



COMBINED EFFECT OF TRIPHALĀ KVĀTHA YONI PRAKṢĀLANA AND TRIPHALĀ GUGGULU ORAL ADMINISTRATION IN THREE TYPES OF VAGINITIS

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ABSTRACT

Vaginitis, inflammation of the vagina is one of the most common gynaecological complaints reported by women irrespective of their age and socio economic status. The common types are Candidial vaginitis (CV), Trichomonal vaginitis(TV) and Bacterial vaginosis(BV) with varying symptoms. The management in contemporary system includes systemic/topical antifungal, antiprotozoal and antibacterial drugs which mostly gives temporary relief with other side effects like gastro intestinal problems, psychological problems, vertigo etc. Ayurvedic Ācārya's emphasized lakṣaṇa of yoni srāva, yoni kaṇḍu, foul smell etc throughout the strīroga prakarana, among which ślaismiki, paittikī, upapluta etc bear the similar symptoms of vaginal infections. On its basis many studies had been conducted on the effectiveness of yonī prakṣālaṇa in vaginitis. But there is no sufficient evidence to prove the efficacy of a single formulation in different types of vaginal infection. Hence the present study aims to find out the combined effect of triphalā kvātha yoni prakṣālaṇa² and triphalā guggulu oral administration in three common types of vaginitis. The treatment when compared between the three types of vaginitis was found to be most effective in candidial vaginitis, moderate effect in bacterial vaginosis and minimum effect in trichomonal vaginitis.

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INTRODUCTION

A woman during her life span may experience different types of discharges per vaginum. Normal vaginal discharge is clear and non-offensive which usually appears around midcycle. Excess of this normal physiological vaginal discharge may not require specific treatment. Abnormal discharge can occur due to many reasons such as nutritional status, emotional stress, genital infections, hormonal imbalance, usage of oral contraceptive pills, sexual arousal etc. The prevalence of reproductive tract infection in females of the reproductive age group is very high. It was found as 45% bacterial vaginosis, 31% vulvovaginal candidiasis, 3% gonorrhoea, 2% trichomoniasis, 5% non-specific urogenital causes and 14% with other causes³. Even though abnormal vaginal discharge neither causes mortality nor morbidity in susceptible women, it may cause mental stress, sexual anxiety, fear of carcinoma, failure to conceive etc. The pH balance of the vagina fluctuates during menstrual cycle and becomes nearly alkaline on the days just prior to and during menstruation. Therefore chances of getting infections like candidiasis, trichomoniasis and bacterial vaginosis are most common during this time, which necessitates timely intervention. The current standard treatment, in contemporary system of medicine includes systemic/topical antifungal, antiprotozoal and antibacterial agents.

These medications decreases infection temporarily and often disrupt the normal vaginal flora which may lead to recurrent infection⁴. When vaginitis is left untreated, it may increase the risk of infertility, premature delivery, low birth weight, endometritis, cervical neoplasia etc as long term complications due to ascending infections.

In Āyurveda, the female reproductive system diseases are explained mainly under the heading of "yonī vyāpat". Yonī vyāpat characterised with abnormal vaginal discharge such as ślaismiki, paittikī, pariṣṭa, upapluta⁵ etc can be considered as the explanation for vaginitis in Ayurvedic classics. In the context of srāva pradhāna yonī roga, various treatment modalities like yonī picu, yonī pariṣeka, yonī lepa, yonī varti⁶ etc are explained with different formulations. Among them yonī prakṣālaṇa may cleanse the vagina from the accumulated secretions. Triphala⁷ with its rasāyana, tridoṣahara, kledahara, śodhana as well as ropana properties, is proven as having antimicrobial action, will be effective in vaginal infections. It is also commonly known, easily available, safe to administer, cost effective and has less chances of adulteration. Triphalā guggulu selected for oral administration is also having the qualities of kaphaghna, śothahara, śodhana and ropana. Being tikta, kaṣāya, guggulu is kaphaghna, kledahara and because of uṣṇavīrya it is vataghna and agnidīpana. Hence the present study aims to find out the combined effect of triphalā kvātha yonī prakṣālaṇa and triphalā guggulu oral administration in three common types of vaginitis.

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MATERIALS AND METHODS

Aim To study the effect of *triphalā kvātha yoni prakṣāḷana* and *triphalā guggulu* oral administration in three types of vaginitis.

Objective

To compare the combined effect of *triphalā kvātha yoni prakṣāḷana* and *triphalā guggulu* oral administration in three types of vaginitis

METHOD

Study setting

The patients were selected as per inclusion criteria from the IPD and OPD of Amrita Āyurveda Hospital, Vallikkavu, Kollam. After careful scrutiny the patients satisfying inclusion criteria were registered under the present study.

Study Drug

The drugs of *triphalā kvātha* are *harītakī* (*Terminalia chebula*), *vibhītakī* (*Terminalia bellerica*) and *āmalakī* (*Embilica officinalis*) and ingredients of *triphalā guggulu* includes *triphalā*, *pippalī* (*Piper longum*) and *guggulu* (*Commiphora mukul*).

Preparation of Medicine

Tripthalā kvātha - *Harītakī*, *vibhītakī* and *āmalakī* are properly cleaned and dried in sunlight. The dried drugs in equal quantity are coarsely powdered. 250 gm of the prepared *triphalā choorna* is taken and boiled in 16 times water and reduced to 1/4th, filtered and used for *yoni prakṣhalana* in luke warm temperature.

Tripthalā guggulu - Three *pala* of powdered *triphalā*, one *pala* of powdered *pippalī* and five *pala* of *guggulu* are to be taken. *Guggulu* was purified using *triphalā kvātha*. Purified *guggulu* along with powdered *triphalā* and *pippalī* are pounded and made into *gutika*. Dose of *triphalā guggulu* is 1 *śāṇa* (3g) and it was given in divided doses of 1.5g twice daily after food.

Sample size

30 patients of vaginitis satisfying the inclusion and exclusion criteria were selected.

Inclusion criteria

- Married women above 21 years
- Diagnosed cases of candidial, trichomonal or bacterial vaginitis on basis of vaginal smear examinations.

Exclusion criteria

- Pregnant ladies
- Diabetic women
- Hypertensive women
- Diagnosed malignant conditions

Design of study

The study was approved by Institutional Ethical Committee. An open label clinical study with pre and post test design was conducted on 30 patients satisfying the inclusion and exclusion criteria. The assessment parameters were recorded on the basis of standard methods and were analysed statistically.

Assessment criteria

The subjective and objective criteria were graded for statistical analysis as given in Table 1.

Table 1 Outcome measures with scoring

Variables	Grade	CV	BV	TV
Colour & Appearance of srāva	0	White	White	white
	1	curdy white	Yellowish white	Yellow
	2	Cheesy	Greyish white	Greenish white
Quantity of srāva	0	Normal	Normal	Normal
	1	Mild	Mild	Mild
	2	Moderate	Moderate	Moderate
	3	Severe	Severe	Severe
Yoniśūla (VAS)	0	0	0	0
	1	1-3	1-3	1-3
	2	4-6	4-6	4-6
	3	7-9	7-9	7-9
	4	10	10	10
Wet mount Test	0	Candid-ve	Clue cell-ve	Trichomonas-ve
	1	Candid +	Clue cell +	Trichomonas +
	2	Candid ++	Clue cell ++	Trichomonas ++
	3	Candid +++	Clue cell +++	Trichomonas +++
Odour	0	NA	Non offensive	Non offensive
	1	NA	Offensive	Offensive
	0	NA	≤4.5	≤4.5
Vaginal pH (Whatmann's pH indicator)	1	NA	4.6- 5.0	4.6- 5.0
	2	NA	5.1-5.5	5.1-5.5
	3	NA	5.6-6.0	5.6-6.0
	4	NA	>6.0	>6.0
Consistency of srāva	0	Thin	NA	thin
	1	Thick	NA	Thin frothy
Pruritis (5-D itch Scale)	0	5	NA	5
	1	6-10	NA	6-10
	2	11-15	NA	11-15
	3	16-20	NA	16-20
	4	21-25	NA	21-25
Whiff test	0	NA	Non offensive	NA
	1	NA	Offensive	NA

Treatment protocol

The procedure *yoni prakṣāḷana* was done for 10 to 20 minutes with 1 litre of *triphalā kasaya* for 10 consecutive days along with *triphalā guggulu* 1.5 mg twice daily and was advised to avoid sexual act during treatment days.

Follow up

Patients in reproductive age group were informed to do follow up after 2 or 3 days of menstrual cycle for consecutive 3 months.

Statistical analysis

Statistical analysis was performed using the IBM SPSS Statistics software, Version 20. The pre and post test evaluation was done using Wilcoxon signed rank test for post Hoc with Bonferroni correction with p values (p<0.025) were considered statistically significant. To compare the effect of treatment in different types of infection statistically, Kruskal Wallis test and Mann Whitney U test were used with p values (p<0.05) to be statistically significant.

RESULTS

Among 30 patients selected for the study, 12 each were diagnosed with CV and BV, 6 were diagnosed with TV. The effect of the treatment was analysed after treatment and after follow up.. In patients with CV the criteria colour, consistency, odour and quantity of *srava*, wet mount test and pruritis were assessed and showed statistically significant result with p<0.0125 whereas *yoni śūla* showed no significance with p>0.0125 as given in Table 2.

Table 2 Effect of medicine in CV – AT & FU 3

Variables	BT	AT	FU 3
	mean	mean	p value
			mean
			p value

Yonishoola	0.92	0.25	>0.0125	0.33	>0.0125
Quantity of srava	1.92	0.42	<0.0125	0.58	<0.0125
Colour of srava	1.33	0.33	<0.0125	0.33	<0.0125
Wet mount	2.08	0.75	<0.0125	0.58	<0.0125
Consistency	1.00	0.25	<0.0125	0.33	<0.0125
Pruritis	1.67	0.17	<0.0125	0.50	<0.0125

In patients with BV, colour and quantity of *srāva*, wet mount test and vaginal pH showed statistically significant change with $p < 0.0125$ and no significant result in *yoni śūla*, whiff test and odour with $p > 0.0125$ as given in Table 3. In patients with TV none of the criteria showed statistical significance with $p > 0.0125$ as given in Table 4.

Table 3 Effect of medicine in BV – AT & FU 3

Variables	BT		AT		FU 3	
	mean	mean	p value	mean	p value	
Yonishoola	1.25	0.333	>0.0125	0.333	>0.0125	
Quantity of srava	2.33	0.83	<0.0125	1.08	<0.0125	
Colour of srava	1.67	0.58	<0.0125	0.75	<0.0125	
Wet mount	2.08	0.67	<0.0125	0.92	<0.0125	
Odour	0.75	0.17	>0.0125	0.42	>0.0125	
Vaginal pH	2.17	0.67	<0.0125	1.00	<0.0125	
Whiff test	1.00	0.67	>0.0125	0.58	>0.0125	

Table 4 Effect of medicine in TV – AT & FU 3

Variables	BT		AT		FU 3	
	mean	mean	p value	mean	p value	
Yonishoola	2.50	1.17	>0.0125	1.67	>0.0125	
Quantity of srava	2.17	0.83	>0.0125	1.33	>0.0125	
Colour of srava	1.67	0.67	>0.0125	1.33	>0.0125	
Wet mount	1.83	1.00	>0.0125	1.17	>0.0125	
Consistency	1.00	0.33	>0.0125	.67	>0.0125	
Pruritis	1.83	0.67	>0.0125	1.17	>0.0125	
Odour	1.00	0.33	>0.0125	.67	>0.0125	
Vaginal pH	3.00	1.17	>0.0125	1.67	>0.0125	

Comparison of effect of medicine after treatment and after follow up(FU3) is detailed in Table 5 and Table 6. There was no significant difference in the variables with $p > 0.05$ except *yoni śūla*, which showed significant difference between the groups with $p < 0.05$. Among CV and TV groups consistency of *srāva* and pruritis showed no significant difference between the groups with $p > 0.05$. Among BV and TV groups, vaginal pH and odour of *srāva* showed no statistically significant difference with $p > 0.05$.

Table 5 Comparison of effect of medicine in three types of infection – AT

Variables	Mean Rank			% relief			t value	P value
	CV	BV	TV	CV	BV	TV		
Yonishoola	13.08	14.17	23.00	72.7	73	53	7.973	0.019
Quantity of srava	12.38	17.58	17.58	78	64	61	3.021	0.221
Colour of srava	13.00	16.75	18.00	75	65	60	2.256	0.324
Wet mount	15.33	14.21	18.42	64	68	45	1.180	0.554
Consistency	9.25	-	10.00	75	-	66	0.131	0.718
Pruritis	8.42	-	11.67	90	-	63	23.00	0.120
Vaginal pH	-	8.21	12.08	-	69	61	20.500	0.094
Odour	-	9.00	10.50	-	78	67	27.00	0.192

Table 6 Comparison of effect of medicine in three types of infection – FU 3

Variables	Mean Rank			% relief			t value	p value
	CV	BV	TV	CV	BV	TV		
Yonishoola	13.17	13.75	23.67	63	73	33	9.319	0.009
Quantity of	12.38	16.38	20.00	70	54	38	3.603	0.165

srava								
Colour of srava	11.67	15.75	22.67	75	55	20	7.406	0.025
Wet mount	13.04	16.13	19.17	72	56	36	2.348	0.309
Consistency	8.50	-	11.50	66	-	33	1.700	0.192
Pruritis	8.42	-	11.67	70	-	36	23.00	0.178
Vaginal pH	-	8.42	11.67	-	54	44	23.00	0.203
Odour	-	8.75	11.00	-	44	33	27.00	0.331

Overall clinical assessment

Out of 12 patients in CV, 83% and 17 % got cured and maximum Improvement respectively. Among 12 patients with BV, 58% and 42 % got maximum improvement and moderate improvement respectively. Among 6 TV patients, 17% got maximum improvement, 33% got moderate improvement and 50 % got mild improvement.

DISCUSSION

Vaginitis is one of the most common gynecological disorders with great concern to the female population. About 10% to 41% of women have abnormal per vaginal white discharge at least once in their lifetime⁸. Female genitals are very much prone to infection, as this region is always covered with moistness and sweat. The most common types of vaginitis are candidial vaginitis, bacterial vaginosis and trichomonal vaginitis. Candidial infection is due to the overgrowth of naturally occurring candida albicans. Bacterial vaginosis resulted from the overgrowth of pathogenic bacteria altering the normal vaginal flora. Trichomonal vaginitis or trichomoniasis is the inflammation of vagina caused by a sexually transmitted parasite called trichomonas vaginalis. If vaginitis left untreated, it may lead to complications like cervicitis, carcinoma of cervix, infertility, invasion of HSV, HPV, premature delivery, low birth weight etc. In contemporary system of medicine, the main aim of the management is focused on antimicrobial effect, but usually it will not improve the local immune response of vagina.

Majority of the subjects from local community presented with bacterial as well as candidial infection. Trichomonal infection is very less among them when compared with that of western population. This finding is in accordance with the previous study reports showing BV and CV is most common among Indians whereas TV is the most common among western group of people. Among local people, less hygiene, sweat and moistness of the genital area, are the causes for increased more candidial and bacterial infection. Because of the increased OCP use from young age decreases the local immunity and multiple sexual partners may also lead to this infection.

On analysing the result we can find that the medicine *triphala kvātha* has got good local action in controlling the infection and it may be due to its antibacterial, antifungal and antiprotozoal (*kṛmihara*) and anti-inflammatory (*śothahara, kledahara*) properties. As it is *sarvadoṣajith*, *śodhana*, *ropaṇa* and *rasāyana varā* it might be effective in improving the local immunity and regeneration of newer healthy cells. As *harītaki* is *anulomana* and all are *madhura vipāka* predominant, causes *vāta śamana*. Due to *laghu rūkṣa guṇa* and *uṣṇa vīrya*, it acts as *kapha śamaka* and because of its *kaṣāya rasa prādhānyata* it mitigates *pitta doṣa* also. *Triphalā guggulu* with *viśada guṇa* also enhanced the treatment effect by *kledācūṣana* and *śothaharatva*. As its *kvātha* is having the acidic pH, it may help in maintaining the normal vaginal pH facilitating the dynamic balance of normal vaginal flora. The main chemical constituent in *triphala kvātha* is tannin which helps in

precipitating proteins and reducing the inflammation and discharge per vaginum. Tannins are proved to have growth inhibiting action of many fungi, yeasts, bacteria, and viruses⁹. The action of ascorbic acid, an immune modulator in *āmalaki*, in maintaining the normal vaginal flora is also already proved. It is found that those having recent attack of infection had higher cure rate than those with chronic history of the disease. Clinically maximum improvement was observed in CV, moderate improvement in BV and mild improvement in TV. During follow up period the percentage relief was found to be reduced than after treatment showing recurrence rate more in patients who had the disease for more than past 3 years. So in such chronic cases, *sthānika cikitsa* should not be limited to a single cycle or repeated courses of treatment may be more beneficial.

During the course of treatment slight *yoni rūkṣata* occurred in few post-menopausal patients after 5-6 days of *prakṣālana* may be due to the hypo estrogenic state and no other side effects were observed. Some of the drawbacks of the present study include less number of patients with trichomonal vaginitis and infection of the male partner was not ruled out. Nugent's criteria for BV could also be included in further studies.

CONCLUSION

The effect of the treatment when compared between the three types of vaginitis was found to be most effective in candidial vaginitis, moderate effect in bacterial vaginosis and minimum effect in trichomonal vaginitis. During follow up the higher recurrence rate is observed in participants with TV. In patients with CV and BV, recurrence was observed in chronic cases, were repeated administration of treatment can be suggested. A large sample size study especially in TV group may help to get more accurate results.

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