

## EXTRA MURAL RESEARCH

### Evidence based clinical study on the effect of homoeopathic medicines in cases of ovarian cysts

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**Background and Objectives:** Patients with persistent ovarian cyst for more than 6 months which do not respond to hormone therapy usually, require surgical treatment. Surgery should be avoided as much as possible in unmarried and childless women where future reproductive functions are of prime concern. There are a few claims by homoeopathic physicians to have treated cases of ovarian cysts with homoeopathic medicines. Such claims, however, have neither been scientifically documented nor published. To give scientific support to such sporadic claims, a clinical study was carried out to evaluate the usefulness of homoeopathic medicines for treatment of patients suffering from ovarian cyst.

**Methods:** A total of 73 patients suffering from ovarian cysts were enrolled, as per inclusion criteria out of which 48 completed the study according to protocol. Medicines selected on the basis of principles of homoeopathy were prescribed and changes in the size of ovarian cysts were assessed at the end of 1 year on the basis of pre and post treatment ultrasonography reports and hormonal tests.

**Results:** After comparing pre and post treatment ultrasonography reports, the difference in mean values of maximum dimension of ovarian cyst was found to be statistically significant ( $p$  value  $< 0.05$ ). Cyst was totally resolved in 8 (16.67%) patients, 10 (20.83%) patients had reduction in the size of the cysts, 21 (43.75%) patients remained status quo while 9 (18.75%) did not improve. *Natrum muriaticum* ( $n=7$ ), *Pulsatilla* ( $n= 3$ ), *Sepia* ( $n=3$ ) and *Calcarea carbonicum* ( $n= 2$ ) were found to be most useful homoeopathic medicines.

**Conclusion:** The preliminary results obtained from this observational study are encouraging. The study indicates the positive role of Homoeopathic therapy in the management of ovarian cysts. Such study with bigger sample size through randomized controlled trial is needed for further validation.

**Keywords:** homoeopathy; observational study; ovarian cyst; natrum muriaticum; pulsatilla; sepia

### Introduction

Ovarian cysts are benign growths arising from the ovary. These may occur at any age from menarche to menopause. Gradual swelling of abdomen with dull ache may be the presenting symptoms. Menstrual disorders are usually absent. However, pressure symptoms such as frequency and retention of urine may be present but most of the cases remain

asymptomatic. Only small evidence suggests that benign ovarian cysts may become malignant.<sup>1</sup> However, it is well known that a significant number of cysts regress spontaneously<sup>2</sup> and malignant potential of simple cyst is extremely low<sup>3,4</sup>. Patients with persistent ovarian cyst of more than 6 months duration and who do not respond to hormone therapy usually require surgical intervention. Surgery should be avoided as much as possible in unmarried and childless women where future reproductive functions are prime concern.

Hormone therapy, including the use of the oral contraceptive pill, is not helpful in causing resolution<sup>5</sup>.

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Homoeopathic medicines when prescribed after individualization, is supposed to strike at the root cause, acting through psychophysical axis possibly causing reversal of hormonal imbalance and regression of ovarian cyst. Homoeopathy, therefore, considers all these psychological factors apart from physical factors in selection of the remedy using the principle of similia. Ultrasonography (USG) is well accepted as a fast and non invasive first choice of examination to evaluate ovarian lesions.<sup>6-10</sup> However, it has limited inter observer variability<sup>11-13</sup>. Gupta et al<sup>14-15</sup> published their research papers based on ultrasonography and shown the usefulness of homoeopathic medicines prescribed on above hypothesis in cases of ovarian cysts. After this, no significant work has been published to elicit the efficacy of homoeopathic medicines in ovarian cyst. Therefore, a collaborative research study was carried out to prove the hypothesis stated above, to evaluate the usefulness of homoeopathic medicines on given pathological condition and thereby generate standardized and quality controlled data for treatment of patients suffering from ovarian cyst.

### Objective

To develop evidence based support on the efficacy of homoeopathic medicines in the management of ovarian cysts.

### Material and Methods

#### Study Design

The study was prospective and observational conducted at Gaurang Clinic and Centre for Homoeopathic Research, Lucknow under the aegis of Homoeopathic Research Foundation(HRF) funded by Department of AYUSH through Central Council for Research in Homoeopathy (CCRH), New Delhi, from February 2008 to February 2010. Change in size of cyst as per abdominal / transvaginal ultrasonography of pelvic region was the parameter for assessment of treatment. Analysis of hormone levels viz. Prolactin, Estrogen, Progesterone, LH and FSH were done at base line. To check the role of homoeopathic medicines on abnormal hormone levels, they were analyzed before and after treatment. The ethical clearance was obtained from Ethical Committee of HRF before undertaking the study. The study protocol was prepared in accordance with the Helsinki declaration on human experimentation.

#### Study Participants

Forty eight (48) patients of different age groups with ovarian cyst of more than > 20 mm size, persisting for more than 6 months on the basis of USG reports

were enrolled in the study. Patients with raised CA-125, Poly Cystic Ovarian Disease (PCOD), Cervical Erosion, under Hormone Replacement Therapy (HRT) and suffering from any systemic illness were excluded from the study. The patients were enrolled in the study only after getting their written informed consent.

### Medicine Selection, Dose, Potency and Repetition

Each patient received medicine selected on the basis of presenting totality of symptoms using complete repertory with the help of HOMPAT version-8.0 or RADAR (student) version-10 software. A single dose consisting four globules of size 40 of indicated medicine was prescribed followed by placebo for such a time till improvement in symptoms and/or reduction in size of cyst in ultrasonographic assessment after every three months was noted. However, the patients reported fortnightly or earlier if required. The potency of prescribed medicines remained between 30C to 10M depending on the type of totality. Higher potencies were prescribed in patients with prominent mental generals while lower potencies were prescribed to the patients with pathological and common symptoms.

### Outcome Assessment Criteria

Patients were followed up for one year on homoeopathic treatment. The outcome assessment of treatment was assessed by evaluating the size of cysts through pre and post treatment USG reports in the following manner:

**Complete resolution of cyst:** No evidence of cyst in final USG report at the end of treatment of one year.

**Improved:** The cases in which size of cyst was reduced by more than 10 mm in comparison to baseline USG report.

**Status Quo:** The cases in which size of cyst remained as such or decreased not more than 10 mm as compared to baseline USG report but there was symptomatic improvement

**Not Improved:** The cases in which size of cyst increased more than 10 mm from the initial USG report.

**Non Conclusive:** The cases in which no conclusion could be drawn from end of treatment with USG report.

### Statistical Analysis

Maximum dimensions of the largest cyst (i.e. pre and post treatment) were taken as two dependent groups and were compared together by paired t- test. A two-tailed ( $\alpha=2$ ) probability ( $p$ ) value <0.05 was considered to be statistically significant. All analyses were performed on SPSS (version 16.0).

## Results

During the period of one year, 121 patients were screened, out of which 48 were excluded due to raised CA-125, having PCOD and cervical erosion. Finally 73 patients were enrolled, out of which 9 did not turn up after baseline investigations, 12 were lost to follow-up and 4 women became pregnant and left treatment. A total of 48 patients completed the study as per protocol during the period. The results, therefore includes analysis of 48 patients. The age of the enrolled patients at baseline ranged from 17-75 years with mean ( $\pm$  SD)  $32.21 \pm 1.52$  years. The incidence of ovarian cyst was found maximum between 21-50 age group (87.50%), followed by < 20 age group (8.33%) followed by >50 age group (4.17%). The detailed status of patients with respect to different factors at the time of enrollment into the study is given in Table 1.

The outcome results of this study are summarized in Table 2. Paired t test for the difference in mean of pre and post treatment maximum dimension of largest cyst was found to be statistically significant  $p=0.003$  (Table 2)

The details of prescribed medicines in patients are summarized in Table 3 which shows that four medicines were indicated most frequently in the patients (85.4%) suffering from ovarian cyst. The medicines were *Natrum muriaticum* (35.4%),

**Table 1 :** Data of 48 cases of ovarian cysts according to selected factors

	n	%
<b>Age (years)</b>		
upto 20	04	08.33
21 – 50	42	87.50
> 50	02	04.17
<b>Parity</b>		
Nullipara	20	41.67
Uni para	16	33.33
Multipara	12	25.00
<b>Menstrual history</b>		
Regular menstruation	33	68.75
Irregular menstruation	09	18.75
Post menopause	04	08.33
Post hysterectomy	02	04.17
<b>Size of ovarian cyst (in mm)</b>		
20-30	02	04.17
31- 50	13	27.08
> 50	33	68.75
<b>Location of cyst</b>		
Left side	23	47.92
Right side	14	29.16
Bilateral	11	22.92

**Table 2:** Ultrasonographic findings and outcome assessment of ovarian cyst

Ovarian cyst (in mm)	n	%	Baseline Mean $\pm$ SD	At end Mean $\pm$ SD	p-value (95%CI)
Overall	<b>48</b>	100	63.12 $\pm$ 23.8	51.02 $\pm$ 35.6	0.003*
20-30	02	04.17	26 $\pm$ 2.82	17.5 $\pm$ 10.6	ns
31- 50	13	27.08	41.62 $\pm$ 5.88	29.38 $\pm$ 25.87	ns
> 50	33	68.75	73.85 $\pm$ 20.64	61.58 $\pm$ 35.09	0.018*
Complete resolution of cyst (max.-89 mm and min.- 40 mm)	08	16.67			
Improved (reduction in size from 13 mm to 51 mm)	10	20.83			
Status Quo	21	43.75			
Not Improved	09	18.75			

\*statistically significant using paired t test.

*Pulsatilla* (20.8%), *Sepia* (24.58%), and *Calcarea carb.* (14.58%). However these medicines could improve 37.5% of patients. The characteristic indications of the medicines found useful are described in Table 4.

Effect of homoeopathic therapy on female hormones is summarized in Table-5 which shows that thirty five (35) patients reported with abnormal hormone levels (one hormone to multiple hormone levels) before treatment. Out of them, 22 (62.8%) responded positively in similar way.

**Table 3:** Homoeopathic medicines and their response

Medicines	n	Complete Resolution of cyst	Improved	Status quo	Not improved	Location of cysts in the improved cases		
						B/L	Right	Left
Natrum muriaticum	17	1	6	8	2	3	2	2
Pulsatilla	10	3	0	4	3	1	1	1
Sepia	7	0	3	2	2	1	-	2
Calcarea carbonica	7	1	1	5	0	2	-	-
Silicea	2	1	0	0	1	1	-	-
Lycopodium clavatum	2	0	0	1	1	-	-	-
Arsenic album	2	1	0	1	0	1	-	-
Phosphorus	1	1	0	0	0	1	-	-
<b>Total</b>	<b>48</b>	<b>08</b>	<b>10</b>	<b>21</b>	<b>09</b>	<b>10</b>	<b>3</b>	<b>5</b>

**Table 4:** Characteristic indications of the medicines

Prescribed medicine/ Patients benefitted	Indications and no. of patients benefitted	
<b>Natrum mur.</b> n – 7	Fastidious – 07 Hot – 06 Offended easily – 05 Anger from contradiction –05 Anticipating anxiety –05 Consolation aggravate –04 Desire salty –04 Weeps easily –04 Fear narrow place –04	Ailment : Discord between relative –03 Solitude desire –03 Dwells on past –03 Hurry tendency –02 Ailment : Anger suppressed –02 Ailment : Death of relatives –02 Ailment : Anger –02 Ailment : Being alone–01
<b>Pulsatilla nig.</b> n – 3	Consolation ameliorate –03 Offended easily –03 Hot patient – 03 Fastidious – 03 Weeps easily – 03	Solitude desire –03 Timidity – 02 Poor thirst – 03 Anger, shouts – 03 Ailments from disappointment – 02
<b>Sepia</b> n – 3	Offended easily – 03 Weeps easily – 03 Anticipation anxiety – 03 Chilly patient – 03 Introverted – 02 Consolation aggravate – 02 Brooding – 02 Obstinate – 02 Desire sweet – 02	Fear : Narrow place – 02 Egotism – 02 Fastidious – 01 Washing hands always – 01 Ailment: Anger suppressed – 01 Dreams: Rape – 01 Fear: Being humiliated – 01 Nervous tendency – 01
<b>Calcarea carb.</b> n – 2	Offended easily – 02 Chilly patient – 03 Delusion: Snake – 03 Weeps easily – 02 Consolation ameliorate – 02 Desire salty – 02	Tendency to catch cold – 02 Dreams: Unsuccessful efforts – 02 Fear: Ghost – 02 Brooding – 01 Obstinate – 01 Perspiration scalp – 01
<b>Silicea</b> n – 1	Ailments from anxiety Dreams of snake Fear: Dark Fear: Misfortune Delusion: Someone behind Company desire	Egotism Desire salty things Chilly Fear: Cats Anticipating anxiety Anxiety future

Prescribed medicine/ Patients benefitted	Indications and no. of patients benefitted	
<b>Arsenic album</b> n – 1	Fear: Being alone Fear: Narrow place Company desire Consolation ameliorates Anxiety about trifles Offended easily Fastidious	Tendency to catch cold Desire sweets Chilly patient Anxiety anticipation Hurry tendency Censorious
<b>Phosphorus</b> n – 1	Fear: Cockroaches Fear: Thunder storm Company desire Consolation ameliorate Offended easily	Extroverted Ambitious Anxiety future Desire spicy food

**Table 5:** Status of hormones at baseline and post treatment in 35 patients reporting abnormal hormonal levels at baseline

Hormone	n <sup>a</sup>	Before treatment Mean (Min, Max)	Post treatment (improved cases) Mean (Min., Max.)	p- value
Progesterone	16	1.10 (0.03, 10.69)	2.27 (0.03, 21.45)	ns
Estrogen	09	184.59 (22.68, 539.50)	56.98 (4.82, 158.80)	ns
Prolactin	07	60.05 (30.56, 142.10)	15.04 (7.85, 19.29)	0.02
FSH	13	17.83 (3.66, 47.55)	25.98 (3.16, 111.00)	ns
LH	08	17.82 (3.66, 47.55)	14.23 (1.90, 56.07)	ns

<sup>a</sup> Sum of the patients in column 2 differs from the no. of patients reporting abnormal hormonal levels since some of the patients reported abnormal levels on more than one hormone; ns- not significant

Out of 28 patients with dysmenorrhoea, 18 (64.2%) improved clinically where as out of 32 patients with abnormal menstrual flow, 16 (50%) shown positive response (Table 6).

**Table 6:** Status of menstrual flow

Menstrual complaints	No. of patients reporting the symptom	Status after treatment	
		Improved	quo
Profuse	17	10	07
Scanty	09	04	05
Absent	06	02	04

Associated complaints were also found relieved in many patients after homoeopathic treatment (Table 7).

The data of 16 patients who were dropped out although treated for more than 03 months is as follows. Out of 4 pregnant patients, complete resolution of cyst seen in 2 patients while 2 other patients got improved.

**Table 7:** Status of associated complaints

Associated complaints	No. of Associated complaints	Status after treatment	
		Improved	Status quo
Leucorrhoea	05	03	02
Dysmenorrhoea	28	18	10
Headache	10	08	02
Painful coition	04	03	01
Pain & heaviness in breast	02	01	01

Two patients left treatment as their cyst resolved within six months. Size of cyst regressed in 06 patients and showed improvement in USG but clinically they were not at ease and left treatment. Two patients remained status quo, one not improved and one declared non conclusive.

## Discussion

This prospective observational study has shown encouraging results with homoeopathic treatment in

cases of ovarian cysts. It was observed that the mean ( $\pm$  SE) of maximum dimension of cyst at entry and at end of follow-up was  $63.12 \pm 3.43$  and  $51.02 \pm 5.13$  respectively. The result showed a statistically significant difference ( $p=0.003$ ) in the post treatment outcome. The study supports the findings of previous studies<sup>14-16</sup>. It also supports the hypothesis drawn for the study and thus it could be said that individualized homoeopathic medicines are useful in treatment of ovarian cysts.

The useful homoeopathic medicines in this study were *Natrum muriaticum*, *Pulsatilla*, *Sepia*, *Calcarea carb*, *Silicea*, *Arsenic alb* and *Phosphorus* which are almost similar to the constitutional medicines used in the previous studies. *Sulphur* and *Carcinosin* were the two medicines additionally prescribed in previous studies. Table 4 shows the symptom syndromes compiled from the improved cases and the verified prescribing indications. It is important to note that patients with ovarian cysts need to be assessed on mental and physical aspects for better prescription.

Out of 35 patients who reported to have abnormal hormone levels, 22 (62.8%) had shown positive response. The difference in two groups supports the hypothesis that medicines prescribed on the basis of individualization act holistically. Out of these 22 patients, 14 patients have also shown positive response with reference to size of cyst too including complete resolution of cyst in 08 patients (Table 2).

Six post menopausal women were also enrolled but response in terms of reduction in the size of the ovarian cyst was observed only in one patient. While four patients who had gone for hysterectomy in the past and having ovarian cysts responded positively and there was reduction in the size of the cysts as well as improvement in the hormone levels. The follow-up time period in present study was one year. The previous studies, however, were not time bound. If the treatment would have been followed-up further in present study, the positive response could have been observed in more number of patients since understanding of the patients becomes better and better and cases are cleared layer by layer as per homoeopathic principles.

The strength of this study over the previous ones is that it provides the role of homoeopathic medicines in correction of abnormal hormone levels especially on prolactin level ( $p < 0.05$ ), menstrual complaints and associated complaints thereby improvement and resolution of the ovarian cysts which was not carried out previously. Although sample size for hormonal profile of patients after treatment was small, further studies are warranted with bigger sample size as well as histopathological evaluation of the cysts for type of cysts responding to homoeopathic treatment.

Established role of homoeopathic therapy may reduce the burden of surgeries for ovarian cysts and may therefore be considered as first line of treatment before referring for the surgery.

## Conclusion

Homoeopathic treatment has a positive role in the management of ovarian cysts. The outcome of this evidence based observational study is valuable for validation of homoeopathic medicines in the treatment of ovarian cysts. It has opened new vistas in the field of clinical research in gynaecological problems. Suitably designed study with bigger sample size for extended time period is suggested for further validation of above findings.

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