
A Single Arm Controlled Clinical Trial to Study the Efficacy of Nagkeshar Choorna with Takra in Swetapradara WSR to Leucorrhoea

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ABSTRACT

Gynaecology is the study of female reproductive system and their diseases. In Ayurveda majority of Gynaecological disorders have been described under the heading of “Yonivyapad”. Out of all Yonivyapad, most of yonivyapad have common symptom such as vaginal white discharge. In Ayurveda, it is termed as “Shwetapradara”. Women are going towards so many unwholesome life styles wearing tight clothes, not maintaining proper hygiene due to fast living modelities. In today’s fast moving competitive and mechanical life woman not only takes care of her family but also supports it financially by working outside. Hence, they tend to neglect taking care of their own health problems. The vaginal area remains constantly wet and it comes in contact with so many body fluids such as vaginal discharge, urine and menstrual flow etc, so this part is more prone to infections resulting into Leucorrhoea type symptom. Female genital system from Introitus to Uterus is described in Ayurveda as Tryavarta Yoni. Rajovahasrotas, which is Bahirmukhasrotas, due to which, it is more prone to the exogenous infections. Leucorrhoea is one of the symptoms which is well known as “Shwetapradara” in Ayurveda. Patients suffering from this have complaints of vaginal white discharge, Backache, General debility, constipation, headache. In Ayurveda, Shwetapradara is described as caused by vitiation of kapha and vata dosha in body. Although it seems to be negligible symptoms initially, if it is not treated in time it leads to many major complications. Ayurveda provides many alternatives which not only cure the disease but also prevent their recurrences. In Ayurveda it gives so many formulations to treat shwetapradara. One such formulation is selected in the present study. A Clinical Trial was carried out on 60 patients detected with Shwetapradara. They were treated with Nagkeshar choorna with Takra thrice daily for 7 days. Signs and Symptoms was observed before and after treatment. The drugs were prepared in the College Pharmacy and the Research was conducted in the PTSR OPD of our institute of which we got satisfactory results of 50 – 75%.

INTRODUCTION

Shwetapradara is one of the common symptoms in OPD. This vaginal white discharge happens due to aggravation of Kapha dosha in female body. Aggravated kapha contaminates the vagina and produces stickiness and thick white discharge. Shwetapradara is generally understood as leucorrhoea, a common gynecological symptom which troubles many women during their life. Vaginal discharge is the most frequently narrated complaint of woman in reproductive age. It constitutes considerable problems for many women causing discomfort and anxiety affecting the quality of life of a woman. Some vaginal discharges are normal but could vary with age, use of contraceptives, menstrual cycle with changing oestrogen levels.

In Ayurvedic literature, Leucorrhoea is not mentioned as disease entity. However, White vaginal discharge is quoted as symptom in multiple gynecological problems. Sometimes, this symptom is so severe that it overshadows the actual disease and women seek for the treatment of only this symptom. In India, vaginal white discharge is one of the commonest

symptoms reported by women. Vaginal discharge happens in regular variation of amount and consistency during the course of menstrual cycle. A greater than usual amount is normal in pregnancy and decrease is to be expected after delivery, during lactation and menopause.

Excess of vaginal white discharge involving infections like candida, trichomonas, gram-negative, gram-positive organisms may necessitate its management. Leucorrhoea neither causes mortality nor morbidity. In susceptible women, it is accountable to cause great extent of mental stress, problems of sexual anxiety and sometimes even fear of carcinoma. It also causes local inconvenience to the patients. It is well noted that the lower genital tract infection may lead to pelvic inflammatory disease, infertility, and other obstetrics complications like premature labour, preterm rupture of membrane [PROM], intrauterine infection and perinatal complications but because of busy life and laziness, people are neglecting this, so study on this topic was carried out.

Management of Shwetapradara in classic text has been described by using Kaphahar chikitsa, therefore in present study, Nagkeshar churna with Takra which has properties like kaphaghna and durgandhanashak has been selected for study which is easily available & easily administrable.

Leukorrhea or (**leucorrhoea** British English), also known as **fluor albus**, is a thick, whitish, yellowish or greenish vaginal discharge.[1][2] [3] It has also been referred to as "**the whites**".[4] There are many causes of leukorrhea, the usual one being estrogen imbalance. The amount of discharge may increase due to vaginal infection and it may disappear and reappear from time to time. This discharge can keep occurring for years, in which case it becomes more yellow and strong-smelling. It is usually a non-pathological symptom secondary to inflammatory conditions of the vagina or cervix.[5]

CAUSES

Leucorrhoea is a condition that does not have a sudden acute onset. It refers to general toxic condition of the female genital system. Leucorrhoea may affect one or more organs of the female reproductive system. Whenever there is an abnormal accumulation of toxins in the body because of unhealthy eating habits, organs like kidney, bowels, and skin find it difficult to expel these toxins from the body. As a result, the body tries to expel these toxins in the form of foul smelling and thick vaginal discharge.

In cases of chronic leucorrhoea, the vaginal discharge may be white, yellow or even greenish and accompanied by pus. Some of the common causes of leucorrhoea includes:

- Hormonal imbalance.
- Conditions like monilial vaginitis, trichomonal vaginitis.
- Bacterial and fungal infection.
- Irritation due to contraceptives that are inserted into the vagina.
- Irritation due to external contraceptives used by either partner.
- Improper lifestyle and unhealthy eating habits.
- Poor genital hygiene.
- Genital wounds caused by excessive itching.
- Stress and anxiety.

Leucorrhoea may occur in young girls during the years before and after the onset of menstruation. In such cases, leucorrhoea could be the result of irritation of the genitals caused

by factors like dirt, Intestinal worms, wet or damp undergarments or masturbation. In young women, leucorrhoea generally occurs between menstrual periods when the mucus membrane thickens. This kind of leucorrhoea causes painful menstruation and other menstruation problems. In older women, leucorrhoea may be a result of other problems like gonorrhoea, which causes vaginal discharge and painful urination. Leucorrhoea in some cases may be the result of womb displacement, which attracts and encourages bacterial growth in the genital organs. Pelvic inflammatory disease causes leucorrhoea, which leads to abnormal vaginal discharge accompanied by lower back pain and lumbar pain.

SAMPRAPTI

Shwetapradara is a symptom not a disease, thus etiopathogenesis of principle disease would be principle of this condition also. However, on the basis of clinical features it appears to be vitiation of kapha, thus its etiopathogenesis may be considered in following way-

Kapha aggravated due to its own vitiating factors, influences or vitiates rasadhatu of reproductive system, already influenced by excessive coitus, improper mode of life and dietetics during menstruation and rutukala along with non-cleanliness and then produces white and painless vaginal discharges due to dominance of its liquid property.

CLINICAL FEATURES

Shwetapradara is a symptom which is found in all yonivyapads arising due to vitiation of kapha and Vatakapha (Atyanand, Karnini, Acharana, Aticharana, Sleshmala, Upapluta and Prasramsini yonivyapada). Shwetapradara is a symptom characterized by white vaginal discharges not associated with pain, burning sensation or mixed with other colors, thus it seems to be the description of leucorrhoea. The patient feels weak, run down, has pain in the back and calves, loss of vital fluids, itching pruritis on and around vulva and thigh.

Chikitsa

Treatment consists of two headings:

- 1) General treatment
- 2) Specific treatment

1] General Treatment

- Nidan parivarjan
- Kaphanashak treatment.
- Treatment prescribed for yoni srava under yonivyapad chapter.
- Symptomatic treatment of yonisrava and yonipacchilya.
- Use of drugs having katu and kashaya rasa.
- Balya chikitsa (use of rasayan drugs).

2] Specific Treatment

Drugs Used Orally:

- Use of Nagkeshar with buttermilk

Nagkeshar Uses

- Bastirogahara – Useful in urinary tract disorder.
- Vishahara – Anti toxic.
- Kandughna – Useful in relieving pruritis (excessive itching).

- Shophahara – relieves swelling, edema, anti-inflammatory.
- Ama pachan- Digestive, relieves Ama dosha.
- Jvarahara– Useful in fever.
- It helps to provide nourishment to heart.
- Helps in healthy urination.
- Helps to control generalized pain in body.
- It gives strength to generalized weak person
- Nagkeshar mostly used in bleeding disorders: All the bleeding disorders due to pitta imbalance. Nagkeshar is mostly indicated in bleeding disorders like piles, menorrhagia, metrorrhagia, epistaxis, because it pacifies the pitta that is it maintains the heat imbalance.

Nagkeshar acts in Shwetapradara by its Tikta-Kashaya rasa, Ushna virya and Aampachak guna. Kapha dosha is the main factor for any vaginal white discharge. Due to Kaphaghna guna of Nagkeshar, it is used in Shwetapradara .

Takra

Takra is Agnidipak, Kaphaghna, Vataghna with all these properties it used in Arsh, Grahani, Pandu, Gulma, Mandagni, Arochak. In all these diseases, there is presence of Aamnirmiti and Agnimandya, so that's why Apachan disorder increases. In that, Takra acts as Pachan. So, Deepan and Pachan gunas of Takra are very useful.

MATERIAL AND METHODS:

Source of Data:

- 60 Diagnosed patients of Shwetapradara were selected from opd of our institute.
- Special proforma was prepared with all points of history taking, physical signs and symptoms. Lab investigations done. The parameters were scored on the basis of standard method of statistical analysis.

INCLUSION CRITERIA

- 1) Married women.
- 2) Age group 18-40 yrs having Shwetapradara.
- 3) Diagnosed Leucorrhoea with Vaginal white Discharge or without Pruritis.

EXCLUSION CRITERIA

- 1) Cervical Erosion
- 2) Cervicitis
- 3) Pregnancy
- 4) Systemic disorders like HTN,DM etc.
- 5) Sexually transmitted Disease (STD's)
- 6) Benign& malignant tumour.
- 7) Acute & chronic PID.

INVESTIGATIONS

- CBC
- Urine analysis
- Vaginal swab culture
- RBS, HIV, HBsAG
- USG (if Necessary)

CRITERIA FOR ASSESSMENT AND RESULTS

A) Subjective Criteria:

- 1] Srava (Excessive Vaginal white discharge).
- 2] Kandu (Itching).
- 3] Katishoola (Backache).
- 4] Dyspareunia.

B) Objective Criteria:

- 1] Evidence of Pruritis.
- 2] Per –Vaginal white Discharge.

Subjective Parameters

1] Srava (Vaginal White Discharge)

- ✓ No Vaginal Discharge = 0
- ✓ Occasionally Wetting the undergarments/Slight Discharge = 1
- ✓ Moderate Discharge, Wetting the undergarments = 2
- ✓ Heavy Discharge, which needs pads = 3

2] Kandu (Itching)

- ✓ No Itching = 0
- ✓ Occasional itching at morning or in night = 1
- ✓ Regular itching disturbing routine work = 2
- ✓ Regular severe itching with disturbing routine work = 3

3] Kati Shoola (Back Ache)

- ✓ No pain = 0
- ✓ Pain during menses, intercourse, = 1
- ✓ No interference with routine work = 1
- ✓ Continuous pain, interference with routine, = 2
- ✓ Subsides after medication = 2
- ✓ Continuous pain, interference with routine work, = 3
- ✓ No relief with medication = 3

4] Dyspareunia:

- ✓ No pain = 0
- ✓ Mild discomfort = 1
- ✓ Pain but tolerable = 2
- ✓ Severe pain = 3

Objective Parameters

1] Evidence of Pruritis:

- ✓ No evidence of Pruritis = 0
- ✓ Reddish Discolouration = 1
- ✓ Edematous –Reddish Discolouration = 2
- ✓ Rashes & Edema in Vulva, Vagina and Thigh = 3

2] Per –Vaginal white Discharge:

- ✓ Normal = 0
- ✓ Scanty = 1

- ✓ Moderate that Mattes the hairs = 2
- ✓ Discharge coming out of vagina = 3

RESEARCH METHODOLOGY

Study Design

60 females aged between 18-40 years suffering from Shwetapradara was included in the study. It was treated with Nagkeshar choorna with Takra thrice daily for 7 days. Signs and Symptoms were observed before and after treatment.

Dose: 1 Karsha (Equivalent to 12gm) (4gm thrice a day)

Kala: Apana kala

Anupana: Takra 50ml

Duration: For 7 days

Follow up: Daily follow up for 7 days

Next follow up: 14th day

Method of preparation of drug:

- Raw material was collected from Government approved pharmacy.
- Takra was prepared as per standard approved Takra Kalpana according to Sushruta Samhita.

Method of preparation of Takra

Takra was prepared according to Sushruta Samhita: - Patients were advised to take one part of Dadhi (Curd) and half part of jala (Water) and stir it well and remove the butter (Makkhan) from it. The remaining part is used as Takra.

OBSERVATION AND RESULTS

General Observation

Frequency Distribution According to Age

Age in yrs	No. of cases	%
<25	2	3.3
25 -30	17	28.4
31 -35	30	50.0
36– 40	11	18.3
Total	60	100

Above distribution shows that Maximum number of patients were found in Age group 30-35 years (50.0%), whereas next Age group prone to this disease is 25-30 years (28.4%).

Frequency Distribution According to Socio-economical status

SES	No. of cases	%
High class	12	20.0
Middle class	32	53.3
Lower class	16	26.7
Total	60	100

Above distribution shows that maximum number of patients were found in Middle Socio-economic status (53.3%), whereas next group prone to this disease is lower socio-economic status (26.7%), whereas in further next group of high socio-economic status, disease is less (20.0%).

Frequency Distribution According to Parity

Parity	No. of Cases	%
0	10	16.7
1	24	40.0
2	19	31.6
3	7	11.7
Total	60	100

Above distribution shows that maximum number of patients found (40.0%) P1, (31.6%) P2 women were next prone group for this disease.

Frequency Distribution According Prakruti:

Prakruti	No. of cases	%
KP	14	23.3
KV	28	46.7
PK	-	-
PV	-	-
VK	18	30.0
VP	-	-
Total	60	100

Above distribution shows that maximum patients were found of KV Prakruti (46.7%), whereas next Prakruti group prone to this disease is VK Prakruti (30.0%).

Frequency Distribution According to Abortion:

Abortion	No. of cases	%
0	33	55.0
1	22	36.7
2	5	8.3
Total	60	100

There were Maximum 55.0% patients found with 0 Abortion.

There were 36.7% patients found with 1 Abortion.

There were 8.3% patients found with 2 Abortions.

Frequency Distribution According to Occupation:

Occupation	No. of cases	%
HW	34	56.7
Service	26	43.3
Total	60	100

There were Maximum 56.7% patients who were House wife, whereas 43.3% patients found with service Occupation.

Frequency Distribution According to Diet

Diet	No. of cases	%
Mixed	41	68.3
Veg	19	31.7
Total	60	100

- There were 68.3% patients found with Mixed Diet.
- There were 31.7% patients found with Veg Diet.

Frequency Distribution According to Excessive Vaginal white discharge:

Excessive vaginal white discharge	BT		AT		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
	2.30	0.530	0.42	0.671	81.9	7.169	<0.001HS

In the Study, the mean score for B.T was 2.30 and had changed to 0.42 after treatment. By Wilcoxon Signed Ranks test it was found that change from B.T to A.T. was highly significant as P value < 0.001.

Frequency Distribution According to Itching:

Itching	BT		AT		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
	1.98	0.537	0.53	0.566	73.1	6.820	<0.001HS

In the Study, mean score for B.T. was 1.98 and had changed to 0.53 after treatment. By Wilcoxon Signed Ranks test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Frequency Distribution According to Backache

Backache	BT		AT		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
	2.10	0.543	0.70	0.619	66.7	6.778	<0.001HS

In the Study, mean score for B.T. was 2.10 and had changed to 0.70 after treatment. By Wilcoxon Signed Ranks test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Frequency Distribution According to Dyspareunia

Dyspareunia	BT		AT		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
	1.72	0.613	0.58	0.530	66.0	6.844	<0.001HS

In the Study, mean score for B.T. was 1.72 changed to 0.58 after treatment, by Wilcoxon Signed Ranks test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Frequency Distribution According to Evidence of Pruritis:

Evidence of Pruritis	BT		AT		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
	0.38	0.715	0.13	0.430	65.2	3.035	<0.002Sig

In the Study, the mean score for B.T. was 0.38 and had changed to 0.13 after treatment. By Wilcoxon Signed Ranks test it was found that change from B.T. to A.T. was significant as P value <0.002.

Frequency Distribution According to Per Vaginal white discharge:

Per Vaginal white discharge	BT		AT		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
	2.28	0.490	0.37	0.581	83.9	7.386	<0.001 HS

In the Study, the mean score for B.T. was 2.28 and had changed to 0.37 after treatment. By Wilcoxon Signed Ranks test, it was found that change from B.T. to A.T. was highly significant as P value <0.001.

OVERALL RESULT

Symptoms	% Relief
Excessive vaginal white discharge	81.9
Itching	73.1
Backache	66.7
Dyspareunia	66.0
Evidence of Pruritis	65.2
Per Vaginal white discharge	83.9

Overall Effect	No. of symptoms
No change (<25%)	-
Mild change (25% – 49.9%)	-
Moderate change (50% -74.9%)	4
Good change (75% +)	2

STATISTICAL METHOD

This study was about whether there is any significant difference between scores of before and after treatment observations. As present data is of qualitative nature, one had to use non parametric +test to test the significant of result.

Test used for Analysis

Here observations collected on different symptoms were graded(scored) as 0 ,1 ,2 ,3. So to test the change in scores from before and after treatment in study, nonparametric test i.e Wilcoxon Signed Rank test was used.

DISCUSSION

Nagkeshar choorna has following properties–

- **Kaphanashak, Bastivatanashak:** Due to kaphanashak guna, it helps to reduce yonigata srava.
- **Kashay rasa:** It acts as Stambhak, so it decreases the discharge secretion.
- **Tikta rasa:** Tikta Rasa has vayu and akasha mahabhuta, helps in shoshana of aap mahabhuta and makes the vilayana (separation/breakdown) of pruthvi mahabhuta of kapha dosha, thus helps in the lekhan of vitiated kapha dosha which is adherent to srotas/yoni.
- **Ushna virya:** It is opposite to the sheeta guna of kapha and vata. Thus, helps in kapha shaman and vata shaman.

CONCLUSION

Among the available treatment for Shwetapradara, Nagkeshar choorna with Takra have been used based on their properties like ushna virya, kashaya rasa, Tikta rasa, Katu vipak, Ruksha guna, Kaphashamak, Durgandhinashak – all these objectives fulfilled to great extent in subsiding the disease symptoms. This herbal combination has proved to be quite effective in the treatment of Shwetapradara without any undesirable side effect which is safe and effective treatment mainly for illness of short duration. So, to conclude Nagkeshar choorna with Takra is effective, inexpensive, easily available / easily preparable type of treatment in Shwetapradara. Since the clinical study was conducted on limited number of patients it may not be claimed as final. More detailed study may be needed in this regard to establish the efficacy of Nagkeshar choorna with Takra.

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