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A multicentric randomized clinical trial of homoeopathic medicines in fifty millesimal potencies vis-à-vis centesimal potencies on symptomatic uterine fibroids

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ABSTRACT

Objective: The primary objective was to evaluate the effects of homoeopathic medicines in fifty millesimal (LM) potencies vis-à-vis centesimal (CH) potencies on symptomatic uterine fibroids.

Materials and Methods: A multicentric randomized clinical trial was conducted at six centers under the Central Council for Research in Homoeopathy. Patients were screened for symptomatic uterine fibroids with the preset inclusion and exclusion criteria. A consultant specialized in obstetrics and gynecology was engaged at each center to screen and follow-up the enrolled patients. Homoeopathic physicians engaged in the study were responsible for prescription and follow up for 12 months. The primary outcome was changes in symptoms of uterine fibroid on a visual analog scale (VAS) of 0–10 and findings through ultrasonography (USG) between LM and CH potencies. The secondary outcome was to assess the changes in uterine fibroid symptom quality of life questionnaire (UFSQOL). Data analysis was done as per intention to treat (ITT) analysis.

Results: Of 216 patients enrolled in the study (LM: 108 and CH: 108), 209 patients were analyzed under modified ITT (LM: 106, CH: 103). Both LM and CH potencies were equally effective in reducing the symptoms (percentage change) due to uterine fibroid on VAS scale after 1 year of treatment ($P > 0.05$). The health-related quality of life (HRQOL) and subdomains of UFSQOL also showed equal effectiveness in both the groups ($P = 0.05$). However, no difference was observed in all the USG findings except for uterine volume ($P = 0.03$). There was overall difference before and after homoeopathic treatment irrespective of assigned groups, i.e., LM or CH ($P < 0.05$) in all the above parameters. The medicines frequently prescribed were: *Pulsatilla*, *Sulphur*, *Lycopodium, Sepia, Phosphorus, Calcarea carbonica*, and *Natrum muriaticum*.

Conclusion: LM and CH potencies are equally effective in giving symptomatic relief to patients suffering from symptomatic uterine fibroids.

Keywords: CH potencies, Homoeopathy, Leiomyomata, LM potencies, Randomized clinical trial, Uterine fibroids

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INTRODUCTION

Uterine fibroids (leiomyomas) are common benign smooth muscle tumors of the uterus. They are found approximately in 25–35% women of reproductive age (30–40 years) and in nulliparous or women of low parity.[1,2] Estimating the overall prevalence of fibroids in the population is difficult as it depends on various factors however the Agency for Healthcare Research and Quality, US, documented the cumulative incidence of 70–80% by age 50.[3] In Mysore, India, Maitri[4] documented 55% of women with fibroids in the third decade of age. Fibroids can lead to a variety of symptoms including heavy periods, pain, difficulty to conceive, or problems with pregnancy such as miscarriage and premature labor. The distribution of fibroid in the body of the uterus is broadly as: Intramural or interstitial (75%), submucous (15%), and subserous (10%).[3] These symptoms and consequences have been shown to diminish the quality of life.[2,5,6]

Both surgical and radiological therapies are frequently used for the management of this tumor; medical therapies are considered the first-line treatment and the ultimate is surgery. Long-term use of these conventional therapeutics has adverse effects.[7-9] For women who wish to retain the uterus for future pregnancies, myomectomy is known but whether this improves fertility outcomes is still questionable.[10] Uterine artery embolism though has an advantage over myomectomy and hysterectomy for symptomatic uterine fibroids but is associated with a higher rate of minor complications and soon requires surgical intervention within 2–5 years of the initial procedure[11] with much costs.[12] Although the presence of myomas is almost never associated with mortality, it may cause morbidity and affect the quality of life.[13,14]

Homoeopathy is a system of medical science wherein prescription is personalized to individuals. Physicians use different scales of potencies such as centesimal (CH), fifty millesimal (LM), and decimal (X) in their practice. These scales differ in their method of preparation, i.e., potentization and succussion.[15] Hahnemann[16] in his 6th edition of Organon of medicine mentions the benefits of new method of preparation of medicines, i.e., renewed dynamization or fifty millesimal (LM) potencies in comparison to potencies in CH scale,[17] i.e., in the later scale the medicine can be repeated with increase in dynamic power of each dose. Further cure of chronic disease can be achieved more rapidly, using gradually increased doses of series of LM medicines. Homoeopathic medicines have shown positive results in treating patients suffering from fibroids. Popov's study[18] shows that homoeopathic medicines can not only control pain and abnormal endometrial bleeding but also reducing the size and stop the growth of the tumor. Iqbal *et al*.[19] in their cohort study showed positive results in terms of reduction and resolution of fibroids. Case reports[20,21] demonstrate both symptomatic relief and reduction of fibroid size with homoeopathic medicines using both (CH) and LM potencies. Adler[22] review of Hahnemann's Paris case records shows the superiority of the LM potencies in comparison with the CH dynamization and it was based on a significant number of experiments with the two potencies. Basing on above results with different scales of potencies in Homoeopathy, a randomized clinical trial was undertaken to evaluate the homoeopathic potencies LM versus CH in the management of symptomatic uterine fibroids.

MATERIALS AND METHODS

Trial Design

A multicentric randomized clinical trial was conducted on women suffering from symptomatic uterine fibroids to evaluate the effectiveness of individualized homoeopathic medicines in LM potencies vis-a-vis CH potencies. The Council's Ethical Committee approved the study protocol. Investigators experienced in dealing with this disorder were trained on the protocol. Written informed consent was received from all the patients enrolled. The study had also been registered retrospectively in clinical trial registry India, CTRI/2011/12/002211. Gynecologists and ultrasonologists were consulted during the study period for diagnosis, screening, enrollment, and follow-up assessment of the enrolled patients.

Participants

The study was conducted for a period of 2 years and 6 months (from June 2009 to November 2011) which includes follow-up period of 1-year, at six centers under the Central Council for Research in Homoeopathy: Central Research Institute (H), Kottayam, Kerala; Central Research Institute (H), Noida, Uttar Pradesh; Regional Research Institute (H), Shimla, Himachal Pradesh; Regional

Research Institute (H), Puri, Orissa; and Regional Research Institute (H), Guwahati, Assam and Clinical Research Unit (H), Chennai, Tamil Nadu. Patients meeting all of the following criteria were eligible for study participation.

The inclusion criteria were as follows: Premenopausal women (18–45 years of age), presence of any of the symptoms such as abnormal uterine bleeding (profuse menstruation or intercyclic menstruation), pelvic heaviness, pain during menstruation, pain during intercourse, and pressure symptoms such as urinary frequency, constipation, uterine fibroids confirmed by pelvic and/or transvaginal ultrasonography, if patient is taking oral contraceptive pills (OCPs) then the patient was advised to stop pills till it exhaust for the ongoing cycle, followed by re-assessment of symptoms in the next cycle enrollment, patients under hormonal replacement therapy were included in the study after a washout period of 3 months and diabetic patients with haemoglobin A1C ≤8%.

Patients with calcified fibroid, coagulation disorders, extrauterine fibroid, polyp, cervical fibroid, any fibroid causing hydronephrosis, fibroid with solid ovarian mass, haemoglobin (Hb) <7 g/dl (severe anemia), inability to comply with the study protocol, including psychiatric diseases, pregnancy, malignant condition of genitourinary tract, H/O any other malignancy, desiring immediate surgical management for uterine fibroid, desiring for childbearing in the next year, insisting to use OCPs were excluded.

Interventions

The homoeopathic medicines in LM or CH potencies were procured from a good manufacturing practices certified company. Investigators were instructed to make an in-depth interview with the patient, as per the guidelines laid down by Hahnemann in the 6th edition of Organon of medicine.[17] The women enrolled in the study were not on any other nonpharmacological intervention. Before selection of a remedy homoeopathic procedure such as analysis, evaluation, and constructing totality of symptoms with repertorization was carried out.[23] However, the final decision of selection of medicine was done after consultation with *Materia Medica*.

LM Potency

Patients randomized to the LM group received individualized homoeopathic medicine for 1 year customized to each patient which started with 0/1 potency, followed by next higher potency, serially, as per the need of the case. The investigator had trained the pharmacist and instructed the patients for the preparation and dispensing of LM potencies with precision as follows: One globule (poppy-seed size) of the desired potency was dissolved in 120 ml of distilled water, containing 2.4 ml (2% v/v) of dispensing alcohol, premixed in it, followed by ten uniformly-forceful downward strokes given against the bottom of the phial. The medicine was given once daily in the morning, on an empty stomach as long as improvement continued. Any change triggered after administration (status quo/improvement/deterioration/) led to frequent repetition/change of remedy following homoeopathic principles.

CH Potency

The dosage and repetition were decided *a priori* by a group of homoeopathic physicians experienced in their clinical practice. Each and every indicated medicine started with 30C potency, three times a day for 3 days. Each dose consisted of four medicated globules of sugar (size no. 20). If the patient reported during menstrual cycle, the indicated medicine was administered from the 5th day of menstrual cycle.[24] In the case of need of a higher potency in the second prescription the repetition schedule for 200 CH potency was one dose daily for three consecutive days; for 1M potency, one dose daily for two consecutive days and in the case of 10M potency only a single dose. If the choice of remedy was a nosode, then the prescription began with 200 CH potency instead of the 30C potency.

Outcomes

Primary outcome

The women were assessed for menstrual bleeding, dysmenorrhea, dyspareunia, and pressure symptoms (constipation, urinary frequency, and pelvic heaviness) at every menstrual cycle by the investigator which was scored on a visual analog scale 0–10, where 0 indicates no severity and 10 indicates maximum severity as described by previous researchers.[25,26] Ultrasonography (abdominal and/or transvaginal) was done at baseline, 6th and 12th month to measure the size of uterine fibroids and uterine volume. The size of fibroids was measured taking the three main diameters (D1/D2/D3) and applying the formula of the ellipsoid (D1 × D2 × D3 × 0.52).[25-27] An arithmetic mean of the sizes was used in the presence of two or more fibroids.

The UFS-QOL as devised by Spies *et al*.[6] was used at the baseline, 6th month, and at 12 months to see the effect of homoeopathic medicines on the quality of life of patients suffering from symptomatic uterine fibroids.

Hemogram which includes Hb, packed cell volume, mean cell volume, mean cell Hb (MCH), and MCH concentration, respectively, were measured at baseline and at every 3 months to assess hemogram.

Sample Size

From the previous study,[18] it has been seen that the percentage of change in the size of uterine fibroid after homoeopathic treatment is 26.8%. Considering it to be the lowest change in percentage assuming 25% change in symptoms for patients taking CH potency and a change of 20% more, i.e., 45% in patients taking LM potency with α-0.05 and power of 85%. As per the sample size table by Fleiss,[28] the sample estimated to be 120 participants in each group.

Randomization

Patients were randomized into two groups as per the random numbers were generated with the help of computer-based software available at www.randomizer.org.[29] Block randomization with a block size of two was considered for randomization to divide the patients equally in both the groups. Due to individualized nature of homoeopathic prescription blinding of the investigator was avoided. After final selection of medicine, all patients were randomized to either CH or LM group.

Statistical Methods

Reporting adhered to the consolidated standards of reporting trials and RedHOT. Statistical Package for the Social sciences (SPSS) version 20 for Windows was used for all the data analysis using modified intention to treat (mITT) principle. As the data were skewed, all test were carried out using nonparametric statistical tools. A percentage change in all symptoms due to uterine fibroid, i.e., bleeding, dysmenorrhea, dyspareunia, and pressure symptoms (constipation, urinary frequency, and pelvic heaviness) was calculated at the 6th month and 12th month and were compared. The formula used for calculation of percentage is as follows: $\frac{\text{Baseline score} - \text{Score at time point}}{\text{Baseline score}} \times 100$

Comparisons were also made for size of fibroid and UFS-QOL which were the secondary outcome of the study. $P < 0.05$ was considered as significant.

RESULTS

Participant including screening, enrollment, and dropouts is shown in Figure 1. Of 878 women screened, a total of 216 women diagnosed with uterine fibroid were enrolled. Data of seven women (two women from LM group and five women from CH group) did not complete their baseline information, so data of these women were not considered for analysis. Of 108 patients in each group, 106 women from Homoeopathic LM potency and 103 women from CH group were analyzed under mITT. The two groups were well matched for baseline characteristics [Table 1] and were comparable ($P \geq 0.05$). Thirty-six women from CH group and 35 from LM group dropped at various levels of follow-up. Their values were carried forward for analysis following last observation carry forward method. The mean age of the patients (participants) was 38.5 ± 5.2 years. The mean duration of the illness/symptoms was 2.7 ± 2.9 years and 2.3 ± 2.4 years in LM and CH potencies, respectively.

Analysis of Symptoms

The primary outcome [Table 2] was to assess the changes in symptoms due to a uterine fibroid. At the end of 6th and 12th menstrual cycle, both the scales of potencies showed equally effective in improving the symptoms (median percentage) of the patients ($P > 0.05$). Thus, there was overall treatment differences for homoeopathic therapy in all the symptoms, i.e., menstrual disturbances, dysmenorrhea, dyspareunia, pelvic heaviness, urinary frequency ($P < 0.005$) except for constipation ($P = 0.18$).

Analysis of the Uterine Fibroid Symptom Quality of Life Questionnaire

The secondary outcome was related to the assessment of uterine fibroid symptom quality of life (UFSQOL). Both the potencies were equally effective in bringing changes in eight subscale scores of UFSQOL [Table 2] i.e., at 6th month; symptom severity ($P = 0.21$), concern ($P = 0.36$), activities ($P = 0.33$), energy ($P = 0.34$), control ($P = 0.46$), self-consciousness (0.67), sexual function ($P = 0.80$), and HRQOL total ($P = 0.26$). At the 12th month, symptom severity ($P = 0.43$), concern ($P = 0.59$),

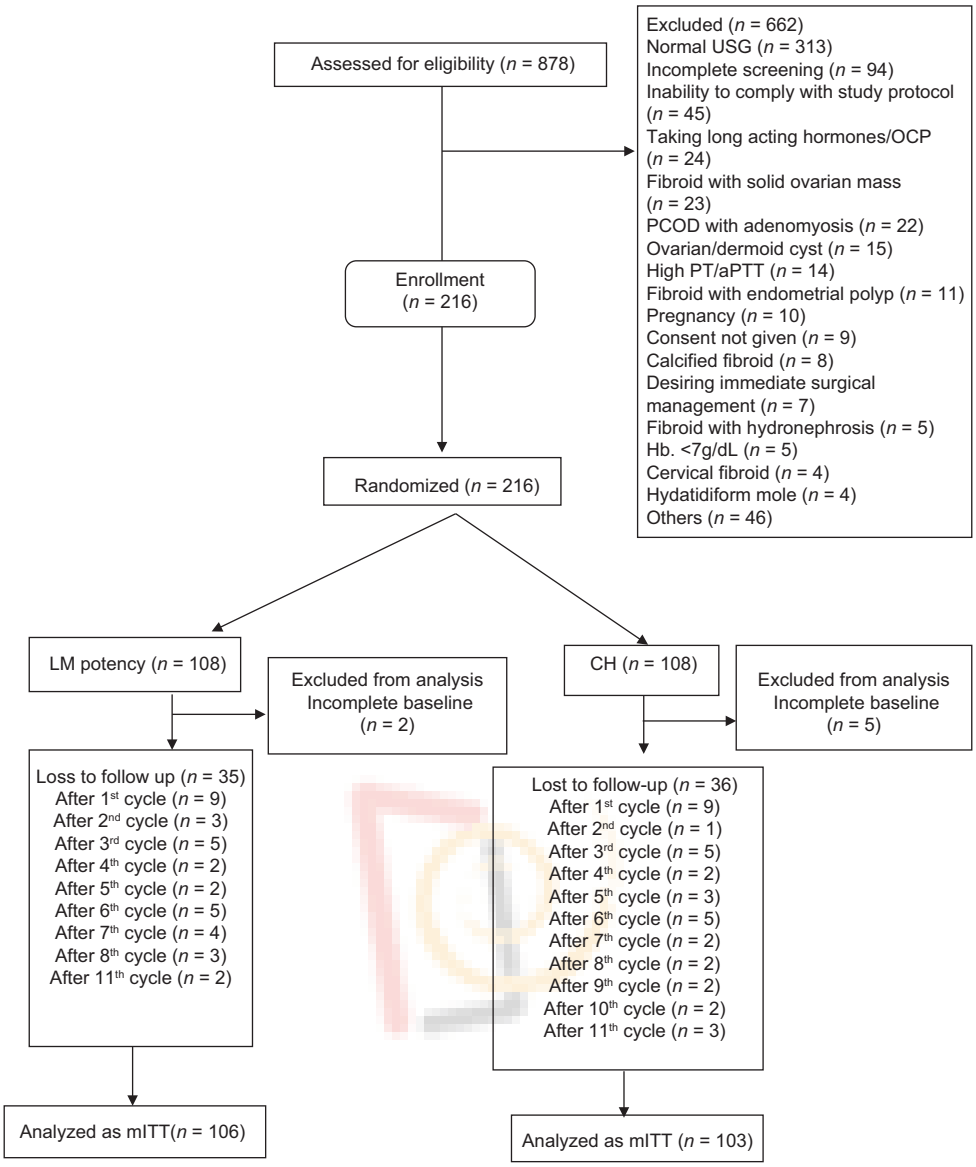

Figure 1: Participant flow diagram

activities ($P = 0.30$), energy ($P = 0.75$), control ($P = 0.19$), self-consciousness (0.88), sexual function ($P = 0.70$), and HRQOL total ($P = 0.64$), respectively. Further, over a period 12 months the symptom severity score of the UFS-QOL decreased significantly (median at 6th month 15.6%, 12th month: 21.9%, $P < 0.001$) in all the patients irrespective of the intervention group. The HRQOL scores also showed a significant increase (median at 6th month 13.8%, 12th month: 21.7%, $P < 0.001$). All other parameters such as concern, activities, energy, control, self-consciousness, and sexual function also improved.

Laboratory Parameters

There were no significant changes from baseline to 6th month and from baseline to 12th month [Table 2] in the size of fibroids, laboratory parameters ($P > 0.05$) between the groups. However, significant improvement was found in uterine volume ($P = 0.01$) Hb (0.5 ± 1.8 g/dL, $P = 0.01$) at 12th month. After 1 year of treatment, 12 fibroids diminished completely, 175 fibroids remained status quo, seven fibroids decreased in size, and 13 increase in size [Table 3]. Only five patients were referred on request due to large fibroid size.

Table 1: Baseline characteristics of women studied under modified intention-to-treat (*n*=209)

Variables	LM (*n*=106)	CH (*n*=103)	*P*
Age (years)	38.3±5.2	38.4±5.4	0.90§
Duration of symptoms (years)	2.7±2.9	2.3±2.4	0.30§
BMI (kg/m^2)	24.3±4.3	24.4±4.6	
Underweight (<18.5)	8 (7.5)	8 (7.8)	0.84§
Normal weight (18.5-24.9)	54 (50.9)	55 (53.4)	
Overweight (25-29.9)	35 (33.0)	25 (24.3)	
Obesity (30 or greater)	9 (8.5)	15 (14.6)	
Marital status			
Married	105 (99.1)	97 (94.2)	0.05€
Unmarried	1 (0.9)	6 (5.8)	
Parity			
Nulliparous	11 (10.4)	15 (14.5)	0.47€
Multiparous	85 (80.2)	81 (78.6)	
Uniparous	9 (8.5)	7 (6.8)	
Family history of fibroids	17 (16.0)	11 (10.7)	0.24€
Menses history			
Regular	95 (89.6)	95 (92.2)	0.65€
Irregular	10 (9.34)	8 (7.8)	
Recent menses (3 months)			
Regular	52 (49.1)	55 (53.4)	0.57€
Irregular	53 (50.0)	48 (46.6)	
Size fibroid uterus in terms of weeks of pregnancy			
<16	101 (95.3)	97 (94.2)	0.62€
16-20	1 (0.9)	1 (1.0)	
>20	1 (0.9)	0	
Symptoms present			
Menstrual disturbances*	102 (96.2); 6.4±2.8; 6 (4.5, 9)	102 (99.1); 6.4±2.6; 7 (5, 8)	0.99‡
Dysmenorrhea	93 (87.7); 5.2±3.2; 5 (3, 8)	90 (87.4); 5.4±3.3; 6 (2, 8)	0.63‡
Dyspareunia	50 (47.2); 2.8±3.4; 0 (0, 5.3)	53 (51.5); 3.0±3.5; 1 (0, 6)	0.52‡
Pelvic heaviness	94 (88.7); 5.0±3.0; 5.5 (2, 6)	85 (82.5); 5.1±3.3; 6 (2, 8)	0.58‡
Urinary frequency	70 (66.0); 3.3±3.1; 3 (0, 6)	65 (63.1); 3.9±3.6; 3 (0, 7)	0.32‡
Constipation	35 (33.0); 1.7±2.9; 0 (0, 3.2)	42 (40.8); 2.2±3.2; 0 (0, 5)	0.22‡
Number of fibroids			
Singular	75 (70.8)	63 (61.2)	0.25€
2-5	27 (25.5)	37 (35.9)	
>5	4 (3.8)	3 (2.9)	
Location of fibroid			
Intramural	75 (70.8)	63 (61.2)	0.36€
Submucosal	14 (13.2)	15 (14.6)	
Subserosal	8 (7.5)	10 (9.7)	
Intramural + submucosal	0	3 (2.9)	
Intramural + subserosal	9 (8.5)	11 (10.7)	
Submucosal + subserosal	0	1 (1.0)	
Size of fibroids (mL)			
IMF	56.6±185.6, 6.9 (2.2, 30.2)	42.1±89.4, 10.3 (2.5, 27.6)	0.57§
SMF	36.0±28.7, 25.3 (14.0, 61.9)	43.5±42.1, 34.1 (11.4, 50.6)	0.58§
SSF	80.4±131.3, 10.8 (5.4, 142.1)	50.3±112.0, 11.3 (6.0, 22.6)	0.60§
Uterine volume (mL)	172.7±133.2, 134 (93.5, 199.4)	199.2±293.9, 139 (98, 232.1)	0.411§

Contd...

Table 1: Contd...

Variables	LM (*n*=106)	CH (*n*=103)	*P*
UFSQOL			
Symptom severity	55.2±21.5; 56.3 (39.8, 69.5)	55.3±21.6; 51.5 (40.6, 71.9)	0.97[§]
Concern	50.3±27.8; 45 (30, 5)	49.1±39.9; 50 (30, 75)	0.79[§]
Activities	49.0±20.8; 46.4 (32.1, 50)	50.3±25.5; 50 (32, 71.4)	0.66[§]
Energy	44.8±19.9; 42.9 (32.1, 57.1)	45.2±23.1; 46.4 (25, 60.7)	0.89[§]
Control	49.2±23.7; 50 (30, 70)	50.9±26.3; 50 (30, 70)	0.63[§]
Self	56.5±26.4; 58.3 (33.3, 75)	53.3±25.3; 58.3 (33.3, 75)	0.38[§]
Sexual	51.3±30.8; 50 (25, 75)	48.3±35.8; 50 (12.5, 75)	0.51[§]
HRQL	49.6±18.8; 49.1 (36.1, 62.1)	50.8±21.5; 50 (35.3, 68.1)	0.67[§]
Hemogram			
Hb (g/dL)	11.2±1.6	11.1±1.4	0.59[§]
PCV (%)	34.6±5.2	35.5±4.6	0.19[§]
MCV (fl)	81.1±9.5	81.5±8.9	0.76[§]
MCH (pg)	25.8±4.6	25.9±4.7	0.86[§]
MCHC (g/dL)	30.6±3.1	30.3±3.1	0.59[§]

*Number is not equivalent to 106 because four women and one woman had normal menstrual bleeding in LM group and CM group, respectively; [§]Compared by using the *t*-test;[‡]Compared by using the Mann–Whitney U-test; [€]Compared by using the Chi-square test. Values are presented in *n* (%), mean±SD, and median (Q1, Q3). IMF: Intramural fibroids; SSF: Subserosal fibroids; SMF: Submucosal fibroids; TF: Total fibroids; SD: Standard deviation; Hb: Haemoglobin; PCV:Packed cell volume; MCV: Mean cell volume; MCH: Mean cell Haemoglobin; MCHC: Mean cell Haemoglobin concentration; HRQL: Health-related quality of life; UFSQOL: Uterine fibroid symptom quality of life

Homoeopathic Medicines

The commonly indicated medicines were *Pulsatilla* (*n* = 33), *Sulphur* (*n* = 23), *Lycopodium* (*n* = 22), *Sepia* (*n* = 18), *Phosphorus* (*n* = 18), *Calcarea carbonica* (*n* = 16), and *Natrum muriaticum* (*n* = 16). The details of medicines prescribed in each group are given in Table 4. The single prescription was given to 163 women while 46 women required a change of medicine [Table 5]. During the study period, no adverse events were noted.

DISCUSSION

Few case reports and observational studies[18-21] carried out with homoeopathic intervention on uterine fibroid showed beneficial effects. None of the studies has systematically evaluated the effects individualized homoeopathic treatment. This trial evaluated the effect of individualized homoeopathic intervention in uterine fibroid comparing LM and CH potencies which are commonly used in homoeopathic practice were discovered by Hahnemann. The former scale of potency is the latest which was published posthumously. There is always a dilemma which potency acts better and can be administered easily. Thus, the trial was conducted to assess between the two potencies. Further due to nature of the disease and ethical reasons, placebo group as comparator arm was not kept. Hormonal replacement therapy of modern medicine was also not kept as comparator due to the nature of action of medicine which is organ specific whereas in Homoeopathy it is holistic.

The results show no significant difference between the different potencies (LM and CH) in improving the symptoms and quality of life of women suffering from symptomatic uterine fibroids; however, the overall percentage reduction in uterine fibroid symptoms due to homoeopathic treatment was highly significant. The quality of life in both the groups improved significantly. Popov study[18] reflects 26.8% improvement in patients taking Homoeopathy in CH potency whereas in our study it is 29% thus the findings are substantiated. Further, neither the investigators nor the patients found it difficulty in preparing the medicine in LM potency. However, few patients showed their unwillingness and found difficulty to take the medicine while travelling as it was of liquid. The compliance of the patients for intake of LM medicines was good if the investigator made the patients understand it. There was no statistically significant reduction in the size of fibroid; however, homoeopathic medicines significantly reduced uterine volume ($P = 0.03$). The reduction may not be due to a decrease in myoma size but rather appeared to affect only myometrium.[30]

The medicines indicated and prescribed, i.e., *Pulsatilla., Sulphur, Lycopodium, Sepia, Phosphorus, Calcarea carbonica*, and *Natrum muriaticum* are notably

Table 2: Changes in primary and secondary outcomes at 6th and 12th month

Variable	6th cycle			12th cycle			Overall		
	LM	CH	*P*	LM	CH	*P*	6th cycle	12th cycle	*P*
Symptoms/signs (primary outcome) changes from baseline are shown percentage#									
Abnormal uterine bleeding	33.3 (0, 60)	17.2 (0, 61.7)	0.26	24.9 (0, 66.7)	29.3 (0, 77.8)	0.67	25 (0, 60)	33.3 (0, 71.4)	0.001*
Dysmenorrhea	57.1 (11.7, 100)	47.2 (0, 81.9)	0.18	63.4 (0, 100)	64.6 (0, 100)	0.51	52.8 (0, 100)	64.6 (0, 100)	0.004*
Dyspareunia	57.1 (12.5, 100)	66.7 (0, 100)	0.59	87.5 (45.8, 100)	100 (19.1, 100)	0.93	62.5 (0, 100)	93.8 (33.3, 100)	0.0001**
Pelvic heaviness	56.4 (0, 92.5)	60 (0, 91.7)	0.72	76.4 (0, 100)	70 (0, 100)	0.51	57.1 (0, 90)	71.4 (0, 100)	0.001*
Urinary frequency	53.6 (0, 100)	60 (0, 100)	0.97	100 (15, 100)	75 (0, 100)	0.35	57.1 (0, 90)	85.7 (0, 100)	0.0001**
Constipation	57.1 (0, 100)	64.6 (0, 100)	0.91	71.4 (0, 100)	64.6 (0, 100)	0.88	60 (0, 100)	66.7 (0, 100)	0.18
UFSQOL (secondary outcome, percent changes from baseline)*									
Symptom severity	18.7 (0, 34.4)	12.5 (0, 31.2)	0.21	21.9 (0, 46.9)	21.8 (0, 43.7)	0.43	15.6 (0, 33.6)	21.9 (0, 43.8)	0.0001
Concern	−15.0 (−30, 0)	−10 (−35, 0)	0.36	−16.4 (−47.5, 0)	−15 (−40, 0)	0.59	−15 (−35, 0)	−15 (−45, 0)	0.0001
Activities	−17.8 (−35.8, 0)	−10.7 (−28.6, 0)	0.33	−23 (−50, 0)	−17.9 (−40, 0)	0.30	−14.3 (−30.5, 0)	−21.4 (−46.6, 0)	0.0001
Energy	−17.8 (−33.1, 0)	−14.3 (−28.6, 0)	0.34	−28.6 (−42.3 (0)	−25 (−39.3, 0)	0.75	−14.6 (−32.1, 0)	−25 (−39.3, 0)	0.0001
Control	−10.0 (−30, 0)	−10 (−30, 0)	0.46	−20 (−45, 0)	−15 (−35, 0)	0.19	−10 (−30, 0)	−20 (−40, 0)	0.0001
Self-consciousness	−8.3 (−25, 0)	−8.3 (−25, 0)	0.67	−8.4 (−41.6, 0)	−12.4 (−35.5, 0)	0.88	−8.3 (−25, 0)	−8.4 (−39.6, 0)	0.0001
Sexual function	0 (−25, 0)	0 (−25, 0)	0.80	−6 (−50, 0)	0 (−50, 0)	0.70	0 (−25, 0)	0 (−50, 0)	0.0001
HRQOL total	−13.8 (−31.5, 0)	−13.3 (−27.5, 0)	0.26	−23.2 (−42.3, 0)	−21.1 (−39.7, 0)	0.64	−13.8 (−29.9, 0)	−21.7 (−41.3, 0)	0.0001
Others									
Ultrasonography (changes from baseline) (mL)									
IMF	0.2 (−0.7, 186.3)	0 (−2.3, 62.8)	0.08	0 (−2.6, 2.6)	0 (−6.1, 0.4)	0.31	0.0 (−0.8, 5.3)	0.0 (−2.6, 3.3)	0.21
SMF	0 (0.5, 19.1)	0 (−18.5, 4.6)	0.60	0 (−6.0, 4.3)	0 (−18.5, 3.7)	0.27	0.0 (0.0, 24.3)	0.0 (0.0, 15.8)	0.70
SSF	−3.8 (−22.6, 0)	0 (−0.9, 0)	0.59	0 (−119.9, 8.0)	0 (−3.6, 0)	0.22	4.2 (0.0, 12.5)	1.4 (0.0, 12.0)	0.41
Uterine volume	0 (−19.1, 31.2)	0 (−15.1, 19.0)	0.63	0 (−2.8, 26.7)	0 (−29.1, 30.1)	0.85	0.0 (−2.2, 32.5)	0.0 (−18.1, 22.6)	0.03
Hemogram									
Hb (g/dL)	−0.2±1.1	−0.4±1.3	0.39	−0.3±1.4	−0.8±2.2	0.93	−0.3±1.2	−0.5±1.8	0.01
PCV (%)	0.9±3.4	1.0±4.7	0.02	0.5±4.3	0.3±4.5	0.15	0.1±4.0	0.4±4.3	0.03
MCV (fl)	0.3±4.8	0.9±5.6	0.82	0.4±6.6	0.3±6.1	0.88	0.6±5.2	0.4±6.3	0.50
MCH (pg)	−0.2±2.3	0.1±2.8	0.66	−0.3±3.1	−0.3±3.6	0.43	−0.3±2.5	−0.3±3.3	0.20
MCHC (g/dL)	−0.5±3.3	0.1±3.0	0.43	−0.7±3.4	−0.6±3.6	0.98	−0.2±3.1	−0.6±3.5	0.02

Values are presented in median (Q1, Q3), mean±SD. Mann–Whitney U-test was used for comparing between the groups. Freidman test was done for comparing overall homoeopathic therapy. #Percentages show improvement. *Negative indicated improvement UFSQOL, i.e., Concern activities, energy, control, self-consciousness, and sexual function whereas positive indicated improvement for symptom severity, i.e., minimum symptom severity. IMF: Intramural fibroids; SSF: Subserosal fibroids; SMF: Submucosal fibroids; TF: Total fibroids; SD: Standard deviation; Hb: Haemoglobin; PCV: Packed cell volume; MCV: Mean cell volume; MCH: Mean cell haemoglobin; MCHC: Mean cell haemoglobin concentration; HRQL: Health-related quality of life; UFSQOL: Uterine fibroid symptom quality of life

in consensus with the study done by Iqbal *et al*.[19] and Popov.[18] Hence, this study reflects the possibility that individualized homoeopathic medication could control the symptoms and slow down the growth of fibroid. However, longer treatment period is required for observing more treatment benefits.

The main strength of this study is that there were no side effects observed during the study period. The intervention is cost effective in comparison modern or conventional medicine[7-12,31,32] wherein the treatment is very costly and ultimate is hysterectomy which has to be done at the cost of fertility. Another strength was involvement of gynecologists, who along with the homoeopathic physicians observed treatment effects, adding credibility to the study.

This study has few limitations. First is a lack of investigator blinding which was not possible due

Table 3: Outcome on number of fibroids

Group	Number of fibroid	At 6th cycle, *n* (%)				*P*	At 12th cycle, *n* (%)				*P*
		Fibroid nil	Increased	Decreased	Status quo		Fibroid nil	Increased	Decreased	Status quo	
LM	Single	2 (2.7)	5 (6.7)	-	68 (90.7)	0.001	3 (4.0)	7 (9.3)	-	65 (86.7)	0.03
	Multiple	1 (3.2)	2 (6.5)	10 (32.3)	18 (58.1)		2 (6.5)	1 (3.2)	3 (9.7)	25 (80.6)	
CH	Single	3 (4.8)	3 (4.8)	-	57 (90.5)	0.001	6 (9.8)	5 (8.2)	-	50 (82.0)	0.01
	Multiple	-	-	8 (20.8)	32 (80)		1 (2.5)	-	4 (10.0)	35 (87.5)	
Overall	Single	5 (3.6)	8 (5.8)	-	125 (90.6)	0.001	9 (6.6)	12 (8.8)	-	115 (84.6)	0.001
	Multiple	1 (1.4)	2 (2.8)	18 (25.4)	50 (70.4)		3 (4.2)	1 (1.4)	7 (9.9)	60 (84.5)	

Increased: The number of fibroids increased; Decreased: The number of fibroids decreased; Status quo: No change in number of fibroids

Table 4: Response of homoeopathic medicines in LM and CH potencies in patients with symptomatic uterine fibroid who were prescribed only one medicine throughout the treatment

Name of medicine	Prescription with outcome							
	LM				CH			
	Number of patients	Improved	Static	Worse	Number of patients	Improved	Static	worse
Pulsatilla	22	12	10	0	11	5	5	1
Sulphur	14	12	1	1	9	4	5	0
Calcarea carbonica	10	5	4	1	6	2	3	1
Lycopodium	9	7	1	1	13	10	2	1
Sepia	8	5	2	1	10	7	2	1
Natrum muriaticum	7	5	2	0	9	6	3	0
Phosphorus	7	5	2	0	11	8	2	1
Arsenicum album	2	2	0	0	1	0	1	0
Silicea	2	1	1	0	0	0	0	0
China	1	0	1	0	0	0	0	0
Graphites	1	1	0	0	1	0	1	0
Lachesis	1	0	1	0	0	0	0	0
Thuja	1	0	0	1	1	0	1	0
Bell	0	0	0	0	1	0	1	0
Bryonia	0	0	0	0	1	1	0	0
Mag carb	0	0	0	0	1	1	0	0
Merc sol	0	0	0	0	1	0	1	0
Nux vomica	0	0	0	0	2	2	0	0
Total	85	55	25	5	78	46	27	5

The outcome was assessed basing on symptom severity of UFSQOL, which contains eight items. Improvement: Reduction in severity symptom score of UFSQOL; Static: No change in severity symptom score of UFSQOL; Worse increase in severity symptom score of UFSQOL. UFSQOL: Uterine fibroid symptom quality of life

to the individualized nature of the intervention and patients were informed in a manner suggesting that two different types of treatment would be compared. The results of this study can be useful to patients where there is no urgency for surgical intervention and reduce out of pocket costs.

CONCLUSION

Homoeopathic medicines may offer an effective treatment option for women with symptomatic uterine fibroid and can improve the patients' quality of life.

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Table 5: Change of prescription during the treatment

Medicine	LM			CH			
	First prescription	Change of medicine		First prescription	Change of medicine		
		Second	Third		Second	Third	Fourth
Calcarea carbonica	3	*Bryonia* (1) *Sulphur* (1) *Tuberculinum* (1)		3	*Lycopodium* (2) *Sulphur* (1)	*China* (1)	*Pulsatilla* (1)
Calcarea phosphorus	1	*Cocculus* (1)		0			
China	1	*Sulphur* (1)		0			
Kali carb	0			2	*Bryonia* (1) *Phosphorus* (1)		
Lycopodium	3	*Phosphorus* (1) *Sepia* (1) *Sulphur* (1)	*Puls* (1)	14			
Natrum muriaticum	1	*Secale cornutum* (1)		4	*Graphites* (1) *Phosphorus* (2) *Rhus* (1)	*Pulsatilla* (1), *Bryonia* (1)	
Nux vomica	2	*Bryonia* (1) *Lachesis* (1)					
Phosphorus	3	*Calcarea carbonica* (1) *Pulsatilla* (2)		3	*Cocculus* (1) *Ignatia* (1) *Sepia* (1)		
Pulsatilla	2	*Calcarea carbonica* (1) *Lachesis* (1)	*Thuja* (1) *Nux vomica* (1)	4	*Calc.* (1) *Natrum muriaticum* (1) *Phosphorus* (1) *Sepia* (1)	*Tuberculinum* (1)	
Psorinum	0			1	*Bell* (1)		
Sabina	0			1	Pulsatilla (2)		
Sepia	3	*Lycopodium* (1) *Phosphorus* (1) *Pulsatilla* (1)		2	*Pulsatilla* (1) *Thuja* (1)	*Sulphur* (1)	
Sulphur	1	*Pulsatilla (1)*		3	*Calc* (2) *Phosphorus* (1) *Sabina* (1)	*Lycopodium* (1)	
Tuberculinum	1	*Phosphorus* (1)	Thuja (1) *Nux* (1)	0			
Total	21	21	5		23		

Number presented in parentheses are number of patients

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Conflicts of Interest

There are no conflicts of interest.

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रोगसूचक गर्भाशय फाइब्रॉयड पर होम्योपैथिक दवाओं के पचास हजारवें भाग (एलएम) की क्षमता की सेंटेस्मल (सीएच) की क्षमता से तुलना का एक बहुकेंद्रिक यादृच्छिक नैदानिक परीक्षण

सार

उद्देश्यः इसका प्राथमिक उद्देश्य लक्षणात्मक गर्भाशय फाइब्रॉयड पर सेंटेस्मल (सीएच) की क्षमता की एलएम क्षमता में होम्योपैथिक औषधियों के प्रभाव का मूल्यांकन करना था।

विधियांः केन्द्रीय होम्योपैथी अनुसंधान परिषद् के तहत छह केंद्रों पर एक बहुकेंद्रिक यादृच्छिक नैदानिक परीक्षण आयोजित किया गया। पूर्व निर्धारित समावेशन और बहिष्कार मापदंड के साथ लक्षणात्मक गर्भाशय फाइब्रॉयड के मरीजों की जांच की गई। नामांकित रोगियों की जांच और अनुवर्ती कार्रवाई के लिए प्रत्येक केंद्र में प्रसूति और स्त्री रोग के विशेष सलाहकार रखे गए थे। अध्ययन में शामिल होम्योपैथिक चिकित्सकों को नुस्खे और 12 महीनों तक अनुवर्ती कार्रवाई की जिम्मेदारी सौंपी गई थी। प्राथमिक परिणाम थे 0–10 के एक दृश्य अनुरूप पैमाने पर गर्भाशय के रेशों के लक्षणों में परिवर्तन और अल्ट्रासोनोलॉजी (यूएसजी) के निष्कर्षों में एलएम और सीएच के प्रभाव में प्राप्त अंतर था। दूसरा परिणाम जीवन प्रश्नावली (यूएफएस क्यूओएल) के गर्भाशय रेशों के लक्षणों की गुणवत्ता में परिवर्तन का आकलन था। इलाज के इरादे (आईटीटी) के विश्लेषण के अनुसार डेटा विश्लेषण किया गया था।

परिणामः अध्ययन में शामिल 216 रोगियों (एलएमः 108 और सीएचः 108) में से, 209 रोगियों (एलएमः 106 सीएचः 103) का संशोधित आईटीटी के तहत विश्लेषण किया गया। एक वर्ष के उपचार के बाद (पीझ 0.05) वीएएस पैमाने पर गर्भाशय के रेशों के वजह से उत्पन्न लक्षणों (प्रतिशत परिवर्तन) को कम करने में एलएम और सीएच शक्ति दोनों समान रूप से प्रभावी रहे थे। जीवन के स्वास्थ्य से संबंधित गुणवत्ता (एचआरक्यूओएल) और यूएफएसक्यूओएल के उप–डोमेन ने दोनों समूहों (पी=0.0) में बराबर प्रभावशीलता दिखाई। हालांकि गर्भाशय की मात्रा (पी = 0.03) को छोड़कर सभी यूएसजी निष्कर्षों में कोई अंतर नहीं पाया गया। समूहों अर्थात् एलएम या सीएच (पीढ0.05) पर विचार किए बगैर होम्योपैथिक उपचार के पहले और बाद, ऊपर के सभी मापदंडों में समग्र अंतर पाया गया था। अक्सर सुझाई जाने वाली दवाओं में पल्सेटिला, सल्फर, लाइकोपोडियम, सीपिया, फास्फोरस, कैल्केरिया कार्बोनिका और नेट्रम म्युरियाटिकम शामिल हैं।

निष्कर्षः लक्षणात्मक गर्भाशय फाइब्रॉयड से पीडित रोगियों को लक्षणों से राहत देने में एलएम और सीएच की शक्तियां समान रूप से प्रभावी हैं।

Ensayo clínico aleatorizado multicéntrico de medicamentos homeopáticos en potencias 50-milesimales (LM o Q) frente a potencias centesimales (CH) en los miomas uterinos sintomáticos

RESUMEN

Objetivos: El objetivo primario fue evaluar los efectos de los medicamentos homeopáticos en potencias LM (Q) frente a las potencias centesimales en los miomas uterinos sintomáticos.

Métodos: Se efectuó un ensayo clínico aleatorizado multicéntrico en seis centros del CCRH (*Central Council for Research in Homoeopathy*, Consejo Central de Investigación en Homeopatía). Las pacientes fueron examinadas en cuanto a miomas uterinos sintomáticos conforme a los criterios de inclusión y exclusión preestablecidos. Un consultor especializado en obstetricia y ginecología se dedica en cada centro para cribar y el seguimiento de los pacientes incluidos. Los médicos homeopáticos que participan en el estudio fueron los responsables de la prescripción y seguimiento durante 12 meses. El parámetro principal fueron los cambios de los síntomas del mioma uterino en una escala analógica visual de 0-10 y de los hallazgos ecográficos (ECO) entre las potencias LM (Q) y CH. El parámetro secundario era la evaluación del UFSQOL (*uterine fibroid symptom and quality of life questionnaire*, cuestionario específico de síntomas del mioma uterino y la calidad de vida). El análisis de datos se realizó de acuerdo con el análisis por intención –de-tratar (IDT).

Resultados: En el estudio, se enrolaron 216 pacientes (LM:108 y CH:108), de las que 209 fueron sometidas al análisis IDT modificado (LM:106, CH:103). Las potencias LM y CH fueron igual de eficaces en reducir los síntomas (cambio porcentual) debido al mioma uterino en la escala VAS tras un año de tratamiento ($p>0,05$). Los cuestionarios de HRQOL (*health related quality of life*) y el subdominio UFSQOL mostraron la misma eficacia en ambos grupos ($p=0,05$). No se observaron diferencias en los hallazgos ECO, exceptuando en el volumen uterino ($p=0,03$). En todos los parámetros arriba mencionados, se produjo una diferencia global de antes y después del tratamiento homeopático, independientemente del grupo asignado, es decir, LM o CH ($P<0,05$). Los medicamentos más frecuentemetne prescritos fueron: *Pulsatilla, Sulphur, Lycopodium, Sepia, Phosphorus, Calcarea carbonica y Natrum muriaticm*.

Conclusiones: Las potencias LM y CH fueron igual de eficaces en aliviar la sintomatología en pacientes con miomas uterinos sintomáticos.