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Individualised Homoeopathic Treatment in Pain Management of Dysmenorrhea in Females Aged 15–30 Years: A Prospective Case Series Study

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ABSTRACT

Background: Dysmenorrhea is one of the commonest gynecological complaints of young women and a frequent cause of pain, absenteeism and reduced daily functioning. Conventional analgesics do not suit or relieve every woman, and evidence for individualised homoeopathic treatment is limited and inconsistent.

Objectives: To describe the change in menstrual pain after individualised homoeopathic treatment in women aged 15–30 years with dysmenorrhea, and to identify the commonly prescribed medicines.

Methods: A prospective, single-arm case series was conducted over 18 months. Thirty women with primary or secondary dysmenorrhea and moderate-to-severe pain (VAS 4–9 on a 10 cm scale) gave written informed consent. Individualised prescriptions were based on detailed case-taking, repertorisation and Homoeopathic Materia Medica. Pre- and post-treatment Visual Analogue Scale (VAS) scores were compared with a paired t-test, with a Wilcoxon signed-rank test as a sensitivity analysis.

Results: The mean age was 21.3 years; 23 women (76.7%) had primary and 7 (23.3%) secondary dysmenorrhea. The mean VAS fell from 8.20 (SD 0.81) to 3.07 (SD 1.51), a mean reduction of 5.13 points (95% CI 4.51 to 5.76; $t = 16.78$; $p < 0.001$). Twenty-eight women (93.3%) were judged improved, and 22 (73.3%) had only mild pain at final follow-up. The two women who did not improve both had secondary dysmenorrhea associated with polycystic ovarian disease. Natrum muriaticum (16.7%), Pulsatilla (13.3%) and Calcarea carbonica (10.0%) were the most frequently prescribed medicines.

Conclusion: Pain scores fell markedly after individualised homoeopathic treatment. Because the study had no comparison group and no blinding, the findings describe outcomes in practice and do not show that the treatment caused the improvement; they support a registered, controlled trial.

Keywords: Dysmenorrhea, Homoeopathy, Visual Analogue Scale, Individualisation, Natrum muriaticum.

Introduction

Dysmenorrhea, or painful menstruation, is among the commonest gynecological complaints of young women, and published prevalence figures vary widely with the population studied and the way pain is defined. (1)(2) It is conventionally divided into primary dysmenorrhea, in which no pelvic disease can be found, and secondary dysmenorrhea, which arises from an identifiable condition such as endometriosis. (3)(5) In primary dysmenorrhea, increased prostaglandin release is thought to provoke forceful uterine contractions and reduced uterine blood flow, producing the typical cramping pain. (1)(4)

The consequences reach beyond the pain itself. Studies in schoolgirls and university students link dysmenorrhea to missed classes, poorer concentration and lost work time, (6)(7) and an association between menstrual pain in adolescence and mental health in adolescence and early adulthood has been reported. (8) For many women the emotional experience of the pain is difficult to separate from its intensity.

Non-steroidal anti-inflammatory drugs and hormonal contraceptives are the usual first-line treatments. (3)(4) They help many women, but not everyone responds, tolerates them or wishes to use them, so other approaches continue to attract interest.

Homoeopathy is widely used in India for menstrual complaints. The practitioner chooses a medicine for each woman according to the whole pattern of her physical, mental and general symptoms rather than the diagnostic label alone. Trial evidence for this approach in dysmenorrhea is limited and not uniform. A placebo-controlled trial in students in Iran found no significant difference between homoeopathy and placebo; (9) a double-blind, placebo-controlled trial in West Bengal favoured individualised medicines; (10) and an open-label randomised trial comparing individualised homoeopathy with conventional treatment reported reduced pain intensity and improved quality of life in the homoeopathy group. (11)

Rationale of study

Dysmenorrhea is common, disrupts school, work and social life, and has no universally satisfactory treatment. Information from routine homoeopathic practice, including which medicines are chosen and how emotional factors relate to the pain, remains scarce. This study therefore followed women aged 15–30 years with dysmenorrhea who were treated with individualised homoeopathy, in order to describe the change in pain intensity, to record the medicines most often indicated, and to note the psychosomatic factors that emerged during case-taking.

Material & Methods

Study design and Study settings

This prospective, single-arm case series was conducted over a period of 18 months in the outpatient and inpatient departments of the college hospital, in medical camps conducted by the college, and in its peripheral OPDs. Thirty women aged 15–30 years with primary or secondary dysmenorrhea were enrolled. Women with moderate-to-severe pain (VAS 4–9 on a 10 cm scale) who provided written informed consent were included. Women with severe pathological gynecological conditions such as cervical cancer, women who were using or had used an intrauterine device, women taking oral contraceptives or hormonal supplements, and women with a psychiatric or neurological disorder such as premenstrual dysphoric disorder were excluded. Women with irregular follow-up or who discontinued the medicine were to be withdrawn. Primary dysmenorrhea was diagnosed clinically in the absence of pelvic pathology, and secondary dysmenorrhea when an underlying condition was identified, with investigations ordered only when clinically needed. There was no comparison group.

Ethical clearance

Ethical clearance for the study was obtained from the Ethical Committee of Motiwala Homoeopathic Medical College and Hospital, Nashik before starting the study. Informed consent was obtained from each patient to participate in the study, and confidentiality was maintained throughout.

Outcome assessment and Data analysis

Data were collected using a structured Case Record Format and the Visual Analogue Scale (VAS), with the aid of repertories, homoeopathic software and the Homoeopathic Materia Medica for remedy selection. (12)(13)(14)(15)(16) Each case was analysed on the basis of the totality of symptoms, and an individualised medicine was prescribed in the 200 potency the medicine was repeated or changed according to the response at follow-up. Follow-up was taken 24 hours after the first dose, on the 7th day, at subsequent menstrual cycles, and otherwise as the case required.

Pain was measured on a 10 cm VAS anchored at 0 (no pain) and 10 (worst imaginable pain), (17) and grouped as mild (1–3), moderate (4–6) or severe (7–10). The post-treatment score was the VAS at the final follow-up visit Improvement was defined as relief of signs and symptoms as judged by the treating physician; lack of improvement was recorded when there was no relief and no change in or an increase in the VAS score. Psychosomatic factors such as anger, stress, sadness and grief identified during case-taking were recorded descriptively; no validated mood or quality-of-life instrument was used.

Statistical analysis

Continuous data are summarised as mean (standard deviation) or median (interquartile range), and categorical data as number (percentage). Pre- and post-treatment VAS scores were compared with a paired t-test (29 degrees of freedom), and the mean difference is reported with its 95% confidence interval. Because VAS scores are ordinal, a Wilcoxon signed-rank test was added as a sensitivity analysis, and the standardised effect size is reported as Cohen's *d*_z (mean difference divided by the standard deviation of the differences). Two-sided *p* < 0.05 was taken as significant.

Statistical results

The mean pre-treatment VAS score was 8.20 (SD 0.81; median 8, IQR 8–9), which reduced to 3.07 (SD 1.51; median 3, IQR 2–3.75) after treatment, yielding a mean difference of 5.13 ± 1.68 (95% CI 4.51 to 5.76). The calculated t-value was 16.78 with 29 degrees of freedom, corresponding to a p-value of <0.001 , and the standardised effect size was very large ($d_z = 3.06$). The Wilcoxon signed-rank test gave the same conclusion ($p < 0.001$). The pain scores of all 30 women are listed in Fig 6. This result shows a statistically significant fall in pain scores after treatment; as the study has no control group, it cannot by itself show that the fall was caused by the treatment.

Observation and Results

A total of 30 women was enrolled, and all 30 had pre- and post-treatment VAS scores and were included in the analysis. Ages ranged from 18 to 27 years (mean 21.3, SD 2.4). The majority belonged to the 16–20-year age group (14 women, 46.67%), followed by 13 women (43.33%) in the 21–25-year group and 3 women (10%) in the 26–30-year group.

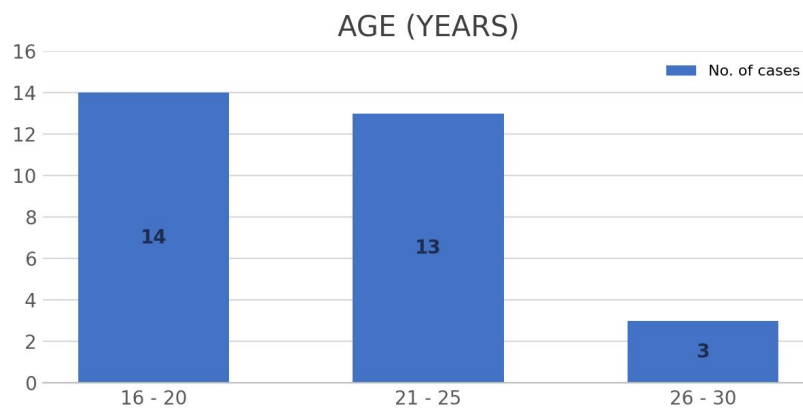


Fig 1. AGE WISE DISTRIBUTION

Twenty-three women (76.67%) had primary dysmenorrhea and seven (23.33%) had secondary dysmenorrhea. Among the secondary cases, six were associated with polycystic ovarian disease and one with an ovarian cyst.

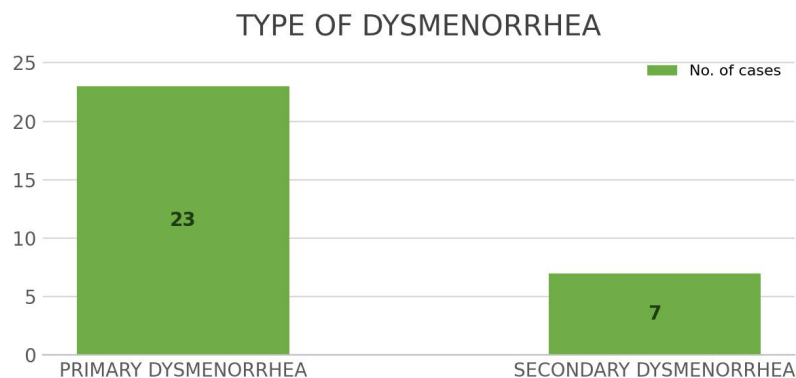


Fig 2. DISTRIBUTION ACCORDING TO TYPE OF DYSMENORRHEA

Regarding prescription trends, sixteen different medicines were prescribed. Natrum muriaticum emerged as the most frequently indicated remedy (5 women, 16.67%), followed by Pulsatilla (4 women, 13.33%) and Calcarea carbonica (3 women, 10%). Phosphorus, Sepia, Silicea, Lachesis and Nuxvomica were each prescribed in two women, and Ignatia, Chamomilla, Alumina, Cimicifuga, Natrum carbonicum, Sulphur, Cocculus indicus and Zincum metallicum in one woman each, reflecting the individualised nature of homoeopathic prescribing.

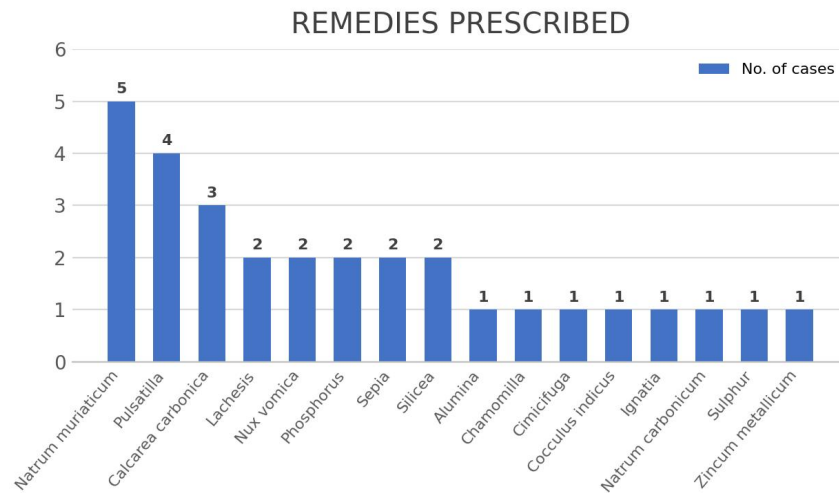


Fig 3. REMEDIES PRESCRIBED

Clinical outcomes revealed that 28 women (93.3%) were judged improved, while 2 women (6.7%) did not improve. Every woman classed as improved had a VAS reduction of at least 3 points, whereas the two who did not improve had reductions of 0 and 2 points. Twenty-six women (86.7%) had a reduction of 50% or more. Both women who did not improve had secondary dysmenorrhea associated with polycystic ovarian disease and had also received supportive medicine; in each, the medicine was changed at follow-up without benefit. All 23 women with primary dysmenorrhea improved, compared with 5 of the 7 women with secondary dysmenorrhea.

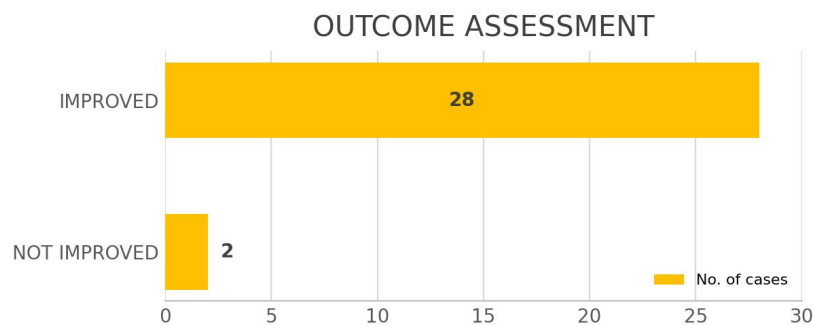


Fig 4. DISTRIBUTION OF OUTCOME ASSESSMENT

At baseline every woman was in the severe category (VAS 7–10). After treatment, 22 women (73.3%) were in the mild category (VAS 1–3), 7 (23.3%) in the moderate category (VAS 4–6) and 1 (3.3%) remained severe. Two women recorded a baseline score of 10, one point above the upper limit of 9 set in the protocol; they were kept in the analysis.

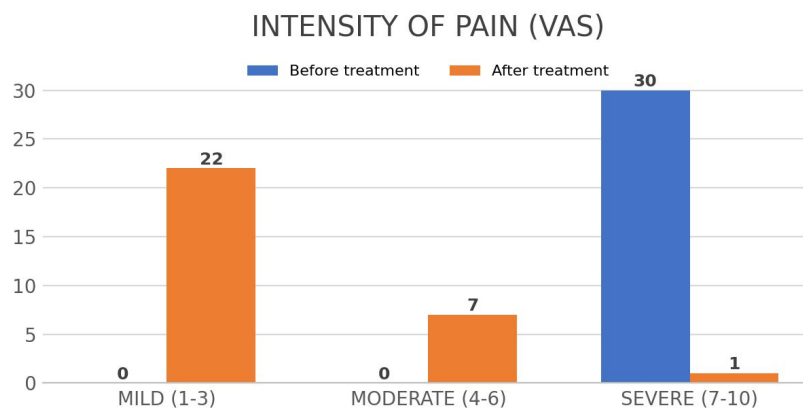


Fig 5. INTENSITY OF PAIN BEFORE AND AFTER TREATMENT

The VAS scores of each woman before and after treatment are shown below. In 28 women the score fell by at least 3 points, whereas two women (cases 29 and 30) showed little or no change.

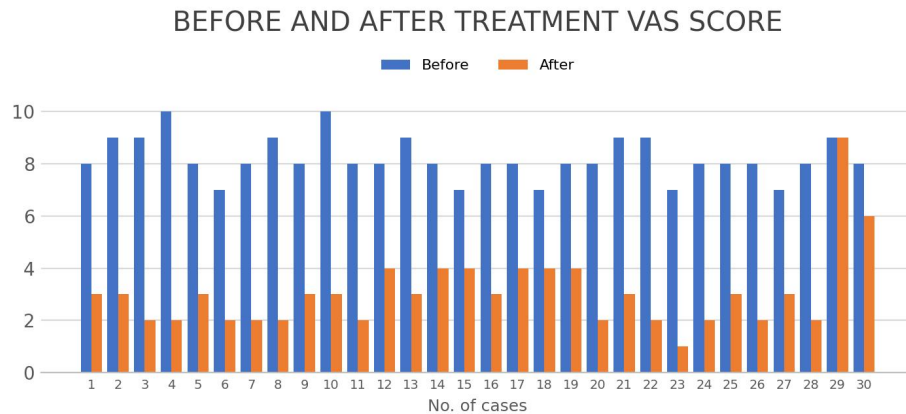


Fig 6. BEFORE AND AFTER TREATMENT VAS SCORE OF INDIVIDUAL CASES

Detailed case-taking frequently brought out anger, stress, sadness or grief as emotional factors accompanying or preceding the menstrual pain, and these features helped to individualise the prescription in many cases. Several women also described feeling calmer and less irritable as their pain eased. These observations were not measured with a validated instrument and are reported as clinical impressions only.

Discussion

Thirty women with moderate-to-severe dysmenorrhea, most of them aged 16–25 years, were followed after individualised homeopathic treatment. Many presented with spasmodic, cramping lower abdominal pain with accompanying complaints such as nausea, back and thigh pain, headache, leucorrhoea and bowel disturbance, and the medicines were chosen after detailed case-taking, analysis and repertorisation. The mean VAS fell by about five points, nearly all women improved, and almost three-quarters reported only mild pain at their final visit. Both women who did not improve had secondary dysmenorrhea associated with polycystic ovarian disease, whereas every woman with primary dysmenorrhea improved. The numbers are too small to conclude that secondary dysmenorrhea responds less well, but the pattern deserves testing in larger samples, since an underlying hormonal or structural condition may need its own assessment and management; the relationship between polycystic ovary syndrome and dysmenorrhea has itself been examined in case-control studies. (20)

The most frequently prescribed medicines, *Natrum muriaticum* and *Pulsatilla*, were also the two most common in the double-blind, placebo-controlled trial from West Bengal, (10) which suggests that clinicians in similar settings draw on a comparable group of remedies for dysmenorrhea. The direction of our pain reduction also agrees with an open-label trial of individualised homeopathy against conventional care. (11) Those trials, however, had comparison groups, and the wider evidence is mixed: in the placebo-controlled trial in Iranian students, pain improved in the homeopathy group relative to baseline, but the difference from placebo was not significant. (9) A pragmatic equivalence trial has also compared individualised treatment with a single biochemic medicine. (18) Taken together, these studies show why before-and-after improvement alone cannot be read as evidence of efficacy.

Several features of the design could have produced or exaggerated the observed fall in pain. Women were enrolled when their pain was moderate to severe, that is, near the top of their usual range, and later scores in a condition that fluctuates between cycles tend to be lower even without treatment (regression to the mean); symptoms of primary dysmenorrhea may also vary over time without treatment. (19) The long, attentive consultations typical of individualised homeopathy, and the patient's own expectations, can also reduce reported pain the treating physician made the assessments, and the timing of the final VAS reading differed between women. Each of these limits the weight that can be placed on the size of the effect.

The psychosomatic observations deserve a similar caution. Emotional factors were conspicuous in the case histories, in keeping with reports linking menstrual pain and mental health, (8) and several women described feeling calmer as their pain settled. Without a validated instrument and a comparison group, however, we cannot say whether treatment changed mood, whether easing of pain improved mood, or whether both followed the natural course of the cycle.

The study has strengths: it was prospective, used a simple and widely used pain scale, (17) took place in a routine clinical setting, and reports individual-level scores for every participant, so that readers can check the analysis and plan further work from the observed variability (SD of the change 1.68 points). Its principal limitations are the small sample, the single setting, the absence of a control group and of blinding, and reliance on a subjective self-reported scale. Medicines were individualised, so no medicine-specific effect can be estimated, and the use of supportive medicines in 17 women confounds attribution. Follow-up was not standardised to a fixed time point, adverse events were not systematically recorded, analgesic consumption and quality of life were not measured, and the sample was young (mean age 21 years), so the findings may not apply to older women.

A randomised, adequately powered, placebo- or active-controlled trial is the logical next step. It should be registered in advance, specify the medicine, potency and repetition rules, fix the timing of outcome assessment, use blinded outcome assessors, and record analgesic use, adverse events and quality of life with validated tools. Primary and secondary dysmenorrhea should be analysed separately, because their causes and expected responses differ.

Conclusion

Among 30 young women with moderate-to-severe dysmenorrhea, pain scores fell substantially after individualised homeopathic treatment, and most women had only mild pain at their final visit. *Natrum muriaticum*, *Pulsatilla* and *Calcarea carbonica* were prescribed most often. Because the design had no comparison group and no blinding, these results describe outcomes in practice rather than demonstrate efficacy. They provide effect-size and feasibility data for a controlled trial.

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Conflict of Interest

There is no conflict of interest

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