



# EVALUATION OF THE EFFICACY OF *GODANTI BHASMA* IN *SHWETA PRADARA* WITH SPECIAL REFERENCE OF LEUCORRHOEA- A CLINICAL STUDY.

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## ABSTRACT:-

Shwetapradara is a common disease occurring to many women and form about 10% of cases attending gynaecological clinic. According to Ayurveda vitiated vata and kapha along with dushita rasa dhatu causes dushti of Artavavaha srotas leading to per vaginal white discharge. From the pilot study Godanti Bhasma was considered to be effective in shwetapradara. To assure the quality and to provide scientific clinical data, an attempt was made with this project on “Evaluation of the efficacy of Godanti Bhasma in shweta pradar with special reference of leucorrhoea”.

60 patients of Shwetapradara, 20 in each group were taken. Godanti Bhasma with Lukewarm water was administered in Grp I, only lukewarm water in Grp II and Azostat kit in Grp III for 30 days. After 30 days of treatment all the symptoms were relieved in 90-100% of patients in Grp I. 50% of symptoms were relieved in 90-100% of patients in Grp III. Some side effects were noted in Grp III. In Pap smear report, Trichomonous vaganalisis, candida albicans and bacterial infection were found negative in Grp I and III patients after treatment, but present in all patients of Grp II. Godanti Bhasma shown significant relief of symptoms than standard drug. Its antimicrobial activity was noted and comparable to that of Azostat kit.

**Key Words:** Shweta pradara, Godanti bhasma, Leucorrhoea

## INTRODUCTION :

In present era abnormal vaginal discharge is quite frequent complaint of women in gynaecologic clinic<sup>1</sup>. Shweta pradara troubles more than 75% of women during their life. Most of the women are working, due to change in life style, food, habit, work load, faces lots of stress and strain. Women are subject to large number of complaints and connected with genital organs. Gender differences play a role in manifestation of disease and health outcomes.

The disease Shweta pradara based on theoretical and clinical symptoms can be compared to Leucorrhoea. The pathogens like Trichomonas vaginalis (94.5%), N genorrhoeae (2.7%) and C albicans (6.7%) were exclusively present in leucorrhoea<sup>2</sup>. Gynaecological complaints includes leucorrhoea, dysfunction uterine bleeding, pelvic inflammatory disease etc, among them leucorrhoea is more prevalent. The external genitalia with long tubular content is susceptible to the infectious conditions from puberty till menopause, either because of unhygienic conditions or coital and even physiologically.

Wide variety of reasons are encountered in its causation, commonly fungal, parasitic, bacterial and sexually transmitted diseases. Most secretions are regarding life cycle physiological and warrant no medical interventions. But it is significant if it is blood stained, profuse, foul smelling or changes in its colour. If not treated infection may continue for months even years and may spread to other areas of genital tract<sup>3</sup>.

Though there is an established line of treatment for leucorrhoea in the allopathic system of medicine, most of the drugs fail to cure the disease completely and recurrence is common. Many ayurvedic formulations have been evaluated clinically, and Godhanti Bhasma is one of the new drug taken up for the trial in this study.

Ayurveda is the safest curative system. There are many drugs described in ayurvedic literature for Shweta pradara among them Godhanti Bhasma is one of the most potent drug for Shweta pradara. On the basis of authentic classical references the easy availability of a drug and cost effectiveness developed interest in selecting this drug for Shweta pradara.

In present study is aimed to evaluate the efficacy of Godhanti Bhasma in the management of Shweta pradara with the view to find out therapeutically efficacious, safer, cost effective and easily available drug

### **AIMS AND OBJECTIVES:**

- To assess clinical efficacy of Godhanti Bhasma in Shwetapradara (Leucorrhoea)
- To provide a safe, alternative and economic medicine in Shwetapradara (Leucorrhoea).

### **MATERIALS AND METHODS:**

#### **Selection of patients:**

Patients attending OPD and IPD of Shri Veer Pulikeshi Rural Ayurvedic Hospital, Badami, fulfilling the diagnostic and inclusion criteria of shwetapradara were selected and registered randomly irrespective of age, sex or religion.

#### **Criteria for Diagnosis:**

Patients having signs and symptoms of shwetapradara were selected percent study. Detailed history was taken and physical examination was according special proforma incorporating the signs and symptoms of the disease.

#### **Symptoms-chief complaints**

1. White discharge p.v
2. Foul smell
3. Vaginal itching
4. Low back pain
5. Body ache
6. Lower abdominal pain
7. General weakness
8. Leg cramps/weakness of lower limb

**Inclusive and Exclusive Criteria:****Inclusion :**

1. Patients with Shwetapradara (Leucorrhoea) were selected according to the clinical features mentioned in ancient Ayurvedic text and supported with investigations.
2. Married patients between 20 to 40 age group.
3. Those who are having regular menstrual cycle.
4. Patients who are not having chronic PID, cervical erosions, Carcinomatous growth of genital organ.

**Exclusion:**

1. Patients below 20 years and above 40 years.
2. Those having chronic PID, cervical erosions, Carcinomatous growth of genital organ.
3. Patients with irregular menstrual cycle.

**Investigations:** Parameters of Shwetapradara

1. HB%
2. V.D.R.L Test
3. Urine consulate
4. Pap smear test

Before treatment all patients who are selected for study.

**Diet and Restrictions:**

1. Basic diet vegetarian and non vegetarian was noted.
2. General Physical examination to report once week during the treatment to record change in clinical symptoms up to 30 days and laboratory investigations reports were collected before and after treatment.

**Method of administration of drugs:**

	<b>Group I (Trial)</b>	<b>Group II (Control)</b>	<b>Group III (Standard)</b>
<b>Drug</b>	Godhanti Bhasma	-	Azostat kit (Fluconazole + Tinidazole)
<b>Dose</b>	250 mg two times a day		Fluconazole 150mg+ Tinidazole 1gm-single dose
<b>Vehicle</b>	Luke warm water	Luke warm water	Luke warm water
<b>Sample size</b>	20 Patients	20 Patients	20 Patients
<b>Duration</b>	30 days	30 days	30 days

**Criteria for assessment:**

The efficacy of the trial drug was analyzed in terms of the relief produced in symptoms before treatment. Assessment parameters are as follows

1. White discharge p.v
2. Foul smell
3. Vaginal itching
4. Low back pain
5. Body ache
6. Lower abdominal pain
7. General weakness
8. Leg cramps/weakness of lower limb
9. Pap Smear test

**OBSERVATIONS AND RESULTS:****1. Foul smell:**

Group-I V/s Group-II : There was significant difference in between the groups at  $p < 0.001$  ( $\chi^2 = 31.0$ ).

Group I Vs Group III : In both groups significant relief of Foul smell was noted i.e in Gr I (100%) and in Gr III (100%). therefore no statistical difference was found.

**2. Vaginal Itching :**

Group I Vs Group II : There was significant difference in between the groups at  $p < 0.001$  ( $\chi^2 = 33.0$ )

Group I Vs Group III : In both groups significant relief of Vaginal Itching was noted i.e in Gr I (100%) and in Gr III (100%). therefore

no statistical significance difference was found.

### 3. Low back pain :

Group I Vs Group II : There was highly significance in between the groups at  $p < 0.001$  ( $x^2 = 39.0$ ).

Group I Vs Group III : There was significant difference in between the groups at  $p < 0.04$  ( $x^2 = 4.34$ ).

### 4. Leg cramps / weakness of lower limbs :

Group I Vs Group II : There was highly significance in between the groups at  $p < 0.001$  ( $x^2 = 24.873$ ).

Group I Vs Group III : There was highly significance in between the groups at  $p < 0.001$  ( $x^2 = 12.982$ ).

### 5. p/v white discharge :

Group I Vs Group II : There was highly significance in between the groups at  $p < 0.001$  ( $x^2 = 28.97$ ).

Group I Vs Group III : In both groups significant relief of p/v white discharge was noted i.e in Gr I (95%) and in Gr III (90%). therefore no statistical difference was found.

### 6. General weakness :

Group I Vs Group II : There was significance difference in both groups at  $p < 0.001$  ( $x^2 = 28.326$ ).

Group I Vs Group III : In both groups significant relief of General weakness was noted i.e in Gr I (94%) and in Gr III (75%). therefore no statistical difference was found.

### 7. Bodyache :

Group I Vs. Group II : There was highly significance in between the groups at  $p < 0.001$  ( $x^2 = 26.027$ ).

Group I Vs Group III : In both groups significant relief of Bodyache was noted i.e in Gr I (94%) and in Gr III (70%). therefore no statistical difference was found.

### 8. Lower abdominal pain :

Group I Vs. Group II : There was highly significance in between the groups at  $p < 0.001$  ( $x^2 = 27.536$ ).

Group I Vs Group III : In both groups significant relief of Lower abdominal pain was noted i.e in Gr I (80%) and in Gr III (83%). therefore no statistical difference was found.

**Pap smear test:**

**In Group I :** Out of 20 Leucorrhoea patients 13 (65%) were observed infective, 7 (35%) were non infective. Out of 13 patients Trichomonas vaginalis in 3 (15%), before the treatment. After the treatment Trichomonas vaginalis was negative in all the patients 3(100%), Bacterial infection was negative in 3 (75%) patients Candida albicans was negative in patients 5 (100%) and mixed infection in 0(0%) patients.

**In Group II :** Out of 20 Leucorrhoea patients 16 patients (80%) were observed infective and 4 patients (20%) were non infective. Luke-warm water was administered as control group but Patients did not respond to treatment, so shifted to Group I after one week.

**In Group III :** Out of 20 Leucorrhoea patients 16 patients (80%) were infective and 4 (20%) non infective Trichomonas vaginalis was observed in 4 patients (20%), Bacterial infection in 9 patients (45%), Candida albicans was in 3 patients (15%), mixed infection was not present in any patients before treatment. After treatment Trichomonas vaginalis was negative in all patients (100%), Bacteria infection was negative in 8 patients (99%), Candida albicans was negative in all patients (100%).

**DISCUSSION**

Clinical study was conducted to assess the clinical efficacy of Godanti Bhasma in Shwetapradara. 60 patients of Shwetapradara, Godanti Bhasma, Lukewarm water and Azostat kit formed as materials for the clinical study.

60 patients of Shwetapradara were randomly selected and distributed 20 in each group. G.B along with Lukewarm water was administered to 20 patients in Group I for 30 days, only Lukewarm water to 20 patients in group II for 30 days as control and Azostat kit (single dose) to 20 patients in group III.

Patients were asked to report at the interval of 7 days and changes in symptoms were noted Blood for % of Hb and VDRL, Urine complete and pap smear test were recorded before and after treatment.

**Group I -** P/V white discharge was absent in 19 (95%) of patients. This may be due to Godanti Bhasma alone contents Calcium & Sulfer which checks the vaginal secretions and reduces the cell permeability and this helps in reducing the P/V white discharge.

Godanti Bhasma may act in such a way by maintaining infection.

Foul smell was absent in 11 (100%) of patients. This may be due to ingredients of G.B or responsible for maintaining vaginal pH as acidic, checks the growth of micro - organisms and thereby preventing foul smell.



Vaginal itching was absent in 15 (100%) of patients. This may be due to G.B. which checks the infection by their antifungal, antibacterial, anti inflammatory and vaso protective action and being antiseptic in nature heals the mucosal erosions and checks the small haemorrhages.

General weakness was relieved in 16 (94%) of patients due to the effect of Calcium.

Bodyache and Low back pain were relieved in 16 (94%) and 19 (100%) of patients respectively. Which may be due to Calcium.

Leg cramps was relieved in 18 (100%) of patients which may be due to Calcium.

**In Group II :** Symptoms such as p/v white discharge, Foul smell vaginal itching, Low back pain, body ache, lower abdominal pain and General Weakness leg cramps/weakness of lower limbs were not relieved. Hence all patients were shifted to group I after one week.

**In Group III :** patients were treated with Azostat kit relieved from the symptoms by the following sequence. Foul smell was absent in 17 (100%) patients, Vaginal itching in 7 (100%) patients, P/V white discharge in 18 (90%) patients, Lower abdominal pain in 15 (83%) patients, Low back pain in 16 (80%) patients, General weakness in 15 (75%) patients, Body ache in 14 (70%) patients and Leg cramps / weakness of lower limbs in 9 (47%) patients.

The above symptoms relieved may be due to selectively high activity against anaerobic organisms.

In modern medical science Tinidazole + Flucanazole (Azostat kit) is drug of choice in Leucorrhoea. It is observed that it has been effective in local manifestations and associated complaints like bodyache, low back pain, General weakness, leg cramps, anaemia remains untreated. Again it requires the combination of medicines i.e., Analgesics and anti inflammatory, General tonics, Appetizers etc. But today`s medical practitioners and patients are in need of a medicine which can cover the prime and associated symptoms manifested in leucorrhoea.

As Godanti Bhasma having antifungal, antibacterial, and anti-inflammatory and it covers the therapeutical validity of multiple drugs prescribed in Leucorrhoea. Cost effective therapeutic activity and safety concerned Godanti Bhasma may be considered as drug of choice in Leucorrhoea.



## CONCLUSION

- In Group I symptoms like foul smell, vaginal itching, Low back pain, Leg cramps or weakness of lower limbs were relieved in 100% of patients and other symptoms were relieved in 80-95% of patients.
- Symptoms were not relieved in Group II patients. Hence all patients were shifted to Group I after one week.
- In Group III symptoms like foul smell, Vaginal itching, P/V white discharge were relieved in 90-100% of patients and other symptoms were relieved in 70-80% of patients.
- Godanti Bhasma has demonstrated significant relief of symptoms in comparison to Group II and Group III.
- Godanti Bhasma was found effective in Trichomonal vaginalis, candida albicans 100%, in Bacterial infection 75% and the result was significant.
- Significant antifungal, antibacterial activity of Godanti Bhasma was noted and comparable to standard drug Azostat kit.
- After 30 days of treatment most of the infective cases of Leucorrhoea in Group I and Group III were found negative and it was significant.
- Antifungal, antibacterial, anti-inflammatory and haematenic properties are noted in Godanti Bhasma.
- Cost effective therapeutic activity and safety concerned Godanti Bhasma may be considered as drug of choice in Leucorrhoea.

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