

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF ASHWAGANDHADI
YOGA IN THE MANAGEMENT OF SHWETA PRADARA W.S.R. TO
LEUCORRHOEA

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ABSTRACT-

Introduction- Vaginal discharge is a common feature that affects all age group of women worldwide. *Shweta Pradara* (white vaginal discharge) is defined as excessive secretion from the female reproductive tract especially from the vagina, cervix or both that can be equated with Leucorrhoea in Bio-medical Science. Recurrence of this condition is a common phenomenon making it a major concern worldwide. **Material & Methods-** The present clinical study was aimed to evaluate the efficacy of *Ashwagandhadi Yoga* mentioned in *Siddha Yoga Sangreh* in the management of *Shweta Pradara*. This single blind clinical study was conducted on 30 patients selected randomly from OPD & IPD of M.M.M Govt Ayurveda College, Udaipur (Rajasthan). *Ashwagandhadi Yoga* in the dose of 2gm with Cow milk as *Anupana* for duration of 2 months was given to all the patients with follow up after every 15 days. The statistical analysis was done using Graph Pad InStat 3 and Mean Difference (MD), Standard Deviation (SD) and Standard Error (SE) of symptoms/variables were calculated for 30 patients. **Results-** Results showed statistically significant difference in the patients before and after the treatment with the trial drug. **Conclusion-** *Ashwagandhadi Yoga* can be used as an effective treatment modality for *Shweta Pradara*.

KEYWORDS- *Ashwagandhadi Yoga*, Leucorrhoea, *Shweta Pradara*, Vaginal Discharge

INTRODUCTION- Vaginal discharge is a common feature that affects all age group of women worldwide. Today's stressful modern life styles, food habits, social status, occupation etc. affect the local environment along with psychological status of the female causing higher

incidences of Leucorrhoea. Usually it occurs in unhygienic conditions, but can also be occurred followed by mismanagement of some obstetrical and Gynaecological procedures causing infection like, bacteria, fungi and protozoa etc. Recurrence also is a common phenomenon; it could be embarrassing, painful and may cause lot of discomfort, stress and even affect the sexual preferences and libido. It may be mild to severe, and varies from person to person.

The World Health Organization estimated that there are 333 million new cases of curable Vulvovaginal infection (VVI) added per year. A Survey study in India has shown that the prevalence of reproductive tract infections was 37.0% based on symptoms and 36.7% by laboratory investigations, including 31% Candidiasis, 3% Gonorrhoea, 2% Trichomoniasis and 45% Bacterial vaginosis.(1) This disease was recognised thousands years ago by the ancient therapists in the ancient societies like India, Greece and China. Most of the Ayurvedic classics accepted this condition as *Shweta Pradara* which is as a symptom of various *Yonivyapat*. (2)

According to the health statistics given by CMDR-Centre for Multi-Disciplinary Development Research in accordance with Rural Welfare Trust, the prevalence of reproductive tract infection in India is 29.7% and prevalence of vaginal discharge in India is estimated to be 30%. Abnormal vaginal discharge also predisposes to significant morbidity in the form of pelvic inflammatory diseases, infertility, endometriosis, urethral syndrome, pregnancy loss, preterm labour etc. (3,4,5) That's why it is necessary to pay immediate attention towards this most troublesome problem as the management of this disease is merely insufficient in other systems of medicine and patients are continuously looking with a hope towards *Ayurveda* to overcome this challenge as most of the drugs fail to cure the disease completely and recurrence is common.

AIMS AND OBJECTIVES:-

- To evaluate the pharmacological efficacy of trial drug *Ashwagandhadi Yoga* in the management of *Shweta Pradara* (Leucorrhoea).
- To compare the results before and after treatment in all the patients.

Ethical Clearance- As this was a clinical study, Institutional Ethics Committee approval was taken prior to initiation of research wide letter no.-DSRRAU/MMM/IEC/116-17/530.

Materials and Methods- *Ashwagandhadi Yoga* indicated in the management of *Shweta Pradara* as per the reference of *Siddha Yoga Sangreh* was prepared in the Pharmacy of M.M.M Govt. Ayurveda College, Udaipur (Rajasthan). (6) Detailed ingredients of trial drug are listed in Table no. 1

Table no. 1 – Ingredients of *Ashwagandhadi Yoga*

S.No.	Name of the Drug	Quantity
1	Ashwagandha (<i>Withania somnifera</i>)	8 parts
2	Vidhara (<i>Argyrea nervosa</i>)	8 parts
3	Mishri	8 parts
4	Ela (<i>Amomum sublatum</i>)	2 parts
5	Kukutanda Twak Bhasma (Egg shell)	2 parts

6	Vanga Bhasma	1 Part
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Study Design- The study was conducted on total 36 patients, in which 30 patients have completed the treatment and 6 patients could not complete the treatment and got LAMA all along the study period. It is a single blind clinical study of *Ashwagandhadi Yoga* on *Shweta pradara* disease in women with pre-test and post-test design. A special performa was prepared with all points of history taking, physical signs and lab investigations included. The parameters of sign and symptoms were scored on the basis of standard method of statistical analysis.

Duration and Method of Administration of the drug:

- ❖ *Matra-2 masha*
- ❖ Dose form-*churna*
- ❖ *Anupana-go-dugdha*
- ❖ Duration-2 months
- ❖ Patient was examined and repetition of drug was done in the interval of each 15 days.
- ❖ The patients were assessed before and after treatment as per assessment criteria.
- ❖ The nature of the study was explained to the patients in detail and pre-treatment Consent was taken.
- ❖ The patients had full rights to withdraw from the study.

Selection of Patients- For the clinical study patients of *Shweta pradara* with confirmed diagnosis were taken randomly from the OPD & IPD of *Prasuti tantram* department, M.M.M Govt. Ayurveda College, Udaipur (Raj). Patients were selected for the study as per following criteria:-

Inclusion Criteria:-

- 1- Menarche women
- 2- Excessive white/yellowish vaginal discharge, with and without other associated symptoms like, *Yoni kandu, Yonidurgandh, Katishul, Yonidaha, Daurbalya, Mutradaha* .

Exclusion Criteria:-

- 1- Girls below menarche age .
- 2- Pregnant women and lactating mothers.
- 3- Any other chronic illness like- Carcinoma of cervix, uterine fibroid.

Criteria for diagnosis: Patients were examined thoroughly both symptomatically and clinically (per vaginal examination).

Criteria for the assessment-

Subjective Parameters-

Table no. 2- Yonigata Atyadhika shweta/pitabh Srava (Excessive White/Yellowish Vaginal discharge)

Grade	Symptom
0	No discharge
1	Frequent excessive vaginal discharge
2	Moderate excessive vaginal discharge (i.e. soiling the undergarments)

3	Severe excessive vaginal discharge (Patient needs to use of pads)
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Table no. 3- Yonikandu (Vulval Itching)

Grade	Symptom
0	No itching
1	Mild Itching (Itching urges occasionally)
2	Moderate Itching (Itching urges continuously)
3	Severe Itching (Making patient irritable with ulceration in vulva and vagina)

Table no. 4- Yonidurgandh (Foul smelling)

Grade	Symptom
0	Non-offensive
1	Mild (Occasional/ Periodic bad smell)
2	Moderate (Continuous bad smell throughout the month)
3	Severe (Continuous foul smell, Intolerable)

Table no. 5- Yoni Vedana

Grade	Symptom
0	Absent
1	Mild pain (only feeling of discomfort)
2	Moderate (occasional pain)
3	Severe (continuous pain)

Table no. 6- Katishoola (Backache):

Grade	Symptom
0	Absent
1	Mild pain (on and off slight pain)
2	Moderate pain (pain during work)
3	Severe pain (continuous even on rest)

Table no. 7- Daurbalaya

Grade	Symptom
0	No Weakness
1	Mild (Patient is able to involve in routine activity)
2	Moderate (Patient is slow to involve in routine activity)
3	Severe (Patient feels exhausted to involve in routine activity)

Table no. 8- Mutra daha (Burning Micturation)

Grade	Symptom
0	Absent
1	Mild (Occasional feeling of Burning Micturation)

2	Moderate (continuous feeling of Burning Micturition)
3	Severe (Patient wants to avoid Micturition)

Objective Parameters: Assessment of the therapy was also carried out by comparing the B.T. and A.T., Values of Routine Haematological, Urine Routine & Microscopic investigations and Microscopic examination of wet vaginal smell.

CRITERIA FOR THE ASSESSMENT OF OVER ALL EFFECT OF THE THERAPY:

To evaluate percentage of improvement in each parameter, total is done of scores observed before treatment (B.T.) and after treatment (A.T.). Average of respective scores is calculated and then percentage of change / improvement is calculated by following formula:

Table no. 9- Overall assessment of therapeutic effect

1	Unchanged	0- 25%- No change in sign and symptoms
2	Mild Improvement	26-50% -relief in the sign and symptoms
3	Moderate Improvement	51-75% -relief in the sign and symptoms
4	Markedly Improve	76-99% -relief in the sign and symptoms
5	Completely cured	100% -relief in all sign and symptoms

Investigation:-

- 1-Routine pathological investigation of haematology-Hb%, TLC, DLC, ESR
- 2-Urine test- Rountein and Microscopic
- 3-Pap smear test (if required).

Statistical Analysis- The statistical analysis of clinical efficacy of the drug was done on the basis of all symptoms mentioned in the assessment criteria by using Graph Pad Instat 3. For providing data in numerical values, Mean Difference (MD), Standard Deviation (SD) and Standard Error (SE) of symptoms/variables were calculated for 30 patients. Initially the variation and significance of effect seen within all the patients were calculated by using paired t test for finding p value.

- p value< 0.001 means Highly significant
- p value< 0.05 means Significant
- p value> 0.05 means Not Significant

Table no. 10- Showing the pattern of clinical recovery in 30 patients of leucorrhoea

<i>Lakshana</i>	Mean			% of Relief	± S.D.	S.E.	P value	P-value	Result
	B.T.	A,T.	D						
<i>Yonisrava</i>	2.300	0.366	1.933	84.04	0.639	0.116	.0028	P<0.0001	E.S.
<i>Yonikandu</i>	1.733	0.300	1.433	82.68	0.727	0.132	0.196	P<0.0001	E.S.
<i>Yonidurgandha</i>	1.400	0.133	1.267	90.50	0.639	0.116	0.027	P<0.0001	E.S.
<i>Yonivedana</i>	1.500	0.166	1.333	88.86	0.606	0.110	0.004	P<0.0001	E.S.
<i>Katishoola</i>	2.233	0.400	1.833	82.19	0.746	0.136	0.031	P<0.0001	S.
<i>Daurbalya</i>	1.767	0.166	1.600	90.54	0.724	0.132	0.204	P<0.0001	N.S.

<i>Mutradaha</i>	1.333	0.133	1.120	84.21	0.610	0.111	0.001	P<0.0001	V.S.
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Table no. 11- Effect of Therapy on laboratory parameters

Lab parameters	P value	Result
Haemoglobin %	(P < 0.005)	Very significant
ESR	(P >0.05)	Non-significant
TLC	(P >0.05)	Non-significant
DLC neutrophils	(P < 0.05)	Just significant
Eosinophils	(P >0.05)	Non-significant
Lymphocyte	(P < 0.05)	Just significant
Monocyte	(P >0.05)	Non-significant
Basophils	(P >0.05)	Non-significant

Table no. 12- Effect of Therapy On Urine Examination:

Urine examination	P value	Result
Urine pus cells	(P >0.05)	Non-significant
Urine epithelial cells	(P >0.05)	Non-significant
Urine Albumin	(P >0.05)	Non-significant

Discussion- The clinical study was carried out on 30 patients of *Shweta Pradara*. The patients were selected randomly irrespective of age, sex, religion etc. Each patient was thoroughly examined on the basis of duly prepared research Performa taking subjective parameters listed in Table no. 2- 8 and overall effect of therapy was taken as listed in Table no. 9. Discussion on their observation & results are following-

Discussion on Demographic profile:

Age- It was found that maximum 73% patients belonged to age Group of 21-40 years. The remaining 23% belonged to age group 41 – 60 years and 3% of patients belonged to age group 14-20 years of age group.

Religion- The study of religion wise distribution of patients shows that maximum 86% patients were Hindu while 13% were Muslim.

Education- The study of Education wise distribution of patients shows that maximum 50% patients were graduated, while 20% were hsc, 16% patients were educated up to matric, remaining 2% post graduate .

Occupation- On considering the nature of occupation, it was found that 70% patients were housewives, while 16% patients were in govt service and 1% were in labour and 6% is student.

Marital status wise distribution- It is evident from above table that maximum numbers of patients 46% patients were married and 20% was unmarried respectively.

Socio- economic status- The study of Socio-economic status wise distribution revealed that the Maximum numbers of patients i.e. 63% were belonging to middle class followed by 3% of poor and 30% were of higher class.

Kostha- The present study shows that maximum number of patients i.e. 50% was having *madhyam kostha*, 13% were having *mridu*, and 36% patients were having *krura kostha*.

Regularity of Menstrual cycle- It was found that out of 30 patient maximum i.e.80% were patients having regular menstrual cycle, while rest of patients i.e. 20% were having irregular menstrual cycle.

Amount of Menstrual blood loss- On considering the amount of menstrual blood loss, it was found that maximum i.e. 60% patients had moderate amount of menstrual blood loss, 26% of patients had scanty while 13% of the patients had excessive amount of menstrual loss.

Parity- The present clinical study reveals that, 70 % of the patients were having 1-3 parity while 1% and 0% were having 4-6 & 7-9 parity respectively.

Abortion- The data of abortion shows that 93% patients had history of no abortion while 6% patients had 1-2 and 0% had 3-4 previously.

Dashvidha Pariksha- Patients examination according to *Dashvidha Pariksha* has been worked out as per classical description in *Charak Samhita*. On this basis maximum patients showed predominance of *vatakaphaj prakriti* 50%, 23% showed *vata pittaj* 26% *kaphapittaj prakriti*. In relation to *manas prakriti* maximum 100% are of *rajsika prikriti*. Most of the patients *satmya* is *sarvarasa*. Patient with *madhyam satva* is 86%, *avara* are 10% rest have *prava satva*. Patient with *madhyam samhanana* are 96%, 3% have *pravara satva* rest have *avara samhanana*. Patient with *madhyamahara Shakti* are 90% and 20% have *avara satva*.

Associated Complaints/Anubandhalakshana- It has been found that out of 30 patients of *Shweta pradar* 93% patients had *Yoni Kandū*, *Mutra Daha* and *Yoni daurgandhya*, 96% patients had *Yoni Vedana*, 100% patients had *Katishoola* and *Daurbalyata*.

Dysmenorrhoea & Character of Menstrual flow: 71 % patients had pain during menstruation. The data reveals almost normal statements and probable cause could not be made.

Discussion on Prasava vritta (obstetric history)-

Obstetric history: In the present study 78% of patients were having 1-3 children, 15% and 2% were having 4-6 & 7-9 children respectively, this disease is more found in the multiparous women, Moreover 88% patients had Full Term Normal Delivery (FTND) while history of two or more than two abortions was found in 18% and 5% of patients, 30% patients had done their delivery at home. Above data revealed that improper management, repeated deliveries and abortion may have lead to weakening of the muscle tone of vagina as well as destruction of its physiological defence mechanism were more prone to *Shweta pradar*.

Coital History: In the present history it was found that maximum 60% patients were having complaints of dyspareunia. Frequent coitus done which may altered vaginal defence, could

also be one of the predisposing factors of vaginal discharge.

Discussion on Gynaecological Examination:

Per speculum & Per vaginal examination observation: During per speculum examination, 50% patients had normal (healthy) vagina, 40% patients had oedematous and 7% had hypertrophic vagina. In cervical examination, 68% patients had oedematous cervix and 27% had normal cervix. 36% patients had moderate discharge and 47% had excessive vaginal discharge, 92% patients had *shwetabha* colour of discharge & 8% patients had *pitabha* colour of discharge, 62% patients had odour in discharge. 45% patients had *Dadhivata* character of discharge, 40% had *pichchila* type of discharge and 15% had *jaliya* type of discharge. (Table no. 5.1.38)

During per vaginal examination, 90% patients had normal vulva, and 7% had inflammation in vulva, 68% patients had normal vagina and 32% had tenderness in vagina, the consistency of cervix was found firm in all patients., The revealed data shows that patients were found the excessive white vaginal discharge due to some physiological and some pathological origin. The data are evidence of active lower reproductive tract infection in some of the patients on per speculum & per vaginal examination.

Discussion on Mukhya vyadhi vritta (chief complaints):

Chronicity/ Duration of complaints: Majority of the patients i.e. 60 % had been suffering from 1-10 years, and 32% from 1-12 months, Chronicity of any disease makes it *Krichhsadhya*. So treatment become more difficult.

Discussion on Effect of therapy(result):

Laboratory parameters:

Haemoglobin %: Regarding the Hb %, very significant result ($P < 0.005$) was observed in patients. The trial drug showed better percentage of relief in Hb % i.e 7.14.

On ESR: Regarding the ESR, non significant result ($P > 0.05$) was observed .

TLC: Regarding the TLC, Non significant result was observed.

On DLC: Regarding the Neutrophills & Lymphocytes, just significant result ($P < 0.05$) was observed the trial drug showed better percentage of relief in Neutrophills i.e. Regarding the Monocytes, non significant result ($P > 0.05$) was observed. Regarding the Eosinophills & Basophiles, non significant result ($P > 0.05$) was observed.

Urine Examination: Regarding the Urine pus cells, Urine epithelial cells & Urine Albumin, non significant result ($P > 0.05$) was observed in study.

Conclusion- On the basis of results obtained it can be concluded that *Ashwagandhadi Yoga* can be used as palliative treatment in the management of *Shweta Pradara* without any adverse effects.

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