

COMPARATIVE STUDY OF NIMBADI YONIVARTI AND NIMBADI GHANAVATI IN THE MANAGEMENT OF SWETAPRADARA W.S.R. ABNORMAL VAGINAL DISCHARGE

Hetal P. Baraiya^{*1}, Shilpa B. Donga² and L. P. Dei³

¹*Reader, Dept. of Streeroga and Prasootitantra, Shri Gulabkunverba Ayurved Mahavidhyalaya, Gujarat Ayurved University, Jamnagar.

²Associate Prof. Dept. of Streeroga and Prasootitantra, I.P.G.T. and R.A., Gujarat, Jamnagar.

³Prof. and HOD, Dept. of Streeroga and Prasootitantra, I.P.G.T. and R.A., Gujarat, Jamnagar.

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*Corresponding Author

Hetal P. Baraiya

Reader, Dept. of Streeroga and
Prasootitantra, Shri
Gulabkunverba Ayurved
Mahavidhyalaya, Gujarat
Ayurved University, Jamnagar.

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. The prevalence of vaginal discharge in India is estimated to be 30%. The current study is an attempt to compare and to evaluate the efficacy of *Nimbadi Yonivarti* and *Nimbadi Ghanavati* in the treatment of *Swetapradara* by local route and oral route of administration. Married woman age group from 20yrs to 60yrs having clinical features of *Shwetapradara* and having positive causative organism by wet smear test have been selected for the trial. Among 103 registered patients, 51 patients were in Group A-

Nimbadi Yonivarti while 52 patients were in Group B- *Nimbadi Ghanavati*. Among registered patients, 50 patients completed the course of treatment in each groups. *Nimbadi Yoga* was used to make both drugs i.e. *Nimbadi Yonivarti* and *Nimbadi Ghanavati*. *Nimbadi Yonivarti* (3 gm each) was given per vaginally once at bed time for 15 days continuously. *Nimbadi Ghanavati* (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 85.13% in group A while 81.83% in Group B without any complication. Complete remission was found 24% in Group A while 12% in Group B. Marked improvement was found 60% in Group A while 70% in Group B. The data revealed that *Nimbadi Yoga* is highly effective in the management of *Shwetapradara* by local as well as oral route of administration. *Nimbadi*

Yonivarti is slightly more effective in relieving abnormal vaginal discharges as a local treatment. This is due to various important properties of drugs used in it. Both drugs can be safely prescribed in management of *Swetapradara*.

KEYWORDS: Abnormal vaginal discharge, *Nimbadi Ghanavati*, *Nimbadi Yonivarti*, *Swetapradara*.

INTRODUCTION

Ayurveda is rich in pharmaceutical preparations. But only few preparations are being used in today's Ayurvedic practice because of inconvenient forms. In management of *Shwetapradara* many *Kalpana* like *Yoni Prakshalana*, *Yoni Avachurnana*, *Yoni Pichu*, *Yoni Varti* etc. 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.^[1] The 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, cuff cellulitis, urethral syndrome, pregnancy loss, preterm labour etc. Most common 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.

Hence, the study was planned with the aim and objective that to know the effect of *Nimbadi Yonivarti* and *Nimbadi Ghanavati* in the management of *Swetapradara* as well as to compare their efficacy from which 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.

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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 (*Nimb, Triphala, Shudhdha 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 and compare the efficacy of *Nimbadi Yoga* by local as well as oral routes of administration so that a significant data based treatment regimen for *Swetapradara* can be established through *Ayurveda*.

Nimbadi Yonivarti was prepared in the Rasashashtra department of IPGT and RA, Jamnagar while *Nimbadi Ghanavati* was prepared in the Pharmacy of Gujarat Ayurved University, Jamnagar after identification of raw drugs in Pharmacognosy department and then analyzed pharmaceutically.

Treatment protocol

In Group A - *Nimbadi Yonivarti* (3 gm each) was given per vaginally once at bed time for 15 days continuously. In Group B - *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

- *Yoniataha 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: Comparative effect between two groups i.e. Group A & Group B was done by applying the unpaired student 't' test as well as by percentage.

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

OBSERVATIONS AND RESULTS

Table 1: Comparative Effect of Group A & Group B on General symptoms.

Symptoms	% of relief		Mean difference		Unpaired "t" test	p
	Group A	Group B	Group A	Group B		
<i>Yonitah Srava</i>	85.00	78.57	2.040	1.980	0.643	>0.05
<i>Yoni Daurgandhya</i>	95.08	100.00	1.487	1.500	0.920	>0.05
Consistency	91.82	89.00	2.020	1.780	0.133	>0.05
<i>Yoni Kandua</i>	80.17	71.64	1.938	1.920	0.882	>0.05
<i>Yoni Vedana</i>	89.53	90.22	1.638	1.660	0.850	>0.05

Table 2: Comparative Effect of Group A & Group B on Associated symptoms.

Symptoms	% of relief		Mean difference		Unpaired "t" test	p
	Group A	Group B	Group A	Group B		
<i>Katishoola</i>	80.00	74.14	1.796	1.720	0.513	>0.05
<i>Udarashoola</i>	90.41	88.16	1.467	1.340	0.250	>0.05
<i>Mutradaha</i>	91.53	89.52	2.204	1.958	0.072	>0.05

Table 3: Comparative Effect of Group A & Group B on Wet vaginal smear.

Wet vaginal smear	% of relief		Mean difference		Unpaired "t" test	p
	Group A	Group B	Group A	Group B		
In Normal saline						
Trichomonas vaginalis	-	-	-	-	-	-
Pus cell	65.96	54.55	0.886	0.769	0.670	>0.05
In KOH						
D – Yeast	33.33	66.67	0.500	0.333	0.625	>0.05
Aerobic Culture						
Pseudomonas areculosa	75.00	80.00	0.750	0.636	0.687	>0.05
Escherichia coli	57.14	62.50	0.000	0.444	0.246	>0.05
Enterobactor species	75.00	-	-	-	-	-
Fungal Culture						
Candida albicans	42.86	60.00	0.250	0.143	0.800	>0.05
Candida glabrata	100.00	66.67	-	-	-	-
Vaginal pH	21.57	08.12	1.480	0.560	5.337	<0.001

Table 4: Comparative effect of Group A & Group B on routine Hematological investigations.

Investigations	% of relief		Mean difference		Unpaired "t" test	P
	Group A	Group B	Group A	Group B		
Hb%	1.70	0.12	0.192	-0.014	0.003	<0.05
TLC	3.50	2.28	-248.00	168.00	0.078	>0.05
N	1.88	3.19	-1.120	1.920	0.014	>0.05
L	3.53	5.32	1.220	-1.780	0.007	<0.05
E	0.57	1.57	0.020	-0.060	0.795	>0.05
M	4.10	3.17	-0.100	-0.080	0.889	>0.05
ESR	4.46	15.79	1.000	3.960	0.421	>0.05

Table 5: Comparative effect of Group A & Group B on routine Urine investigations.

Investigations	% of relief		Mean difference		Unpaired "t" test	p
	Group A	Group B	Group A	Group B		
Urine pus cell	40.82	33.84	2.800	1.602	0.680	> 0.05
Epi. Cell	36.61	0.37	1.230	-0.00816	0.437	> 0.05
RBC	83.78	72.83	7.750	7.179	0.934	> 0.05
Albumin	56.25	37.50	0.450	0.261	0.484	> 0.05

DISCUSSION

In the present study, 103 patients had been selected on the basis of prepared inclusion & exclusion criteria. Out of them 50 patients each were divided in two groups (excluding drop outs) named Group A and Group B. Group A receives *Nimbadi Yonivarti* and Group B receives *Nimbadi Ghanavati* as trial drugs.

Overall effect on subjective and objective parameters was found 85.13% in group A while 81.83% in Group B without any complication. Complete remission was found 24% in Group A while 12% in Group B. Marked improvement was found 60% in Group A while 70% in Group B. Moderate improvement was found 10% in Group A while 12% in Group B. Mild improvement was found 6% in both Groups. No any patient remains unchanged.

Regarding general symptoms, in relieving *Yonitah Srava*, Group A showed better results. In relieving *Yoni Daurgandhya*, Group B showed better results. Better percentage of relief & Mean difference was found in Group A in relieving *Srava* consistency. *Yoni Kandu* was better relieved in Group A. Better percentage of relief & Mean difference was found in Group B in relieving *Yoni Vedana*. The difference in the mean values of the two groups in chief symptoms is not great enough to reject the possibility that the difference is due to random sampling variability. There is statistically insignificant difference between the input groups ($p > 0.05$). (Table 1).

Regarding associated symptoms, the Group A showed better results in relieving *Katishoola*, *Udarashoola* and *Mutradaha*. There is statistically insignificant difference between the input groups ($p > 0.05$) (Table 2). On relieving pus cells, *Nimbadi Yonivarti* showed slight better results. Better percentage of relief was showed in *Nimbadi Ghanavati* treated group, while compared with the *Nimbadi Yonivarti* group in the D-yeast in KOH preparation. In Aerobic culture report, better percentage of relief were showed in *Pseudomonas areculosa* & *Escherichia coli* respectively in *Nimbadi Ghanavati* treated group, while compared with the *Nimbadi Yonivarti* group. This comparative data is statistically insignificant ($p > 0.05$). In Fungal culture report, better percentage of relief i.e 60% was showed in *Candida albicans* in *Nimbadi Ghanavati* treated group, while compared with the *Nimbadi Yonivarti* group i.e. 42.86% relief. This comparative data is statistically insignificant ($p > 0.05$). Better percentage of relief i.e. 100% was showed in *Candida glabrata* in *Nimbadi Yonivarti* treated group, while compared with the *Nimbadi Ghanavati* group i.e. 66.67% relief. Better percentage of relief was found in Group A in maintaining vaginal pH. This value is statistically highly significant ($p < 0.001$). (Table 3).

Better percentage of relief was observed in the *Nimbadi Yonivarti* group in raising the Hb%, when compared with the *Nimbadi Ghanavati* group. This value is statistically just significant ($p < 0.05$). Better percentage of relief was observed in the Total leukocyte count & Monocyte count in treated with group A, while in the Neutrophil, Lymphocyte, Eosinophil count and

ESR better percentage of relief was observed in treated with group B. But the data is statistically insignificant ($p>0.05$) except in Neutrophil i.e. just significant ($p<0.05$). (Table 4).

Other parameter of urine routine & microscopic examination i.e. Urine pus cell, Epi. Cell, RBC & Albumin, better results has been found in *Nimbadi Yonivarti* treated group. But the data is statistically insignificant ($p>0.05$). The difference in the mean values of the two groups is not great enough to reject the possibility that the difference is due to random sampling variability. There is statistically insignificant difference between the groups ($p>0.05$). (Table 5).

In follow up study no patient had complaint of recurrence of symptoms within one month. On the basis of proposed data it is evident that *Nimbadi Yoga* is very much effective by locally as well as orally in the management of recurrent *Shwetapradara* or abnormal vaginal discharge.

Nimbadi Yonivarti is slightly more effective in relieving abnormal vaginal discharge as a local treatment. This is due to various important properties of drugs used in it. Group A provided better result than Group B.

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 Yoga* has *Kashaya, Tikta, Amla, Madhura* and *Katu Rasa; Laghu, Ruksha, Sheeta, Guru* and *Snigdha Guna; Sheeta and Ushna Virya; Madhura* and *Katu Vipaka* and *Tridosahara* specially *Kapha-Pittahara* properties by which it breaks the *Samprapti*.

Nimbadi Yoga 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 Yoga* is *Tikta, Amla & Madhura Rasa*. *Tiktarasa* 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 Yoga* possess *Madhura Rasa* which is *Vata* and *Pitta Shamaka* and also has *Prinana*, *Jeevana* property etc.^[14] *Balya*, *Poshana Karma* of *Madhura Rasa* helped in promotion of healing by *Dhatuwardhana*^[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 *Nimbadi Yoga*. This *Rasa* is formed by *Vayu* and *Agni Mahabhuta*,^[16] having qualities opposite to *Kapha* (*Prithvi & Jala*), thus, reduces *Srava*. *Katu Rasa* 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 *Nimbadi Yoga* possess *Laghu* and *Ruksha Guna*. By the virtue of this property this may pacify vitiated *Kapha* and *Kleda* and supports the function of the other *Rasas*. *Ruksha Guna* also restrains *Srava* by virtue of its *Stambhana* action. *Snigdha* and *Guru Guna* is predominant in some ingredients. So, these ingredients alleviate vitiated *Vayu* while *Sheeta Guna* alleviates vitiated *Pitta*. Thus, ultimately help to stop secretion. *Madhu* has *Yogavahi Guna* so, it may act quickly even in smaller dose.

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

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

- *Yoni Shodhana*- Clean the vagina- by *Vrana Shodhana* Property
- Restrain *Srava* - *Kashaya*, *Tikta* and *KatuRasa* property *Laghu* and *Ruksha Guna*.
- Kill causative microorganism - *Krimighna*, antimicrobial, antibacterial, anti fungal, antiviral properties
- Rejuvenate the epithelium – *Rasayana Prabhava*, antioxidant and *Madhura Rasa* property like *Prinana*, *Jivana* etc.
- Improving the body defense system -Immunomodulator property

The modern technology has proved that drugs of *Nimbadi Yoga* e.g. *Nimba* has anti-inflammatory, antimicrobial^{[19],[20],[21],[22]} anti-bacterial^[23] and immuno-modulatory^[24] pharmacological properties by which it kills the causative microorganism, reduces inflammation and also supports the vaginal defense mechanism. *Triphala* destroys microorganisms, 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 *Nimbadi Yoga as Nimbadi Yonivarti* and *Nimbadi Ghanavati* is highly effective in reducing subjective & objective variables of *Shwetapradara* i.e. abnormal vaginal discharge & will also help in deriving new wrapping up and proverbs in the syndromic i.e. Candidiasis, Bacterial vaginosis, Chlamydia, etc. management of abnormal vaginal discharge. *Nimbadi Yonivarti* as a local treatment is slightly more effective as it significantly reduces the vaginal discharge and allow the vagina floral environment to be healthy by their *Srotoshodhaka* property and also due to *Kashaya, Tikta & Amla Rasa* it is very helpful in maintaining the vaginal pH.

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