COMPARATIVE STUDY OF NIMBADI YONIVARTI AND NIMBADI GHANAVATI IN THE MANAGEMENT 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. 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.
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, Nimbad Ghanavati, Nimbad Yonivart, 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 Nimbad Yonivart and Nimbad 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.
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 Swetaprada.
- 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 *Shwetaprada* due to its *Stambhana, Krimighna, Kendudhna, 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 *Swetaprada* 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.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>% of relief</th>
<th>Mean difference</th>
<th>Unpaired “t” test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
<td>Group A</td>
<td>Group B</td>
</tr>
<tr>
<td>Yonitah Srava</td>
<td>85.00</td>
<td>78.57</td>
<td>2.040</td>
<td>1.980</td>
</tr>
<tr>
<td>Yoni Daurgandhya</td>
<td>95.08</td>
<td>100.00</td>
<td>1.487</td>
<td>1.500</td>
</tr>
<tr>
<td>Consistency</td>
<td>91.82</td>
<td>89.00</td>
<td>2.020</td>
<td>1.780</td>
</tr>
<tr>
<td>Yoni Kandu</td>
<td>80.17</td>
<td>71.64</td>
<td>1.938</td>
<td>1.920</td>
</tr>
<tr>
<td>Yoni Vedana</td>
<td>89.53</td>
<td>90.22</td>
<td>1.638</td>
<td>1.660</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>% of relief</th>
<th>Mean difference</th>
<th>Unpaired “t” test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
<td>Group A</td>
<td>Group B</td>
</tr>
<tr>
<td>Katishoola</td>
<td>80.00</td>
<td>74.14</td>
<td>1.796</td>
<td>1.720</td>
</tr>
<tr>
<td>Udarashoola</td>
<td>90.41</td>
<td>88.16</td>
<td>1.467</td>
<td>1.340</td>
</tr>
<tr>
<td>Mutradaha</td>
<td>91.53</td>
<td>89.52</td>
<td>2.204</td>
<td>1.958</td>
</tr>
</tbody>
</table>
Table 3: Comparative Effect of Group A & Group B on Wet vaginal smear.

<table>
<thead>
<tr>
<th>Wet vaginal smear</th>
<th>% of relief</th>
<th>Mean difference</th>
<th>Unpaired “t” test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
<td>Group A</td>
<td>Group B</td>
</tr>
<tr>
<td>In Normal saline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trichomonas vaginalis</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pus cell</td>
<td>65.96</td>
<td>54.55</td>
<td>0.886</td>
<td>0.769</td>
</tr>
<tr>
<td>In KOH</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D – Yeast</td>
<td>33.33</td>
<td>66.67</td>
<td>0.500</td>
<td>0.333</td>
</tr>
<tr>
<td>Aerobic Culture</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pseudomonas areculosa</td>
<td>75.00</td>
<td>80.00</td>
<td>0.750</td>
<td>0.636</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>57.14</td>
<td>62.50</td>
<td>0.000</td>
<td>0.444</td>
</tr>
<tr>
<td>Enterobactor species</td>
<td>75.00</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fungal Culture</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Candida albicans</td>
<td>42.86</td>
<td>60.00</td>
<td>0.250</td>
<td>0.143</td>
</tr>
<tr>
<td>Candida glabrata</td>
<td>100.00</td>
<td>66.67</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Vaginal pH</td>
<td>21.57</td>
<td>08.12</td>
<td>1.480</td>
<td>0.560</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Investigations</th>
<th>% of relief</th>
<th>Mean difference</th>
<th>Unpaired “t” test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
<td>Group A</td>
<td>Group B</td>
</tr>
<tr>
<td>Hb%</td>
<td>1.70</td>
<td>0.12</td>
<td>0.192</td>
<td>-0.014</td>
</tr>
<tr>
<td>TLC</td>
<td>3.50</td>
<td>2.28</td>
<td>-248.00</td>
<td>168.00</td>
</tr>
<tr>
<td>N</td>
<td>1.88</td>
<td>3.19</td>
<td>-1.120</td>
<td>1.920</td>
</tr>
<tr>
<td>L</td>
<td>3.53</td>
<td>5.32</td>
<td>1.220</td>
<td>-1.780</td>
</tr>
<tr>
<td>E</td>
<td>0.57</td>
<td>1.57</td>
<td>0.020</td>
<td>-0.060</td>
</tr>
<tr>
<td>M</td>
<td>4.10</td>
<td>3.17</td>
<td>-0.100</td>
<td>-0.080</td>
</tr>
<tr>
<td>ESR</td>
<td>4.46</td>
<td>15.79</td>
<td>1.000</td>
<td>3.960</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Investigations</th>
<th>% of relief</th>
<th>Mean difference</th>
<th>Unpaired “t” test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
<td>Group A</td>
<td>Group B</td>
</tr>
<tr>
<td>Urine pus cell</td>
<td>40.82</td>
<td>33.84</td>
<td>2.800</td>
<td>1.602</td>
</tr>
<tr>
<td>Epi. Cell</td>
<td>36.61</td>
<td>0.37</td>
<td>1.230</td>
<td>-0.00816</td>
</tr>
<tr>
<td>RBC</td>
<td>83.78</td>
<td>72.83</td>
<td>7.750</td>
<td>7.179</td>
</tr>
<tr>
<td>Albumin</td>
<td>56.25</td>
<td>37.50</td>
<td>0.450</td>
<td>0.261</td>
</tr>
</tbody>
</table>

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, Nimbad Yonivarti showed slight better results. Better percentage of relief was shown in Nimbad Ghanavati treated group, while compared with the Nimbad 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 Nimbad Ghanavati treated group, while compared with the Nimbad 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 Nimbad Ghanavati treated group, while compared with the Nimbad 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 Nimbad Yonivarti treated group, while compared with the Nimbad 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 Nimbad Yonivarti group in raising the Hb%, when compared with the Nimbad 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 Tridoshahara 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. Vayu is Ruksha in quality 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. The second dominant Rasa in Nimbadi Yoga is Tikta, Amla & Madhura Rasa. Tiktarasa is a combination of Vayu and Akasha Mahabhuta. These two Mahabhutas are having qualities opposite to Kapha. Tikta Rasa is having Kandughna, Kleda, Puya and Kaphashoshna pharmacological properties. While Amla Rasa is possess
Laghu and Ushna Guna which quash the Kapha. Some of the ingredients of Nimbadi Yoga possess Madhura Rasa which is Vata and Pitta Shamaka and also has Prinana, Jeevana property etc. Balya, Poshana Karma of Madhura Rasa helped in promotion of healing by Dhatuwardhana (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, having qualities opposite to Kapha (Prithvi & Jala), thus, reduces Srava. Katu Rasa also has Shothaghna, Kandughna and Abhisyanda-Kleda-Sneha Upahanti properties. By these properties it eases Srava as well as reduces Shotha. Kashaya, Tikta and Katu Rasa have Krimighna 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 H\(_2\)O\(_2\) 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. *Candiasis*, *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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