



## Evaluation of efficacy of Ayurvedic formulation – Somha Tablets in patients suffering from Non Specific Leucorrhoea

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### Abstract:

**Objective** – The objective of the study was to evaluate efficacy of an Ayurvedic Formulation – Somha Tablets in females suffering from non-specific leucorrhoea.

**Materials & Method** – The study was an open label, non-comparative, single centre, retrospective, interventional clinical study. A total of 120 female patients between the age of 20-45 years having complaints of excessive vaginal discharge on Non-Period days causing discomfort with or without associated symptoms like Vaginal/Vulval itching, foul smell and low back/abdominal pain were recruited in the study. Participants were advised to take proprietary marketed product viz. Somha Tablets containing ingredients like *Lodhra*, *Shatavari*, *Daruharidra*, *Guduchi* etc. in a dose of 2 tablets twice daily with water for 60 days. Follow up was done at 15 days interval to assess change in symptoms associated with leucorrhoea (Itching, Foul smell, wetting of garments, Lower abdominal pain, Low back

ache, Pruritus vulva, Genital ulceration, Burning micturition), Vaginal discharge and nature of discharge. Participants having any serious abnormalities were excluded from the study.

**Results** – Female participants of average age  $26.52 \pm 5.46$  complaining of non-specific excessive vaginal discharge over a period of  $45.44 \pm 10.80$  days were recruited. A total of 95/120 participants reported of complete recovery from excessive discharge and associated symptoms at the end of 60 days of study. The mean score of vaginal discharge was  $2.06 \pm 0.25$  at baseline, which reduced to  $1.30 \pm 0.43$  ( $p < 0.05$ ) at the end of 30 days and further to  $0.52 \pm 0.51$  ( $p < 0.05$ ) at the end of 60 days. The mean score of nature of vaginal discharge was  $3.16 \pm 0.83$ , which reduced to  $1.13 \pm 0.73$  ( $p < 0.05$ ) at the end of 30 days and further to  $0.45 \pm 0.13$  ( $p < 0.05$ ) at the end of 60 days. Other associated symptoms like itching, abdominal pain/backache and foul smelling also showed significant reduction with 60 days

use of Soma Tablets. None of the participants showed worsening in their condition. No adverse drug reaction was observed and the study products were well tolerated.

**Conclusion-** Ayurvedic tablets (Somha) was found to be effective in significantly reducing excessive vaginal discharge (non-specific) and its associated symptoms. The product was also found to be safe without causing any adverse effects.

**Keywords** – Non Specific Vaginal Discharge, Somha Tablets

#### **Introduction –**

Normal Vaginal discharge is a physiological condition that serves an important housekeeping function in the female reproductive system. The discharged fluid secreted by glands inside the vagina and cervix carries away dead cells and bacteria in the vaginal and uterine regions thus helping in keeping the vagina clean and preventing infection<sup>(1-3)</sup>. While most of the time, vaginal discharge is normal, the amount of discharge can vary, as can odour and colour (which can range from clear to a milky white), depending on the time of menstrual cycle viz. excess discharge can occur when ovulating, breastfeeding, or sexually aroused<sup>(1-5)</sup>. While this discharge may be physiological required for lubrication, if the colour, smell, or consistency is different than usual, and is associated with vaginal itching or burning, then there may be chances of infection or other disease conditions.

Leucorrhoea is the most commonly experienced condition of women of reproductive age characterized by thick, whitish, yellowish or greenish vaginal

discharge<sup>(6)</sup>. The condition can be embarrassing for women and may even lead to psychological impact. The most common cause of leucorrhoea is physiological, followed by vaginal infections due to bacteria, virus, fungi and parasites and hormonal irregularities<sup>(6)</sup>. Other causes include foreign bodies, cervicitis and atrophic vaginitis<sup>(7,8)</sup>. Leucorrhoea can be quite an uncomfortable condition for women due to symptoms such as intense itching of the vulva, yellowish or fish-like smelly discharge, vaginal bleeding in between two menstrual cycles; and severe pain in the abdomen. This condition can be quite embarrassing if characterised by foul-smelling vaginal discharge<sup>(9,10,11)</sup>. Leucorrhoea can often be a pointer to various gynaecological conditions and infertility, and hence requires evaluation and treatment. Treating the underlying cause is important for the successful management of Leucorrhoea. The treatment modalities include use of antibiotics, or antifungal drugs depending on the causative organism<sup>(2,12)</sup>.

The present study presents the effect of an Ayurvedic Proprietary formulation viz. Somha Tablets manufactured and marketed by Gynoveda in females suffering from non-specific Leucorrhoea.

#### **Objectives:**

The current in-clinic response study is aimed to evaluate the therapeutic effect of Somha Ayurvedic Tablets in Patients suffering from non-specific leucorrhoea.

#### **Materials & Methods**

##### **a. Study design –**

Retrospective, open labelled, single centric, non comparative clinical study.

### **b. Sample size –**

A total of 120 participants were reviewed who had been prescribed Somha Tablets for non-specific leucorrhoea for a period of 60 days.

### **c. Study site –**

Patients visiting OPD of Dhanwantari Ayurveda Centre, Pallakad, Kerala, India, who were recommended Somha Tablets were considered for analysis in this study.

### **d. Details of study product**

i. Name of the Product – Somha Ayurvedic Tablets manufactured and marketed by Gynoveda Pvt. Ltd as Ayurvedic Proprietary Medicine

ii. Key Ingredients - *Lodhra, Shatavari, Daruharidra, Guduchi* etc. Detailed composition in Table.

iii. Recommended dosage – 2 Tablets two times a day with warm water after meals for a period of 60 Days.

### **e. Inclusion criteria –**

Non-pregnant, non-breastfeeding females between the ages of 20 and 45 years, (both inclusive), presenting with complaints of moderate grade Vaginal white discharge (moderate discharge, 3-4 days in a week, required change of undergarments once daily), from last 15 days and not currently menstruating or expected to in the next 4 days were included in the study.

### **f. Exclusion criteria –**

Patients suffering from bacterial vaginosis (Purulent discharge with fishy smell) as per Investigator's opinion or those who had used prescribed medications (oral or topical

antibiotics including metronidazole, clindamycin, tinidazole etc. Anti-fungal drugs including clotrimazole and ketoconazole etc.) for vaginal complaints in the past 2 weeks were excluded from the study. Patients on Oral Contraceptive Pills or IUCD (Intrauterine Contraceptive Device) for the last one month. Also patients with history of significant per vaginal bleeding over the last 1 month or having prolapsed uterus were excluded from the study. Any other condition due to which patients were deemed unsuitable by the investigator for reason(s) not specifically stated in the exclusion criteria. Patients suffering from any acute or chronic medical or surgical condition requiring regular and continuous medical care and management were excluded from the study. Patients who were non compliant to the study requirement (like not taking regular medicines) were also excluded from this evaluation.

## **Observations & Results –**

### **A. Baseline demography –**

A total of 120 patients were considered for assessment of efficacy and safety in the study. Female participants of average age  $26.52 \pm 5.46$  (range 20 to 45 years), complaining of excessive vaginal discharge over a period of  $45.44 \pm 10.80$  days were recruited. The mean weight of participants at baseline was  $56.14 \pm 7.29$  with an BMI of  $23.25 \pm 2.95$ . A total of 82 participants (68.33%) were married while 38 participants (31.66%) were unmarried. A total of 92 patients (76.66%) had a history of Leucorrhoea in the past and had taken treatment for the same.

**Table 1– Baseline demography**

Parameter	Values
Average age	26.52 ± 5.46 (range 20 to 45 years)
Average Weight	56.14 ±7.29 in Kg
Average BMI	23.25 ±2.95 Wt in Kg/Ht in m <sup>2</sup>
Married Participants	82(68.33%%) N
Unmarried Participants	38 (31.66%) N
Average time since having Leucorrhoea	45.44 ± 10.80 days
History of Leucorrhoea in Patients	92 (76.66%)
Itching (in days)	36 ±9.64
Foul Smell (in days)	22.10 ±8.75
Wetting of Garments (in days)	48.13 ±3.53
Lower Abdominal Pain (in days)	41.43 ±8.93
Low Back Ache (in days)	53.07 ±5.05
Burning Micturition (in days)	24.10 ±3.42

### B. Assessment of Vaginal Discharge (severity and nature) :

Vaginal discharge was graded on a scale of 1-3 (1= scanty (small quantity of discharge, 1 or two days in a week, did not require change of undergarments), 2=moderate (moderate discharge, 3-4 days in a week, required change of undergarments once daily), 3=profuse (profuse discharge almost every day in a week, required change of undergarments 2 to 3 times in a day). The mean score of vaginal discharge was 2.06 ±0.25 at baseline, which reduced to 1.30 ±0.43 (p<0.05) at the end of 30 days and further to 0.52 ±0.51 (p<0.05) at the end of 60 days.

Nature of vaginal discharge was graded on scale of 1-4, 1= purulent, 2= frothy, 3 =Curdy white, 4=Watery discharge. The mean score of nature of vaginal discharge was 3.16 ±0.83, which reduced to 1.13 ± 0.73 (p<0.05) at the end of 30 days and further to 0.45 ±0.13 (p<0.05) at the end of 60 days.

**Table 2: Assessment of Vaginal Discharge (Severity and Nature)**

Symptom	Baseline Visit	Day 30	Day 60
Vaginal Discharge (Severity)	2.06 ±0.25	1.30 ±0.43*	0.52 ±0.51*
Nature of Vaginal Discharge	3.16 ±0.83	1.13 ± 0.73*	0.45 ±0.13*

\*p<0.05 (Significant)

### C. Assessment of proportion of subjects and number of days required for change in the symptoms, discharge and nature of discharge:

At baseline visit, a total of 75 subjects reported itching, which was completely alleviated in 66 subjects at the end of the study while 9 subjects showed reduction in itching but still had mild itching. 45 subjects had foul smell, which was completely alleviated in 42 subjects at the end of the

study while 3 subject reported of reduction though not complete absence of foul smell. All the 120 subjects had wetting of garments at baseline visit, which was completely alleviated in 87 subjects at the end of the study while 33 subjects showed reduction in the symptom though not completely. At baseline visit 83 subjects had lower abdominal pain, of which 60 subjects reported of complete relief while 23 subjects reported of reduction in symptom at the end of the study. At baseline visit, 95 subjects reported low backache, of which 55 subjects reported of complete relief while the other 40 subjects reported of reduction in their

symptom at the end of the study. At baseline visit, 28 subjects reported burning micturition, of which 14 subjects reported of complete relief while 14 subject showed mild improvement in their symptoms. Further analysis for the number of days required for complete cessation or reduction of symptom observed that the average no of days required for itching to subside was  $21.90 \pm 7.43$  days, for foul smell it as  $19 \pm 6.37$  days, for wetting of garments it was  $22.42 \pm 7.48$  days, for Lower abdominal pain it was  $24.61 \pm 7.76$  days, for low back ache it was  $25.90 \pm 7.15$  days, and for burning micturition it was  $20.59 \pm 6.52$  days.

**Table 3- Proportion of subjects for symptoms assessment over 60 days**

Symptoms	No of subjects with symptom at baseline	No of subjects showing complete cessation of symptom after 60 days	No of subjects showing reduction in symptoms
Itching	75	66 (88%)	9 (12%)
Foul Smell	45	42 (93.33%)	3 (6.66%)
Wetting of Garments	120	87 (72.5%)	33 (27.5%)
Lower Abdominal Pain	83	60 (72.28%)	23 (27.71%)
Low Back Ache	95	55 (57.89%)	40 (42.10%)
Burning Micturition	28	14 (50%)	14 (50%)

**Table 4: Number of days required for change in symptom over 60 Days**

Symptoms	No of days required for complete cessation or reduction
Itching	$21.90 \pm 7.43$
Foul Smell	$19 \pm 6.37$
Wetting of Garments	$22.42 \pm 7.48$
Lower Abdominal Pain	$24.61 \pm 7.76$
Low Back Ache	$25.90 \pm 7.15$
Burning Micturition	$20.59 \pm 6.52$

**D. Assessment of adverse effects –**

None of the patients experienced any adverse drug reaction due to the consumption of Somha Tablets in a dose of 2 tablets twice daily over a period of 60

days. The vitals assessment of pulse, respiration rate, blood pressure and temperature also did not show any significant difference and the levels were

within normal range throughout the study period.

### Discussion –

Management of Leucorrhoea requires medications that have potent anti-inflammatory, anti-microbial, astringent and hormone balancing activity. Along with this medications that help to improve the levels of Iron and Calcium in the body also are helpful in the management of Leucorrhoea. The results of the present study indicate that Somha Tablets was significantly effective in relieving symptoms of leucorrhoea. Ingredients of Somha Tablets such as *Udumber*, *Aswattha* etc. exerts antibacterial activity against both gram-positive and gram-negative bacteria<sup>(13)</sup>. Due to astringent and haemostatic properties, *Ashoka*, *Lodhra* and *Khadira* are useful in the management of vaginal discharge, leucorrhoea and menorrhagia<sup>(14)</sup>. *Daruharidra* and *Kumari* are useful in reducing leucorrhoea and provide relief from associated symptoms of leucorrhoea such as vaginal irritation, pain and itching. Astringent action of *Nagkesar* makes it useful in the management of vaginosis<sup>(15)</sup>. *Hirabola* possesses uterine stimulant, analgesic, antipyretic, anti-inflammatory antioxidant, antibacterial, and antifungal activities<sup>(16)</sup>. *Shatavari* and *Ashwagandha* helps to decrease inflammation of sexual organs and normalizes uterine function<sup>(17)</sup>. *Ashoka* possesses antimicrobial, analgesic, anti-inflammatory and astringent activities<sup>(18)</sup>. The astringent activity of *Saraca indica* (*Ashoka*) is considered to be useful in arresting excessive abnormal vaginal discharge. Also, *Ashoka* exerts antimicrobial

activity in vaginal candidiasis, trichomonas and bacterial vaginosis<sup>(19)</sup>. These multiple activities of ingredients of Somha act synergistically to relieve leucorrhoea and associated symptoms. Ingredients like *Loha Bhasma*, *Kukkutanda Twak Bhasma* act as natural sources of iron and calcium and thus are useful in the management of Leucorrhoea<sup>(20)</sup>.

It was evident from the results of the study that Somha Tablets were well tolerated as there were no adverse drug reactions reported in any of the subjects. Vital parameters like pulse rate, respiration rate, body temperature and blood pressure were within normal range at all visits during the study. These results indicate that Somha Tablets are safe to be used in patients suffering from leucorrhoea.

### Conclusion –

The present study concludes that Somha tablets are effective in the management of non-specific Leucorrhoea. Somha tablets not only help to reduce excessive vaginal discharge but also provide relief from the symptoms associated with leucorrhoea. Also Somha tablets were found to be safe without producing any adverse effects. Controlled, randomized studies on larger populations need to be carried out to establish the efficacy.

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