

ORIGINAL ARTICLE

Role of homoeopathic medicines in treating uterine fibroid: a prospective observational study

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Background & objective: Uterine fibroids (UF) or leiomyomas are found in 25% to 35% women of reproductive age. It is one of the most common indications for hysterectomy further leading to complications. The present observational study on UF was undertaken to arrive at a group of useful homoeopathic medicines for the treatment of the same.

Methods: A prospective observational study was conducted at Princess Durru Shehvar Children's and General Hospital, Hyderabad in coordination with its Extension Unit of Drug Standardization Unit (Hyderabad) of Central Council for Research in Homoeopathy during September 2006 - August 2009. One hundred and thirty eight patients with UF were screened as per the pre-set criteria and 103 patients were enrolled. Homoeopathic Medicines were prescribed to the enrolled patients on the basis of repertorization of the symptom totality. The improvement of the patients was assessed subjectively through the clinical symptoms and objectively through USG pelvis.

Results: Out of 103 patients enrolled, follow up of 71 patients was completed as per protocol and their data was analyzed. In 12 patients, fibroids resolved completely. There was statistically significant reduction in some of the symptoms/signs as well as in size of fibroid(s) ($p < 0.05$). *Calcarea carbonica* (n=16), *Pulsatilla* (n=14), *Phosphorus* (n=7), *Lycopodium* (n=5), *Sulphur* (n=3) and *Kali carbonica* (n=2) were found to be most useful among the prescribed homoeopathic medicines.

Limitations: This was an observational study with no control arm, with the duration of follow up being only 8 months.

Conclusion: This study has shown positive results in terms of reduction and resolution of UFs with homoeopathic treatment. Further RCTs with long follow ups need be conducted for definite conclusions.

Keywords: Homoeopathy; USG Pelvis ; Uterine leiomyoma

INTRODUCTION

Uterine Leiomyomas/fibroids (UF) are benign smooth muscle tumors that represent one of the most common gynaecological problems in women of reproductive age. They are the primary indication for nearly 600,000 hysterectomies performed each year in the United States, and for 37,000 myomectomies performed annually. In a comprehensive review of patients in United States conducted by Schwartz, incidence rates varied from 2.0 to 12.8 per 1000 women per year.¹ Presently people with uterine fibroids undergo total abdominal, vaginal or laparoscopic assisted hysterectomies around the world. In less developed

and more populous countries like India, the numbers may be even higher.²

However, the exact incidence of UF in reproductive age women is difficult to ascertain for several reasons. Primarily, the majority of fibroids are asymptomatic, resulting in low clinical detection rates.^{3,4} Risk factors primarily include a) age with increasing incidence as women approach perimenopause and b) African-American race. The other risk factors are c) positive family history (having a family member with fibroid increases the risk by 3 times), d) obesity (there is 2.3 times increased risk in women with BMI > 25.4 kg/m²) etc. Symptoms differ widely but may include menorrhagia, pelvic pain & pressure, infertility and pregnancy related complications. Diagnosis can be made with the help of radiographs, trans-abdominal & trans-vaginal ultrasound, MRI and Hysteroscopy. As this is becoming the common reason for hysterectomies these days, there is an increasing need for non invasive

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alternatives for uterine fibroids.⁵ A study by Popov shows that Homoeopathy can stop the growth of the tumor, reducing size (26.8%) as well as to control pain (78.9%) and abnormal endometrial bleeding (75%). He also highlights that certain patterns of response to treatment were found i.e. in certain patients positive response was observed at the beginning of the treatment, but subsequently ceased. Secondly in few patients menorrhagia improved but the growth of the tumor was observed. The various medicines which were used are *Nux vomica*, *Sulphur*, *Lycopodium*, *Calcium iodatum*, *Apis mellifica*, *Cimicifuga*, *Calcarea carbonica*, *Silicea*, *Ignatia*, *China officinalis*, *Argentum nitricum*, *Sabina*, *Iodatum*, *Sepia*, *Calcarea fluoricum*, and *Pulsatilla*.⁶ A single case record by Iqbal Jahan et al has also highlighted the resolution of fibroid with *Lycopodium*.⁷

Thus an Extra Mural Project was taken up by the Princess Durru Shehvar Children's and General Hospital, Hyderabad in coordination with its Extension Unit of Drug Standardization Unit (Hyderabad) of Central Council for Research in Homoeopathy to identify the potential role of homoeopathic medicines and to ascertain if homoeopathy can offer an alternative for the treatment of UF.

MATERIAL AND METHODS

Study Design and setting

This was a prospective observational study conducted at Princess Durru Shehvar Children's

and General Hospital, Hyderabad in coordination with Extension Unit of Drug Standardization Unit (Hyderabad) under Central Council for Research in Homoeopathy during the period September 2006 to August 2009. The protocol was approved from the Ethical Committee of the study site. Informed consent was taken from all the patients who were willing to participate in the study.

Patient selection

For patient selection, the ICD 10 Criteria as following was considered:

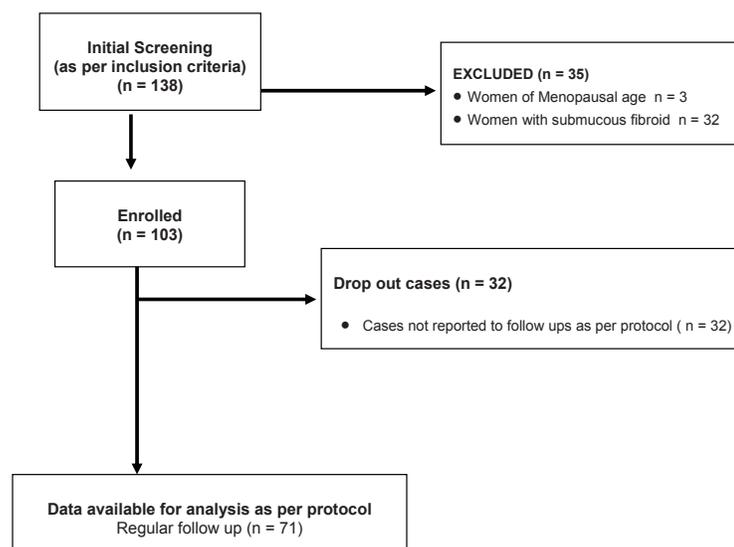
Benign neoplasms of uterus with morphology code /0

Fibromyoma of uterus

- D25.1 submucous leiomyoma of uterus
- D25.0 intramural leiomyoma of uterus
- D25.2 subserosal leiomyoma of uterus
- D25.9 leiomyoma of uterus, unspecified

Out of these groups, females in the childbearing age group i.e., 30 to 40 yrs of age diagnosed with subserosal & intramural fibroid on ultrasonography were included in the study. Asymptomatic patients presenting with UF growing in size were also included. Woman with heavy, prolonged menstrual periods and unusual monthly bleeding which can lead to hypovolemia & severe anaemia (Haemoglobin < 6mg%); pregnancy; non-symptomatic fibroids in the females of menopausal age; woman diagnosed on scan having sub mucosal fibroids were excluded.

Figure 1: Flow of patients in the study



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Treatment and follow up

Homoeopathic treatment was given as per instructions given in Hahnemann's Organon of Medicine.⁸ Its characteristics are: Selection of one drug at a time, using the 'similia principle' and the drug picture and disease picture should be as similar as possible. Homoeopathic Medicines were prescribed to the enrolled patients by repertorising the symptom totality. The repertorisation was done using the Complete Repertory from the software of Homopath Classic.⁹

The final selection of the medicine was done after confirming with the Materia Medica.^{10,11,12} Selected medicine was given in 30c potency in single dose. After a particular prescription, if the improvement remained stand still, 200c potency was given and later as per requirement. Placebo pills were given as soon as the improvement was observed. Investigators were allowed to change the prescription if the first prescription

didn't work as per the follow up symptom totality by reanalyzing the case.

Outcome measures

The patients were assessed at 7 days, 15 days, 1 month, 4 months and 8 months for clinical symptoms. Periodical ultrasonographic scans were conducted over 8 months. The final assessment was done as shown in Table 1. Fibroid size and number were assessed by vaginal and/or abdominal ultrasonogram at baseline and 8 months. UF sizes is evaluated, measuring the three main diameters (D1,D2,D3) and applying the formula of the ellipsoid ($D1 \times D2 \times D3 \times 0.52$). An arithmetic mean of the sizes was used in presence of two fibroids.¹³ However in this study as two diameters were only measured, the highest diameter amongst the two diameters was considered as third diameter for calculating the volume.

Table 1 : Parameters adapted for assessment of response to treatment

1. Improvement:	Marked	More than 75% improvement in the size of fibroid(s) with clinical improvement as compared to baseline
	Moderate	50% to less than 75% improvement in the size of fibroid(s) with clinical improvement as compared to baseline
	Mild	25% to less than 50% improvement in the size of fibroid(s) with clinical improvement as compared to baseline
2. No significant change		Less than 25% improvement in the size of fibroid(s) with clinical improvement as compared to baseline
3. Not improved		No change in the size of fibroid(s) as compared to baseline
4. Worsened		Increase in the size of fibroid(s) as compared to baseline
5. Static		No change of the size of fibroid(s) with clinical improvement after sufficient trial of best indicated medicines have been tried

Statistical analysis

The result analysis was done by using SPSS (Statistical package for social science) Version 16 & System Stats Version 10 on the clinical parameters and on the size of uterine fibroids before and after 8 months of treatment (t test, McNemmar test) as per nature of data.

RESULTS

One hundred and thirty eight patients with UF were screened and 35 patients were excluded. Among 103 patients enrolled, 32 patients were not analyzed as they deviated from the protocol norms. The analysis

reflects the data of 71 patients who were analyzed as per protocol. The flow of the patients in the study is given in Figure 1. Baseline details of the patients are given in Table 2.

McNemar test showed significant changes in proportion of patients with symptoms/signs such as disturbances in menstrual cycle, pain during menses due to UF in patients (Table 3a). The reduction in number and size of the uterine fibroids after 8 months of treatment as assessed ultrasonographically was also found to be significant statistically in patients irrespective of single or with multiple (2-4) fibroids (Table 3b). An overall assessment of study patients

Table 2 : Baseline data of 71 patients analyzed in the study

Variable	No. of patients(%)	Variable	No. of patients(%)
1. Age group in years		7. Menarchal Age	
30 - 35	23(32.4)	10-12yrs	29(40.8)
36 - 40	48(67.6)	13-15yrs	36(50.7)
2. Body Mass Index (BMI)		16-18yrs	6(8.5)
< 18.5	2(2.8)	8. Number of fibroids	
18.5-24.9	21(29.6)	Single	51(71.83)
25-29.9	34(47.9)	Multiple	20(28.17)
30-39.9	14(19.7)	9. Type of fibroid	
3. Marital Status		Intramural	54(76.1)
Unmarried	2(2.8)	Subserosal	9(12.7)
Married	59(83.1)	Both	8(11.3)
Widow	7(9.9)	10. Clinical presentation	
Divorced	3(4.2)	Absent	8(11.3)
4. Parity (Children)		Present	63(88.7)
Nullipara	14(19.7)	10.a) Disturbances in menstrual cycle	
1-3	36(50.7)	Absent	13(18.3)
4-6	17(23.9)	Present	58(81.7)
7-9	4(5.6)	10.b) Menstrual pain	
5. Family History of Uterine Fibroid(s)		Absent	39(54.9)
Present	19(26.8)	Present	32(45.1)
Absent	52(73.2)	10.c) Pressure symptoms	
6. Use of Oral contraceptive pills (OCP)		Absent	67(94.4)
Used	15(21.1)	Present	4(5.6)
Not used	56(78.9)	10. d) Infertility	
		Absent	57(80.3)
		Present	14(19.7)

Table 3 (a) : Clinical outcome parameters of studied patients

Number and type of Fibroid	At entry	%	At end	%	P value
<i>Clinical presentation</i>					
Absent	8	11.3	56	78.9	0.008*
Present	63	88.7	15	21.1	
• Disturbances in menstrual cycle					0.001**
Absent	13	18.3	67	94.4	
Present	58	81.7	4	5.6	
• Menstrual pain					0.001**
Absent	39	54.9	70	98.6	
Present	32	45.1	1	1.4	
• Pressure symptoms					0.25*
Absent	67	94.4	70	98.6	
Present	4	5.6	1	1.4	

McNemar Test (significant at $p < 0.05^{**}$, not significant $p > 0.05^{*}$)

based on both clinical and ultrasonographic parameters is given in Table 3c.

It is observed that 9 medicines were used frequently for prescribing to the patients of UF (Table 4) *Calcarea carbonica* ($n=16, 22.5\%$), *Pulsatilla* ($n=14, 19.7\%$),

Thuja ($n=11, 15.5\%$), *Natrum muriaticum* ($n=7, 9.9\%$), *Phosphorus* ($n=7, 9.9\%$) and *Sepia* ($n=6, 8.5\%$). Among the medicines less used in this study are *Lycopodium* ($n=5, 7.0\%$), *Sulphur* ($n=3, 4.2\%$) and *Kali carbonica* ($n=2, 2.8\%$).

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Table 3 (b) : Statistical evaluation of size of uterine fibroids

Size of fibroid in cm ³	Mean(SD)		Mean diff(95% CI)	P-value
	At entry	At end		
Single fibroid (n= 51)	43.82(74.38)	24.22(65.72)	19.59(10.07 to 29.11)	0.001**
Multiple fibroids (n= 20)	17.20(25.26)	10.66(20.19)	6.53(2.15 to 10.91)	0.006**

Paired t test (significant at p<0.05**, not significant p>0.05*)

Table 3 (c) : Outcome assessment of studied patients

Improvement status	Single fibroid (n=51)	Multiple fibroid (n=21)	Total
	No of patients (%)		
Marked	24(47.1)	5(25)	29(41)
Moderate	8(15.7)	4(20)	12(17)
Mild	14(27.5)	3(15)	17(24)
Not significant	2(3.9)	6(30)	8(11)
Worse	3(5.9)	2(10)	5(7)

Figure 2 : Symptom-wise improvement status of patients

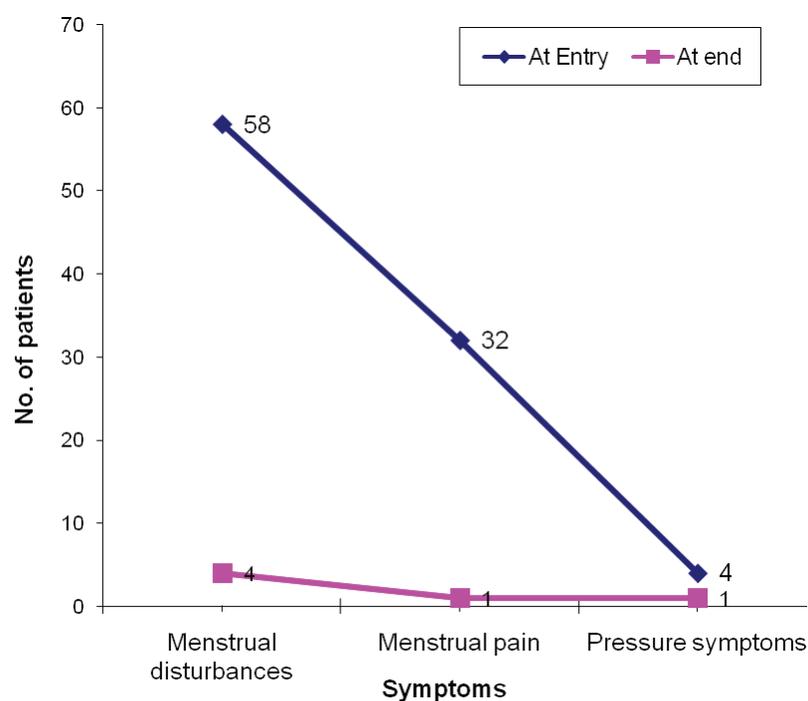


Table 4: Improvement status with homeopathic medicines used

Medicine prescribed	No. of cases	%	Improvement assessment			
			Marked improvement	Moderate improvement	Mild improvement	No Significant
Calcarea carbonica	16	22.5	8	5	2	1
Kali carbonica	2	2.8	2	-	-	-
Lycopodium	5	7.0	3	-	2	-
Natrum muriaticum	7	9.9	3	-	1	3
Phosphorus	7	9.9	1	1	4	1
Pulsatilla	14	19.7	5	2	5	2
Sepia	6	8.5	3	0	0	1
Sulphur	3	4.2	3	-	-	-
Thuja	11	15.5	1	4	3	-
Total	71	100	29	12	17	8

81.7% of UF patients (n=58) showed various levels of improvement at various stages of their treatment during the study period of eight months (Figure 2); 29 patients showed marked improvement where in 12 patients fibroid has been completely resolved, 12 patients showed moderate improvement, 17 patients showed mild improvement, 8 patients showed no significant improvement respectively whereas in 5 patients it got worsened.

DISCUSSION

This was a prospective observational study conducted in India for treating patients of UF with homeopathic medicines and it reflected the positive results of homeopathic therapy in these patients.

Patients diagnosed with uterine fibroid of variable duration were enrolled. The incidence found to be more in 35-40yrs of age. The studies conducted by Marshall et al¹⁴ demonstrated an increased incidence rates of fibroid as women approach the perimenopause and the same is corroborated in this study. When risk factors are compared, majority cases showed Body Mass Index > 25. This has been investigated as an independent risk factor for fibroid growth in epidemiological studies.¹⁴ Faerstein et al¹⁵ demonstrated a 2.3 fold increase of risk in women with BMI > 25.4 Kg/m². The same is corroborated in this study. Family history of fibroids is being reported first by Winkler and Hoffman¹⁶, who demonstrated a 4.2 fold increase in fibroids among first degree relatives. In this study 26.8% patients have family history of UF.

Abnormal uterine bleeding is the most frequently cited symptom in women with fibroids as per *Stewart's classification system*¹⁷ of clinical presentation of fibroid and in the present study 30 cases reported with profuse bleeding per vagina as the chief complaint. In this study, clinical presentation improved in 76.2% patients. Of the 58 patients presenting with disturbances in menstrual cycles such as bleeding, short cycle duration and irregular cycles, 54 patients improved and only 4 patients, some disturbances in the cycles persisted after 8 months of treatment. Dysmenorrhoea improved in all the cases, who had initially presented with this complaint, except in one case.

The medicines found useful in this observational study were *Calcarea carb.*, *Pulsatilla*, *Phosphorus*, *Lycopodium*, *Sulphur* and *Kali carb.* As rightly said by *Thomas Skinner*¹⁸ "Constitutional treatment alone was and is all that is necessary for successful treatment of all vaginal, uterine and ovarian diseases". The same holds true in this study as the medicines prescribed are wholly on the symptom totality and the constitutional basis on repertorization and final decision with the consultation of *Materia Medica*.

The strength of this study is that it represents a pragmatic setting of homeopathic practice which reflects the day-to-day clinical practice. To validate the efficacy of Homeopathy in the treatment of UF, Randomized Control Trials (RCT) are needed. To assess the improvement of the cases more authentically colour doppler ultrasonography evaluating volume,

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echogenecity and vascularity of the fibroids can be considered. Also further studies can be conducted to verify the action of homoeopathic medicines in fibroid size reduction to basically evaluate the reason whether the reduction is due to the diminution in the blood supply or due to the degenerative changes resulted.

CONCLUSION

This study has shown positive results in terms of reduction and resolution of UFs with homoeopathic treatment. Further RCTs with long follow ups need to be conducted for definite conclusions.

Conflict of Interest

We declare no conflict of interest.

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