

A randomized single blind controlled clinical trial to evaluate the efficacy of Nimba-jambu-vasa kwath yoniprakshalan in the management of Kaphaj yonivyapad w.s.r. To trichomonas vaginitis

Research Article

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Abstract

Kaphaj yonivyapad is one of twenty *Yonivyapadas* (gynaecological disorders) which shows the symptoms of *Picchila Yonisrava* (unctuous discharge) and *Yonikandu* (itching sensation in vagina), *yonigat alpavedana* (pain in abdomen), *Atishital Yoni* (coldness per vagina) as described by Acharya Charak. According to modern this condition can be compared with trichomonas vaginitis i.e., type of vaginal infections. On the topic of kaphaj yonivyapad many researchers have done work by taking different drugs, this study was aimed to evaluate the efficacy of Nimba-Jambu-Vasa Kwath (decoction) yoniprakshalan (vaginal douche). Study was done after ethical committee clearance on 90 patients of kaphaj yonivyapad in OPD of streerog-prasutitantra department of SST's Ayurved Medical College, Sangamner. Patients were divided into two groups trial group had been given Nimba-Jambu-Vasa Kwath yoniprakshalan and control group had been given Triphala Kwath yoniprakshalan for 7 days.

Key Words: *Kaphaj yonivyapad, Yonivyapad, Ayurveda, Vaginal infections, Yoniprakshalan, Vaginitis.*

Introduction

Ayurveda has elaborated gynaecological disorders under the entity of *Yonivyapadas* (gynaecological disorders). Change in life style leading to *Tridosha Vriddhi* (increase in tridosha) where vitiated *Vata Dosha* gives rise to disorders of *Yoni* (vagina).

Kaphaj Yonivyapad is one of twenty *Yonivyapadas* (gynaecological disorders) which shows the symptoms of *Picchila Yonisrava* (unctuous discharge) and *Yonikandu* (itching sensation in vagina), *yonigat alpavedna* (pain in abdomen), *Atishital Yoni* (coldness per vagina) as described by Acharya Charak.(1)

Main characteristic features of this condition are presence of itching in vagina and unctuous discharges which are found in trichomonas vaginitis and monilial vulvovaginitis. *Charak* has mentioned dull pain while *Vagbhat* painless state. In very severe trichomonas infection, there may be mild pain due to inflammation, however in majority of cases it is a painless disease, thus both the statements are correct. In chronic

trichomoniasis there may be menstrual irregularity which has been referred by *Charak*. In this infection vaginal canal is sometimes covered with strawberry coloured patches as well as white or yellowish thick curdy discharges, these features may give yellowish, fiery red in color. Considering all clinical features in totality the condition appears to resemble with trichomonas vaginitis. (2)

Vaginal discharge is one of the most common problems seen in women as she do not give much attention towards this complaint unless she feels uncomfortable or hamper their day to day life.

In modern antibacterial, antifungal drugs are given for trichomonas vaginitis. (3) These drugs have side effects like nausea, vomiting, rash, itching and fever etc. (4)

The *Ayurvedic* treatment not only cures the pathology in reproductive organs but with holistic approach treats the woman as whole, thereby improving general health also.

Historical Review

Twenty *yonivyapada* including *kaphaj (shleshmaj) yonivyapad* are mentioned in *Charaka Sutrasthana, Sushruta samhita, Madhavnidan, Ashtang sangraha, Ashtang hridaya, Sharangdhara samhita, Yogatnakar, Bhavprakash.*

Kaphaj yonivyapad with symptoms of whitish unctuous discharge, itching per vagina. *Charak* has mentioned dull pain while *Vagbhat* given painless state.

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Aims and Objectives

Aims

To study the efficacy of *Nimba-Jambu-Vasa Kwath Yoniprakshalan* in the management of *Kaphaj Yonivyapad*.

Primary objectives

To study the effect of *Nimba-Jambu-Vasa Kwath Yoniprakshalan* in the management of *Kaphaj Yonivyapad*.

Secondary objectives

To compare the effect of *Nimba-Jambu-Vasa Kwath Yoniprakshalan* with *Triphala Kwath Yoniprakshalan* in *Kaphaj Yonivyapad*.

To study *Kaphaj Yonivyapad* in details.

Materials and methods

1	Study design	Randomized single blind control trial.
2	Study setting (Location)	OPD of <i>Prasutitantra</i> and <i>Stree-rog</i> department of <i>SST Ayurved Hospital & research centre</i>
3	Study population	Study was carried out on the patients suffering from signs and symptoms of <i>Kaphaj Yonivyapad</i> those attending OPD
4	Trial drug	<i>Nimba-Jambu-Vasa Kwath yoniprakshalan</i>
5	Control drug	<i>Triphala Kwath</i>
6	Duration of study	18 months
7	Sampling technique	Simple randomized sampling technique by lottery method
8	Sample Size	90 (trial group 45 patients control group 45 patients)

Inclusion criteria

- Married patients within age group of 18 to 45 years.
- Patients willing for a treatment.
- Patients having complaints of *Yonigat Picchila Srav, Atishital Yoni, Yonigat Vedana, srav Gandha*.

Drug formulation details

Table 1: Trial drug

Sr. no.	Drug	Latin Name	Rasa	Virya	Vipak	Guna	Karma
1	<i>Nimba</i>	<i>Azadirachta indica</i> A. Juss	<i>Tikta, Kashay</i>	<i>Sheet</i>	<i>Katu</i>	<i>Laghu, Ruksha</i>	<i>Kapha-Pittashamak, grahi, kandughna, daurgandhyahar, vranropana, krumighna, garbhashayottejak, garbhashayshodhan</i>
2	<i>Jambu</i>	<i>Eugenia jambolana</i> Linn	<i>Kashay, Madhur, Amla</i>	<i>Sheet</i>	<i>Madhur</i>	<i>Laghu, Ruksha</i>	<i>Kaphashamak-Pittashamak, Stambhan, twakdoshahar, raktastambhan, grahi, nigrhak, raktastambhan, deepan, pachan, yakrutottejak</i> Astringent, stryptic, wound healing
3	<i>Vasa</i>	<i>Adhatoda vasica</i> J.adhatoda	<i>Tikta, Kashay</i>	<i>Sheet</i>	<i>Katu</i>	<i>Laghu, Ruksha</i>	<i>Kapha-Pittashamak, Jantughna, shothaghna, kushtaghna, vedanahara, krumighna, raktastambhak, stambhan, deepan, shleshmahar.</i>

Exclusion criteria

- Age <18 years and >45 years
- Unmarried girls
- Pregnant woman
- *Sutika*
- K/C/O HTN, DM and Severe anemia.
- K/C/O HIV, Tuberculosis, malignancy, other sexually transmitted disease.
- Post menopausal.
- Patients who will not give written consent.

Withdrawal criteria

- If a patient fails to report follow up or who will not complete duration of treatment, withdrawal of patient will be done on ethical ground after discussion with respected guide.
- Patients who want to discontinue the treatment.
- If adverse effects of drug are seen ADR will be reported and withdrawal of patients will be done.

Diagnostic criteria

Diagnosis will be done on the basis of the local signs and symptoms of *Kaphaj Yonivyapad* as described by *Charak*. Patients with following features:

1. *Picchila* (unctuous) and *Sheet Srav*
2. *Kandugrathata* (itching sensation in vagina)
3. *Alpa Vedana* (mild pain)
4. *Gandha* (foul smelling)

Operational Definitions

1) Vaginitis – Vaginitis, also known as vulvovaginitis, is inflammation of vagina and vulva. Symptoms may include itching, pain, discharge and a bad smell. (5)

2) Trichomonas vaginitis – Vaginal trichomoniasis is the most common and important cause of vaginitis in the childbearing period. (6)

3) Kaphaj yonivyapad - *Kapha* vitiated due to excessive use of *Abhishyandi* substances reaches reproductive system and causes unctuousness, coldness, itching and dull pain in vagina. (7)

Table 2: Control Drug

Sr. no.	Drug	Latin Name	Rasa	Virya	Vipak	Guna	Karma
1	Amalaki	<i>Embllica officinalis</i>	Pancharasatmak Except lavana rasa	Sheet	Madhur	Laghu, Ruksha Sheet	Tridoshhar
2	Haritaki	<i>Terminalia chebula Retz</i>	Pancharasatmak Except lavana rasa	Ushna	Madhur	Laghu, Ruksha	Tridoshhar
3	Bibhitak	<i>Terminalia bellirica Roxb</i>	Kashaya	Ushna	Katu	Ruksh, Guru	Tridoshhar

Criteria for assessment

Subjective criteria

- i) *Yonigat Picchila Srav* (unctuous discharge through vagina)
- ii) *Yonikandu* (Itching sensation per vagina)
- iii) *Atishital Yoni* (Coldness per vagina)
- iv) *Sravgandha* (Foul smell of discharge)
- v) *Yonigat Vedana* (pain per vagina)

Table 3: Grading of parameters

Sr.	Symptoms	No.	Criteria	Grad
1	<i>Yonigat Picchila Srav</i> (unctuous discharge through vagina)	1	No discharge	0
		2	Slight discharge	1
		3	Cloth gets wet	2
		4	Pad is required	3
2	<i>Yonikandu</i> (Itching sensation per vagina)	1	Least itching	0
		2	Mild itching	1
		3	Moderate itching	2
		4	Severe itching	3
3	<i>Atishital Yoni</i> (Feeling of per)	1	Absent	0
		2	Present	1
4	<i>Sravgandha</i> (Foul smell of discharge)	1	Least	0
		2	Mild	1
		3	Moderate	2
5	<i>Yonigat Vedana</i> (pain per vagina)	1	No pain	0
		2	Pain precipitating from time to time by	1
		3	Continues pain during	2
		4	Unable to do any	3

Table 4: Treatment details

Group	Group A : Trial	Group B: Control
No. of	45	45
Treatment	<i>Nimba-Jambu-vasa</i>	<i>Triphala Kwath</i>
Dose	200 ml	200 ml
Route	Per vaginally	Per vaginally
<i>Kalpana</i>	<i>Kwath</i>	<i>Kwath</i>
<i>Kaal</i>	Once a day in a	Once a day in a
Duration	7 days	7 days
Follow up	14 th day	14 th day

Scoring of Kaphaj yonivyapad

To give some objective, the score was assigned to each of major symptoms of *Yonikandu*, *Yonigat Srav*, *Atishital Yoni*, *Yonivedana* etc.

Overall assessment of the results

Total assessment of the therapies was done on the basis of relief in the main signs and symptoms of

disease. On the basis of this criteria total patients were divided into four categories as below: (Table no. 5)

Table 5: Overall assessment

Observation	Grade	Percentage
Marked improvement	I	Above 75%
Moderate improvement	II	50%-75%
Mild improvement	III	25%-50%
Poor improvement	IV	Less than 25%
Unchanged	-	0%

Observations and results

Summary of Patients according to different aspects

Distribution of patients according to Age

In Group-A (Trial Group), 10 patients (22%) with age between 20 – 24 years, 30 patients (67%) between 25-29 years and remaining 5 patients (11%) are of age greater than 30-34 years. In Group-B (Control Group), 16 patients (36%) between 20 – 24 years, 18 patients (40%) between 25-29 years and remaining 11 patients (24%) are of age greater than 30-34 years.

Distribution of patients according to Occupation

In Group-A (Trial Group), 6 patients (13.33%) are farmers, 20 patients (44.44%) housewives, 13 patients (28.89%) have job, 2 patients (4.44%) are students and remaining 4 patients (8.89%) are teachers. In Group-B (Control Group), 5 patients (11.11%) are farmers, 21 patients (46.67%) housewives, 13 patients (28.89%) have job, 3 patients (6.67%) are students and remaining 3 patients (6.67%) are teachers.

Summary of White blood cells

The average WBC score of Group A before treatment is 11546.62 and standard deviation is 413.696. Also the average WBC scores of Group- A after treatment are 10690.22 and standard deviation is 763.168. This gives evidence that there is decrease in average WBC score after treatment.

The average WBC score of group B before treatment is 11551.244 and standard deviation is 413.696. Also the average WBC score of Group B after treatment is 10232.667 and standard deviation is 1107.354. This gives evidence that there is decrease in average WBC score after treatment.

Table 6: Result chart: Statistical analysis

Symptoms	GROUP	Mean score		Mean	Median	Wilcoxon signed rank	P Value	S.D.	S.E	U value
		BT	AT							
<i>Yonigat picchila srav</i>	Trial	2.311	1.089	1.222	1.00	861	<0.001	0.599	0.089	1713.5
	Control	2.111	0.467	1.644	1.00	990	<0.001	0.645	0.096	
<i>Yonikandu</i>	Trial	2.177	0.822	1.356	1	946	<0.001	0.570	0.084	1086
	Control	1.689	0.933	0.756	0	561	<0.001	0.484	0.072	
<i>Dourgandhya</i>	Trial	1.311	0.444	0.867	1.00	741	<0.001	0.405	0.060	1819.5
	Control	1.356	0.222	1.133	1.00	741	<0.001	0.661	0.098	
<i>Yonigat vedana</i>	Trial	1.044	0.466	0.577	0	351	<0.001	0.499	0.074	2047.5
	Control	1.155	0.577	0.577	0	351	<0.001	0.499	0.074	
<i>Atishital yoni</i>	Trial	0.867	0.467	0.4	0	171	<0.001	0.495	0.073	1867.5
	Control	1	0.422	0.578	0	351	<0.001	0.499	0.074	

Table 7: Overall efficacy of *Nimba-Jambu-Vasa Kwath Yoniprakshalan* over *Triphala Kwath Yoniprakshalan*

Parameter	Control Group	Trial Group	Comparative efficacy
<i>Yonigat picchila srav</i>	Significant	Significant	<i>Triphala Kwath Yoniprakshalan</i> is more effective
<i>Sravgandha</i>	Significant	Significant	
<i>Yonikandu</i>	Significant	Significant	<i>Nimba-Jambu-Vasa Kwath Yoniprakshalan</i> is more effective
<i>Yonigat vedana</i>	Significant	Significant	Both are equally effective
<i>Atishital yoni</i>	Significant	Significant	
Overall Average % increment	Significant	Significant	Both are equally effective

Discussion on Mode of Action of *Nimba-Jambu-Vasa Kwath*

According to *Rasapanchaka*

Due to the *Kaphaghna*, *Kapha kleda shoshak* action, *shoolaghna* action and *shothaghna* action of trial group showed results. *Nimba*, *Jambu* has *Kashaya*, *kashaya* & *Tikta rasa*, *Katu Vipak*. *Guna* because of these properties it acts as *Kaphaghna*, *Krumighna* & *Kandughna*. *Katu rasa* has *Kledaghna* property it reduces *srava*.

Probable mode of action of *Nimba-Jambu-Vasa kwath*

Nimba is of *tikta rasa*, *Kashay rasatmak* causes *stambhan* and *kleda shoshan*, *Jambu* is also *stambhak* and *grahi* in nature which will help in reducing *srav*. By decreasing *srav* it will also reduce *gandha*. *Nimba*, *Vasa* has also been screened for its antimicrobial activity which can help in reducing *yonikandu* (itching).

Probable mode of action of *Triphala kwath*

- The major constituents of the formula are the tannins, Gallic acid, elegendic acid, and chebulinic acid, which are potent antioxidants that may account, at least in part, for the observed immuno modulatory activity of the formula.
- *Triphala* is also *kashay rasatmak* which stops the *srav* and also absorbs the *sthanik kleda* thus reducing *gandha*.
- The *Triphala* extracts have demonstrated greater efficacy on pathogenic bacteria such as *Escherichia coli* and *Staphylococcus aureus*. *Triphala* was reported to exert antibacterial effects on both gram-positive and gram-negative species. Thus may help in reducing *kandu*.

According to results and observations

The present study was conducted among 45 patients for each trial and control group. All patients were assessed on the basis of scores given to them before and after treatment. *Nimba-Jambu-Vasa kwath yoniprakshalan* was given to 45 patients for 7 days. *Triphala kwath yoniprakshalan* was given to 45 patients in the control group. Significant relief was observed in the symptoms of *kaphaj yonivyapad* like *yonigat picchil srav*, *yonikandu*, *yonigat atishitata*, *yonigat vedana*.

The difference between the scores before treatment and after treatment was calculated for both groups separately. The differences thus obtained were compared using the Wilcoxon signed ranked test and the Man-Whitney U test. From statistical analysis, both *Nimba-Jambu-Vasa kwath* and *Triphala kwath* were found effective in *kaphaj yonivyapad*. There is no significant difference between the average scores of both the medicines for the factors viz., *yonigat vedana* and *atishital yoni*. In the case of *srav praman* and *srav gandha*, *Triphala Kwath* is more effective than *Nimba-Jambu-Vasa Kwath*. The overall average improvement of *Nimba-Jambu-Vasa Kwath* is 73.778%, and the *yoniprakshalan* of *Triphala Kwath* is 74.222%. Thus, it can be concluded that *Nimba-Jambu-Vasa kwath yoniprakshalan* is significantly less effective than *Triphala kwath yoniprakshalan* in the treatment of *kaphaj Yonivyapad*.

Conclusion

After the present study, it can be concluded that *Nimba-Jambu-Vasa kwath* is quite effective in reducing *shweta srav praman*, *sthanik kandu*, *Yonigat vedana* and *gandha*. It appears that *Nimba-Jambu-Vasa kwath* is effective in early stages in localized symptoms of *kaphaj yonivyapad*. Method of preparation & application of *Nimba-Jambu-Vasa kwath* is easy.

Though there is no big difference but statistical table suggests *Nimba-Jambu-Vasa kwath* is quite effective as control group and considering toxicity & side effect it can be used as first line treatment. This study on *Kaphaj Yonivyapad* by using *Nimba-Jambu-Vasa kwath yoniprakshalan* does not end here but this study enlightens the path for the next research work. It needs deep and more clinical trial for its future evaluation.

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