

ROLE OF NIMBADI GHANAVATI IN THE TREATMENT OF SWETAPRADARA w.s.r. ABNORMAL VAGINAL DISCHARGE

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ABSTRACT

Shwetapradara (Abnormal Vaginal discharge) in the reproductive age group is the most common complaint encountered everyday both by gynecologists and general practitioners. It occurs in 1-14% of all women in the reproductive age group. It is responsible for 5-10 million OPD visits per year throughout the world. The prevalence of vaginal discharge in India is estimated to be 30%. The current study is an attempt to evaluate the efficacy of *Nimbadi Ghanavati* in *Swetapradara*. Married woman age group from 20yrs to 60yrs, with clinical features of *Shwetapradara* and having positive causative organism by wet smear test have been selected for the trial. Total 52 patients were registered from the OPD of *StreeRoga* and *Prasooti Tantra* Department, IPGT & RA, Jamnagar. Among registered patients, 50 patients completed the course of treatment. *NimbadiGhanavati* (two tablets of 500mg each) was given orally thrice a day before meal for 15 days continuously. Overall effect on subjective and objective parameters was found 81.23% of patients without any complication with complete remission (12%), markedly improvement (70%) and moderately improvement (12%). The data revealed that *Nimbadi Ghanavati* is very much effective therapy in the management of abnormal vaginal discharge. It can be safely prescribed in syndromic management of *Swetapradara*.

Keywords: Abnormal Vaginal discharge, *Nimbadi Ghanavati*, *Swetapradara*.

INTRODUCTION

Ayurveda is rich in pharmaceutical preparations. In management of *Shwetapradara* many *Kalpana* like *Yoni Prakshalana*, *Yoni Avachurnana*, *Yoni Pichu*, *Yoni Vartietc.* are mentioned. *Shwetapradara* (Abnormal Vaginal discharge) in the reproductive age group is the most common complaint encountered everyday both by gynaecologists and general practitioners. It occurs in 1-14% of all women in the reproductive age group and is responsible for 5-10 million OPD visits per year throughout the world. The prevalence of vaginal discharge in India is estimated to be 30%.^[1] Abnormal vaginal discharge also predisposes to significant morbidity in the form of pelvic inflammatory diseases, infertility, endometriosis, cuff cellulitis, urethral syndrome, pregnancy loss, preterm labour etc. Most com-

mon cause of symptomatic vaginal discharge is bacterial vaginosis (33-47%)^[2], followed by candidiasis (20-40%) and trichomoniasis (8-10%)^[3]. These three conditions account for 90% of all aetiologies of abnormal vaginal discharge. Multiple infections can also coexist.

Due to today's food habits, changing life style and especially due to continuously nagged and accepted as an essential feature of womanhood vaginal discharge has emerged out as one of the commonest reproductive health problem of women. Regarding the gravity of the disease, it neither causes mortality nor morbidity but it is accountable to the problem of sexual anxiety and even sometimes fears of carcinoma or failure to conceive. Apart from this, it also causes mental stress, local inconvenience to the

patient which deteriorates the day to day work and the quality of life. Thus it does not cut the years of life but the life of the years. Hence, it was planned with the aim and objective that to evaluate the efficacy of *Nimbadi Ghanavati* in *Swetapradara* and a significant data based treatment regimen can be established through *Ayurveda*.

MATERIALS AND METHODS

The Patients attending from Out-Patient Department of *Stree Roga* and *Prasooti Tantra*, IPGT&RA, Jamnagar fulfilling the criteria for selection were included into the study irrespective of caste, religion etc. A special research proforma was prepared.

Ethical clearance

Study started only after obtaining Ethical clearance from the Institutional Ethics Committee. Ethical clearance No.: PGT/7/-A/Ethics/2013-2014/2753 dated on 13/11/2013
CTRI Registration No.: CTRI/2015/07/006024

Criteria for selection of cases

Written informed consent of the patients had been taken before including in the study.

Inclusion criteria:

- Married women
- Age between 20 years to 60 years.
- The patients having clinical signs & symptoms of *Swetapradara*.
- The patients having positive causative organism by wet smear test.

Exclusion Criteria:

- Unmarried women
- Age below 20 years and above 60 years
- Pregnant women
- Patients suffering from Tuberculosis, Sexually Transmitted Disease like VDRL, HIV, gonorrhea, Genital malignancy and Congenital and any other pathologies of reproductive tract.

Criteria for Diagnosis:-

- Abnormal vaginal discharge present during examination.
- Pathogens present in wet slide study and vaginal swab culture.

Laboratory Investigations:

- Routine Hematological Examination - Hb, T.L.C., D.L.C., E.S.R.
- Routine and Microscopic Examination of Urine
- Serological test-VDRL, HIV
- RBS
- U.S.G. if required

- Wet slide study of vaginal smear
- Vaginal swab culture and sensitivity
- Gram stains for Bacteriology
- Vaginal pH
- Microbial study

Selection of drug

Nimbadi Yoga is an *Anubhuta Yoga*^[4] which was used for *Shwetapradara* due to its *Stambhana*, *Krimighna*, *Kandudhna*, *Vranashodhana*, *Vranaropana*, *Putihara* etc. Properties due to raw drugs (*Nimba*, *Triphala*, *Shuddha Sphatika* and *Madhu*) used in it. Previously two research works which were carried out on local route of administration of *Nimbadi Yoga* gave very encouraging results.^{[5],[6]} Hence, it was planned to continue this study with the aim to evaluate the efficacy of *Nimbadi Yoga* as a *Nimbadi Ghanavati* by oral route of administration so that a significant data based treatment regimen for *Swetapradara* can be established through *Ayurveda*.

The drug *Nimbadi Ghanavati* was prepared in the Pharmacy of Gujarat Ayurved University, Jamnagar after identification of raw drugs (fresh *Nimba Patra*, *Triphala Yavakuta*, *Shuddha Sphatika* & *Madhu*) in Pharmacognosy department and then analyzed pharmaceutically.

Treatment protocol

Nimbadi Ghanavati (500 mg each) was given orally thrice a day before meal for 15 days continuously with the consent of the patient.

Criteria of Assessment:

Assessment criteria had been adopted in detail on basis of both subjective & objective parameters.

Subjective parameters:

- *Yonitaha Srava* (White discharge per vagina)
- Smell
- Consistency
- *Yoni kandu* (Itching vulva)
- *Katishula* (Backache)
- *Udarashula* (Pelvic pain)
- *Mutradaha* (Burning Micturation)
- During examination local tenderness

Objective parameters:

- Based on 10% KOH Preparation
- Based on Aerobic Culture
- Based on Fungal Culture
- Based on wet preparation (pus cell)
- Based on wet preparation (*Trichomonas Vaginalis* examination)
- Based on Vaginal pH

Overall assessment of the therapy

- < 25 % : Unchanged
- 26 -50 %: Mild Positive Response
- 51- 75%: Moderate Positive Response
- 76-99% : Marked Positive Response
- 100% : Complete Remission

Statistical test: Timely noted observation had been subjected to statistical analysis for the level of significance with paired student ‘t’ test as well as with percentage.

Follow up: Patients had been followed after completion of the treatment for 1 month.

OBSERVATIONS AND RESULTS

Table 1: Effect of *Nimbadi Ghanavati* on General symptoms of 50 patients of *Shwetapradara*

Sr.no	Investigation	Mean Score		% of relief	S.D. (±)	N	S.E. (±)	‘t’	P
		B.T.	A.T.						
1.	<i>Yonitah Srava</i>	2.52	0.54	78.57	0.622	52	0.088	22.496	<0.001
2.	<i>Yoni Daurgandhya</i>	1.5	0	100.0	0.583	50	0.0842	17.812	<0.001
3.	Consistency	2	0.22	89.00	0.815	52	0.115	15.436	<0.001
4.	<i>Yoni Kandu</i>	2.68	0.76	71.64	0.528	52	0.0747	25.695	<0.001
5.	<i>Yoni Vedana</i>	1.84	0.18	90.22	0.519	52	0.0735	22.598	<0.001

Table 2: Effect of *Nimbadi Ghanavati* on Associated symptoms of 50 patients of *Shwetapradara*

Sr.no	Investigation	Mean Score		% of relief	S.D. (±)	N	S.E. (±)	‘t’	P
		B.T.	A.T.						
1.	<i>Katishoola</i>	2.32	0.6	74.14	0.497	52	0.070	24.495	<0.001
2.	<i>Udarashoola</i>	1.52	0.18	88.16	0.479	51	0.068	19.801	<0.001
3.	<i>Mutradaha</i>	2.188	0.229	89.52	0.617	50	0.090	21.975	<0.001

Table 3: Effect of *Nimbadi Ghanavati* on Wet vaginal smear and culture investigations of 50 patients of *Shwetapradara*

Wet vaginal smear	% of relief	Mean score		S.D. (±)	N	S.E. (±)	Paired “t” test	P
		BT	AT					
In Normal saline								
Trichomonas vaginalis	-	-	-	-	-	-	-	-
Pus cell	54.55	1.375	0.625	1.235	40	0.195	3.840	<0.001
In KOH								
D – Yeast	66.67	0.900	0.400	0.707	10	0.224	0.052	>0.05
Aerobic Culture								
Pseudomonas areculosa	80.00	0.909	0.273	0.674	11	0.203	0.011	<0.05
Escherichia coli	62.50	0.889	0.444	0.726	09	0.242	0.104	>0.05
Enterobactor species	-	-	-	-	-	-	-	-
Fungal Culture								
Candida albicans	60.00	0.714	0.571	0.900	07	0.340	0.689	>0.05
Candida glabrata	66.67	1.000	0.333	0.577	03	0.333	0.184	>0.05
Vaginal pH	08.12	6.900	6.340	0.675	50	0.0954	5.867	<0.001

Table 4: Effect of *Nimbadi Ghanavati* on routine Hematological investigations of 50 patients of *Shwetapradara*

Sr.no	Investigation	Mean Score		% of relief	S.D. (±)	N	S.E. (±)	't'	P
		B.T.	A.T.						
1.	Hb%	11.56	11.55	0.12	0.352	50	0.0498	0.281	>0.05
2.	TLC	7364	7196	2.28	1172.55	50	165.824	1.013	>0.05
3.	N	60.18	58.26	3.19	6.599	50	0.933	2.057	<0.05
4.	L	33.48	35.26	5.32	5.64	50	0.798	2.232	<0.05
5.	E	3.82	3.88	1.57	1.867	50	1.867	0.227	>0.05
6.	M	2.52	2.6	3.17	0.778	50	0.11	0.727	>0.05
7.	ESR	25.08	21.12	15.79	20.589	50	2.912	1.36	>0.05

Table 5: Effect of *Nimbadi Ghanavati* on routine Urine investigations of 50 patients of *Shwetapradara*

Sr.no	Investigation	Mean Score		% of relief	N	S.D. (±)	S.E. (±)	't'	P
		B.T.	A.T.						
1.	Urine pus cell	4.74	3.13	33.84	49	9.84	1.406	1.14	>0.05
2.	Epi. Cell	2.20	2.20	0.37	49	7.504	1.072	0.00761	>0.05
3.	Urine RBC	9.86	2.68	72.83	14	15.789	4.22	1.701	>0.05
4.	Albumin	0.70	0.44	37.50	23	0.915	0.191	1.367	>0.05

DISCUSSION

Out of 52 registered patients, 50 patients had completed the course of treatment. Overall effect was found 81.23% with 83.56% in subjective parameters and 60% in objective parameters. 06 patients (12%) got complete remission, 35 patients (70%) were found markedly improved, 06 patients (12%) were found moderately improved, 3 patients (6%) were found mild improvement & no any patients remain unchanged.

Regarding general symptoms as well as associated symptoms, highly significant improvement ($p < 0.001$) was observed by paired 't' test and percentage relief was found around 70 to 80% (Table 1 & 2). Effect on all general *Yonigata Symptoms* may be due to *Kashaya & Tikta Rasa*, *Kandughna*, *Krimighna* and *Kapha-Kleda Hara* properties of *Nimbadi Yoga* by oral route of administration. Relief in all associated symptoms is due to *Tridosahara* and *Rasayana* properties of drug. Highly significant improvement in relieving *pus cells* in Normal saline and in maintaining vaginal pH while significant improvement was noted in aerobic bacteria. Good percentage relief was found in fungal culture report. *Kashaya*, *Tikta & Amla Rasa* of the drug is very helpful in maintaining the vaginal pH (Table 3). No remarkable change was found in Hematological investigations & Urine routine as well as microscopic examination and all the values remained within normal limits after the treatment. It may be because the effect of drugs did not have any major effect systemically (Table 4 & 5). In follow up study no patient had complaint

of recurrence of symptoms within one month and no any adverse drug reaction was found during treatment & in follow up period.

Probable Mode of action of Drug

Cure of disease takes place due to *Samprapti Vighatana*. This can be explained by the action of *Rasa*, *Guna*, *Virya*, *Vipaka* and *Prabhava* of drugs in the various *Srotasa* and on *Dosha* and *Dushya* in human body. *Nimbadi Ghanavati* has *Kashaya*, *Tikta*, *Amla*, *Madhura* and *Katu Rasa*; *Laghu*, *Ruksha*, *Sheeta*, *Guru* and *Snigdha Guna*; *Sheeta* and *Ushna Virya*; *Madhura* and *Katu Vipaka* and *Tri-doshahara* specially *Kapha-Pittahara* properties by which it breaks the *Samprapti*.

Nimbadi Ghanavati possesses mainly *Kashaya Rasa*. *Kashaya Rasa* is mainly formed by conjugation of *Vayu* and *Prithvi Mahabhuta*.^[7] *Vayu* is *Ruksha* in quality^[8] and dries up the excessive fluids present in the tissues while *Prithvi* by virtue of *Kathina* and *Sthira Guna* which are opposite to *Drava* and *Sara Guna* reduces the *Srava*. So, *Kashaya Rasa* by virtue of its *Guna* restrains *Srava*.^[9] The second dominant *Rasa* in *Nimbadi Ghanavati* is *Tikta*, *Amla & Madhura Rasa*. *Tiktara* is a combination of *Vayu* and *Akasha Mahabhuta*.^[10] These two *Mahabhutas* are having qualities opposite to *Kapha*.^[11] *Tikta Rasa* is having *Kandughna*, *Kleda*, *Puya* and *Kaphashoshna* pharmacological properties.^[12] While *Amla Rasa* is possess *Laghu* and *Ushna Guna* which quash the *Kapha*.^[13] Some of the ingredients of *Nimbadi Ghanavati* possess *Madhura Rasa* which is *Vata* and *Pitta Shamaka* and also

has *Prinana*, *Jeevana* property etc.^[14] *Balya*, *Poshana-Karma* of *MadhuraRasa* helped in promotion of healing by *Dhatuvarhdhana*^[15] (re-growth of the tissue) leading to minimal inflammation. Hence, *Tikta*, *Amla* and *Madhura-Rasa* alleviate *Srava*.

The third dominant *Rasa* is *Katu Rasa* in *NimbadiGhanavati*. This *Rasa* is formed by *Vayu* and *Agni-Mahabhuta*,^[16] having qualities opposite to *Kapha* (*Prithvi* & *Jala*), thus, reduces *Srava*. *KatuRasa* also has *Shothaghna*, *Kandughna* and *Abhishyanda-Kleda-Sneha Upahanti* properties.^[17] By these properties it eases *Srava* as well as reduces *Shotha*. *Kashaya*, *Tikta* and *Katu Rasa* have *Krimighna*^[18] property which directly inhibits the growth of *Krimi* and finally diminishes *Srava*.

Most of the ingredients of *NimbadiGhanavati* possess *Laghu* and *RukshaGuna*. By the virtue of this property this may pacify vitiated *Kapha* and *Kleda* and supports the function of the other *Rasas*. *RukshaGuna* also restrains *Srava* by virtue of its *Stambhana* action. *Snigdha* and *Guru Gunais* predominant in some ingredients. So, these ingredients alleviate vitiated *Vayu* while *SheetaGuna* alleviates vitiated *Pitta*. Thus, ultimately help to stop secretion. *Madhu* has *YogavahiGuna* so, it may act quickly even in smaller dose.

The equal ingredients of *NimbadiGhanavati* are having *Sheeta* & *UshnaVirya*. *SheetaVirya* drugs normalize the condition of vitiated *Pitta*. And the *UshnaVirya* drugs pacify vitiated *Vata* and *Kapha*. By virtue of these qualities *NimbadiGhanavati* may alleviate the vitiated *Vata*, *Pitta* and *Kapha* which eradicates *Shwetapradara*. *SheetaVirya* drugs also act in *Srotasa* and cause *Stambhana*. In this way trial drug restrains *Srava* by *Stambhana* action.

So, Probable mode of action of *NimbadiGhanavati* can be understood as:

- *Yoni Shodhana*- Clean the vagina- by *VranaShodhana* Property
- Restrain *Srava* - *Kashaya*, *Tikta* and *KatuRasa* property *Laghu* and *RukshaGuna*.
- Kill causative microorganism - *Krimighna*, antimicrobial, antibacterial, anti fungal, antiviral properties
- Rejuvenate the epithelium - *RasayanaPrabhava*, antioxidant and *MadhuraRasa* property like *Prinana*, *Jivana* etc.
- Improving the body defense system - Immunomodulator property

The modern technology has proved that drugs of *NimbadiGhanavati* e.g. *Nimba* has anti-inflammatory, antimicrobial^{[19],[20],[21],[22]} anti-bacterial^[23] and immunomodulatory^[24] pharmacological properties by which it kills

the causative microorganism, reduces inflammation and also supports the vaginal defense mechanism. *Triphala* destroys micro-organisms, repairs damaged tissue and also increases immunity by its rejuvenative nature and exhibits antiviral, antibacterial, anti fungal, immuno-modulatory and antioxidant properties.^[25] Honey has also anti bacterial property^[26]. It kills bacteria by plasmolysis & no organism can successfully multiply to significant amounts in honey. A functional relationship between hydrogen peroxide produced in honey and antibacterial activity strongly pointed to H₂O₂ as the main contributor to antibacterial activity.^[27] Thus, it inhibits the micro-organism growth and break the *Samprapti*. *Sphatika* has styptic and astringent Properties by which it restrains *Srava*. It also acts as adjuvant.^[28]

CONCLUSION

The study is overall concluded that the *NimbadiGhanavati* is highly effective in reducing subjective & objective variables of *Shwetapradar* i.e. abnormal vaginal discharge & will also help in deriving new conclusion and proverbs in the syndromic (Candidiasis, Bacterial vaginosis, Chlamydia, etc.) management of vaginal discharge.

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