

## **A CLINICAL STUDY TO EVALUATE THE ROLE OF SHIVAGUTIKA IN CYSTIC OVARIAN DISEASE**

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### **Abstract**

The human ovary has a striking propensity to develop a wide variety of tumors, the majority of which are benign. Symptoms like pain abdomen, per vaginal discharge, dysmenorrhea, dyspareunia and tenderness in fornices are common in the different varieties of ovarian cysts. The concept of Arbuda and granthi in Ayurveda mimics this condition. This article reviews the clinical effect of an Ayurvedic formulation Shivagutika on certain symptoms of cystic ovaries through clinical trials with an intention to maximize its clinical effectiveness and hasten its integration into wider clinical practice. Shivagutika was purchased from Nanjangud Sadwidyashala Mysore, Karnataka. It was administered twice daily with honey after food intake for sixty days. The signs and symptoms and the size of the cyst in cystic ovaries were graded before and during the course of treatment. In most of the cases, there was a progressive reduction in the symptoms and size of the cyst as evident in the USG with time, indicating the efficacy of the formulation in cystic ovaries.

**Keywords:** Cystic Ovarian Disease, Menstrual abnormalities, Shivagutika, Vaginal discharge.

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## **INTRODUCTION**

An ovarian cyst is an accumulation of fluid within an ovary that is surrounded by a very thin wall. Any ovarian follicle that is larger than approximately two centimeters is an ovarian cyst.<sup>[1]</sup> They can range widely in size, the majority being benign. Ovarian cysts or tumors may be functional, or pathological like inflammatory, metaplastic, or neoplastic. During the childbearing years, 70% of non-inflammatory ovarian tumors are functional. The remainder is either neoplastic (20%) or endometriomas (10%).<sup>[2]</sup>

Many women with ovarian cysts experience minor or major signs and symptoms. Cysts may interfere with conception as they alter ovulation.<sup>[3]</sup>

Arbuda and Granthi, have been explained in detail by Sushruta the pioneer in ancient Ayurvedic Surgery, and have remarkable similarities with modern interpretation of tumor and cystic growths. In modern system of medicine, the treatment for cysts depends on the size of the cyst and symptoms. Pain caused by ovarian cysts may be treated with NSAID.<sup>[4]</sup> There is a great scope of research to find out management with long lasting effect, to treat the entire feature complex with single regimen. The aim of this study is to find out a safe, potent, cost effective nonsurgical management for ovarian cysts.

## **MATERIALS AND METHODS**

The study employed a single arm before-after clinical trial design. Patients who fulfill the criteria with Cystic Ovarian Disease were assessed for signs and symptoms prior to and during the course of the treatment. The approval from the institutional ethical committee was taken (Ref. No. IMS / 153 / 2009 / 271676) and informed consent from each patient obtained.

## **Details of the drug**

Shivagutika which is explained in Rasayana Adhyaya of Chakradutta served as the trial drug in this study. Shivagutika with shilajith as its main ingredient is indicated for various types of Yoniroga, Arbuda, Pradara and considered as Rasayana. The pharmacological activity of Shilajatu shows good anti-inflammatory and analgesic properties which is recommended in Cystic Ovarian Disease. Hence it was selected as the trial drug in this study. The trial drug in this study, Shivagutika was purchased from Nanjangud Sadwidyashala Mysore, Karnataka.

## **Ingredients of Shivagutika**

The ingredients of Shivagutika are explained in Table 1.

## **Clinical study**

### **Setting and Sample**

The study population consisted of 15 subjects with Cystic Ovarian Disease. The OPD of Prasuti Tantra, served as settings for the study.

### **Inclusion and exclusion criteria**

#### **Inclusion criteria**

Patients of active reproductive/child bearing age, with symptoms of cystic ovaries such as lower abdominal pain, abnormal vaginal discharge, menstrual abnormalities and dyspareunia and infertility, who have been diagnosed to have cystic ovaries with USG evidence and are ready to undergo relevant investigations and hospital admission.

#### **Exclusion criteria**

Pregnant or unmarried women, patients suffering from any systemic disease like tuberculosis, hypertension, diabetes etc ,with

history of drug allergy and psychological disorders, patients having specific pathology of genital tract i.e. benign or malignant tumor, erosion of cervix etc, subjects with history of recent delivery or abortion and patients with large ovarian cysts with size more than 50 sq.cm.

#### **Method of administration of the drug:**

Shivagutika (500 mg) was administered twice daily with honey after food intake for sixty days.

#### **Study Variables**

The primary study variables were the following:

- 1) Clinical signs and symptoms of cystic ovaries.
- 2) USG Findings.

A clinical signs and symptoms checklist was developed to measure the presence or absence of signs and symptoms of cystic ovaries, i.e. Pain abdomen, per vaginal discharge, dysmenorrhea, dyspareunia and tenderness in fornices. Ultrasonography of Pelvic organs was carried out for assessment of the cyst size. The symptoms were noted before the treatment began.

The patients were then subjected to treatment, which included internal administration of Shivagutika (500 mg) twice daily with honey after food for sixty days. Presence (mild / moderate) or absence of each of the above mentioned signs and symptoms were then assessed after treatment.

#### **Statistical analysis**

The statistical analysis was done using paired student t test and wilcoxon signed rank test wherever applicable.

#### **OBSERVATIONS**

Among the 15 patients registered in the study, the incidence of cystic ovaries was more in the age group 31-35 yrs (32%), majority ones being house wives (85%), with larger percentage having irregular bowel habits (71%). Utmost percentage of patients were with gravidity 3 (32%), parity 2 (39%) and no history of abortion (53%). The age of menarche was 13-14yrs in 82% of patients, duration of menstrual bleeding 3-4 days in 60% of patients, amount of menstrual bleeding average in 64%. 35% of patients used barrier or safe period method for contraception. Frequency of sexual intercourse was 2-3 times/ week in 75% of patients.

Pain in lower abdomen was absent in 16%, mild in 50% and moderate in 34% of patients. Incidence of abnormal per vaginal discharge reported mild discharge in 50% of patients and moderate in 17% and absent in 33%. Pain during menstruation was absent in 42%, mild in 42% and moderate in 16% of patients. 50% of the study subjects reported with Dyspareunia whereas it was absent in the other 50%. Tenderness in fornices was absent in 50% and present in the other 50%.

#### **RESULTS**

##### **Effect of therapy on Clinical signs and symptoms of Cystic ovaries**

Pain abdomen, Per vaginal discharge, Dysmenorrhea, Dyspareunia and Tenderness in fornices showed statistically significant reduction following the treatment. The details of these are given in table 2. During the follow up, there were three dropouts and hence the statistical analysis was done for only 12 subjects.

**Table 1: Ingredients of Shivagutika**

Sl. No.	Name	Latin name	Quantity
1.	Shilajithu	Bitumen	640 g
2.	Shunti	<i>Zingiber officinale</i>	80 g
3.	Pippali	<i>Piper longum</i>	80 g
4.	Katuka	<i>Picrorhiza kurroa</i>	80 g
5.	Karkatashringi	<i>Pistacia integerrima</i>	80 g
6.	Maricha	<i>Piper nigrum</i>	80 g
7.	Vidarikanda	<i>Pueraria tuberosa</i>	40 g
8.	Talisapatra	<i>Abies webbiana</i>	160 g
9.	Vamshalochana	<i>Bambusa arundinacea</i>	20 g
10.	Patra	<i>Cinnamomum zeylanicum</i> (leaves)	20 g
11.	Twak	<i>Cinnamomum zeylanicum</i> (bark)	20 g
12.	Nagakesara	<i>Mesua ferrea</i>	20 g
13.	Ela	<i>Elettaria cardamomum</i>	20 g
14.	Sesamum oil		80 ml
15.	Sugar		640 g
16.	Ghee		160 g
17.	Honey		320 g

**Table 2: Effect of therapy on Clinical signs and symptoms of Cystic ovaries**

Criteria	Score	BT%	AT%	BT Mean±SD	AT Mean±SD	% of relief	t	P
<b>Pain abdomen</b>	0	16.66	83.33					
	1	50	16.66	1.167±0.717	0.166±0.389	80	4.690	p<0.001
	2	33.33	0					H.S
<b>Vaginal discharge</b>	0	33.33	66.66					
	1	50	33.33	0.833±0.717	0.333±0.492	50	3.317	p<0.001
	2	16.66	0					H.S
<b>Pain in Menstruation</b>	0	41.66	58.33					
	1	41.66	41.66	0.750±0.753	0.416±0.514	28	1.773	p>0.05
	2	16.66	0					N.S
<b>Dyspareunia</b>	Absent	50	75	-	-	50	Z-1.732	p>0.05
	Present	50	25					N.S
<b>Tender in Fornices</b>	Absent	50	100	-	-	100	Z-9.33	p<0.01.
	Present	50	0					S

A.T: After treatment; B.T: Before treatment; S.D: Standard deviation; H.S: Highly significant; N.S: Non significant; S: significant.

**Table 3: Effect of therapy on USG Findings**

USG	BT Mean±SD	AT Mean±SD	Z	P
Cyst size	20.41±10.66	5.58±7.80	Z-2.805	P<0.01

## Effect of therapy on USG Findings

The size of the ovarian cyst was markedly reduced in the follow up visits as compared to the initial size. Comparison of USG finding between initial and last follow up showed significant values ( $p < 0.01$ .) as stated in table 3.

## DISCUSSION

Women with symptomatic cystic ovaries commonly have pain abdomen, per vaginal discharge, dysmenorrhea, dyspareunia and tenderness in fornices<sup>5</sup>. Though majority of the Cystic ovaries are self limiting, improvement of the above mentioned symptoms and physical findings, prevention or minimization of long-term sequelae forms the major endeavor of the treatment.<sup>[6]</sup>

Shilajatu, the main ingredient of shiva gutika has kashaya (astringent), amla rasa (sour taste), katu vipaka (pungent in biotransformation), anushnasheeta veerya (not too cold in potency).<sup>[7]</sup> It is useful in alleviating tridoshas (three humours). It possess rasayana (rejuvenation), vrishya (aphrodisiac) properties.<sup>[8]</sup> It is useful in the treatment of Prameha (diabetes mellitus), Pandu (anemia), Arbuda (tumour), Granthi (cystic lesions), Gulma (palpable mass), Pleeharoga (splenic disorders), Sthaulya (obesity), Shotha (swelling), Jvara (fever) etc. It is said that there is no such disease which cannot be cured with Shilajatu.<sup>[9]</sup> Shilajatu is also used as yogavahi as it increases efficacy of many drugs. Apart from this the other drugs in shivagutika have kaphavata shamaka property. Shilajatu has significant anti-inflammatory, analgesic, immuno modulatory, antiviral and antioxidant activity.<sup>[10]</sup> The above observations states that shivagutika is a good drug of choice in the treatment of Ovarian Cysts.

## CONCLUSION

From the above clarifications it can be concluded that Shiva gutika efficiently decreases the symptoms of cystic ovaries, clinically improves the patient's condition and can be recommended in the management of Cystic ovarian diseases. Further research works on the effect of this drug in cystic ovarian diseases with larger sample size can also be taken up.

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