYPOTHESES

- ❖ **Null hypotheses (H0):** (a) Neither *Lachesis mutus* nor *Sepia officinalis* is effective in menopausal syndrome; (b) *Lachesis mutus* is not effective; (c) *Sepia officinalis* is not effective.
- ❖ **Alternative hypotheses (H1):** (a) *Lachesis mutus* and *Sepia officinalis* are effective in menopausal syndrome; (b) *Lachesis mutus* is more effective than *Sepia officinalis*; (c) *Sepia officinalis* is more effective than *Lachesis mutus*.

MATERIALS AND METHODS

Study design and setting: This is a prospective, observational, comparative clinical study. Participants will be recruited from the outpatient and inpatient departments of S. S. Agrawal Homoeopathic Medical College and General Hospital, Navsari, and from its peripheral centres.

Duration, sample size and sampling: The study will run for twelve months, with data collection planned for months 1–8, a buffer for completion of follow-up in month 9, and analysis in months 9–12. Sixty cases will be enrolled using purposive sampling.

Eligibility criteria:

- **Inclusion criteria**
 - Women aged 40–55 years.
 - Menopausal syndrome diagnosed on clinical presentation, including women who are newly presenting and those who have used other systems of medicine without satisfactory relief or who have had recurrence, and who now seek homoeopathic care.
- **Exclusion criteria**
 - Associated malignancy or other advanced pathology.
 - Surgical menopause following panhysterectomy.
 - Psychiatric illness.
 - Current use of oestrogen- or progestin-containing medication.
- ❖ **Diagnostic considerations:** Menopause is confirmed clinically by amenorrhoea of twelve consecutive months. Supportive features include hot flushes and night sweats, a vaginal maturation index suggestive of low oestrogen, serum oestradiol below about 20 pg/mL, and raised FSH and LH (above 40 mIU/mL) on repeated measurement [1,2]. In keeping with the clinical orientation of the study, diagnosis will primarily rest on the clinical picture.
- ❖ **Case-taking and remedy selection:** A detailed case record will be taken in the institutional case proforma, covering presenting and associated complaints, personal, menstrual, past and family history, physical and systemic examination, mental and physical generals, thermal state and miasmatic background. Case-taking will follow Aphorisms 83–104 of the *Organon of Medicine* [7]. Symptoms will be analysed and evaluated to form the totality, and the similimum will be selected from either *Sepia officinalis* or *Lachesis mutus* on the strength of that totality, with attention to susceptibility and the potency and repetition required. Participants will be allocated to the *Sepia* or *Lachesis* group according to the remedy indicated, not by randomization.
- ❖ **Outcome measurement:** The primary outcome is the change in the severity of menopausal symptoms. This will be measured with the Menopause Rating Scale (MRS), a standardized, self-administered instrument developed to rate the severity of ageing-related symptoms and their effect on health-related quality of life [8,9]. The scale lists eleven items: hot flushes and sweating, heart discomfort, sleep problems,

depressive mood, irritability, anxiety, physical and mental exhaustion, sexual problems, bladder problems, vaginal dryness, and joint and muscular discomfort. Each is scored from 0 (none) to 4 (extremely severe), giving a total of 0–44. Scores will be recorded at baseline and at follow-up visits, and severity will be graded before and after treatment using the bands specified in the approved protocol (0–10 mild, 11–21 moderate, 22–44 severe).

- ❖ **Statistical analysis:** Only participants who satisfy the protocol criteria will be analyzed. Demographic and clinical characteristics will be summarised descriptively and expressed as percentages and means. Pre- and post-treatment MRS scores within each group will be compared with the paired t-test, and the change in score between the Sepia and Lachesis groups will be compared with the independent-samples t-test. A p-value below 0.05 will be considered statistically significant.
- ❖ **Ethical considerations:** The protocol is submitted to the Institutional Ethics Committee of the host college for approval. Written informed consent, in English or Gujarati, will be obtained from every participant after the nature and purpose of the study have been explained in her own language. Participation is voluntary, no financial compensation is offered, records will be kept confidential, and a participant may withdraw at any point without giving a reason. Any suspected adverse reaction will be documented on the institutional pharmacovigilance reporting form.

CLINICAL PROFILES OF THE STUDY MEDICINES

- The following summary is drawn from standard materia medica sources [4–6,10] and is intended to show why these two medicines were chosen for comparison.
- ❖ **Sepia officinalis:** Sepia is prepared from the ink of the cuttlefish. The classical description fits tall, slim, dark-haired women with relaxed tissues. Emotionally she is irritable, easily offended and indifferent toward the family she loves best, tearful when relating her symptoms, sad about her health and household matters, and averse to consolation, though she dislikes being left entirely alone. She is markedly chilly. Aggravation is noted in the forenoon and evening, in cold air and before thunderstorms, and relief with exercise, warmth and pressure. In the female sphere the picture includes flushes of heat that rise from the pelvis and are accompanied by faintness and sweating, a bearing-down sensation as if the pelvic contents would escape, vaginal dryness with painful intercourse, aversion to coition, and irregular or scanty menses.

Lachesis mutus: Lachesis is prepared from the venom of the bushmaster. It is traditionally suited to thin, emaciated women around and after the climacteric. Mentally the picture is of great talkativeness with rapid shifts of subject, suspicion, jealousy, alternation of elevated and low moods, and complaints following prolonged grief or disappointed love. The patient is hot-blooded, with marked thirst, and is worse after sleep, on the left side, from tight clothing or constriction, and from hot drinks. Climacteric complaints include flushes of heat, palpitation, vertex headache, fainting spells and a tendency to haemorrhage, and complaints are relieved when a discharge appears.

Rationale for the comparison: The thermal state, the temperament, the nature of the flushes and the modalities differ sharply between the two medicines, so they are natural candidates for a head-to-head clinical comparison. A comparative design allows the clinical picture associated with each medicine to be examined alongside its measured response.

EXPECTED OUTCOMES AND SIGNIFICANCE

The study is expected to show whether individualised prescribing of *Sepia officinalis* and *Lachesis mutus* is accompanied by a measurable fall in MRS scores, and whether the magnitude of change differs between them. Such information can assist clinicians in refining their prescribing in menopausal practice and provide a basis for future randomised, controlled trials with larger samples.

LIMITATIONS

The design carries several limitations that should be acknowledged. Allocation follows the remedy indicated, so the groups may differ at baseline; there is no placebo or untreated control, so improvement cannot be attributed to the medicine alone because natural fluctuation, expectation and the consultation effect may contribute; the sample of sixty drawn by purposive sampling limits generalizability and the MRS is a subjective, self-reported instrument. These points should be borne in mind when the results are interpreted.

CONCLUSION

Menopausal syndrome is common and often disabling, and women need treatment options that are safe and acceptable to them. *Sepia officinalis* and *Lachesis mutus* are two homeopathic medicines with long-standing use in this setting, but comparative clinical data are lacking. This protocol describes a structured, prospective study that applies standardised case-taking and a validated symptom scale to compare their outcomes. Its findings will be reported on completion of the study.

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