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Research Article

A PILOT STUDY OF *PIPPALYADI TAILA YONIPICHU* IN THE MANAGEMENT OF *KAPHAJA YONIYVAPAD* (NON-SPECIFIC VAGINITIS)

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KEYWORDS: Non-specific vaginitis, *Kaphaja yonivyapad, pippalyadi taila,* Pilot study, *Streeroga.*

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ABSTRACT

Vaginitis is an inflammatory process involving the vagina, expanding often to the contiguous anatomical structures (cervix and vulva). Non-specific vaginitis is usually caused by an alteration (disruption) of the normal vaginal microflora, usually represented by the presence of Lactobacilli. Non-specific vaginitis can be correlated to *Kaphaja Yonivyapad* based on its *Lakshanas*. **Objectives:** To evaluate the efficacy of *Pippalyadi taila yoni pichu* in management of *Kaphaja yoni vyapad.* **Design:** This was a pilot study that included twenty female patients of *Kaphaja yonivyapad* (non-specific vaginitis) from the Dept. of Prasooti tantra and Stree roga OPD of Rajiv Gandhi educational society's Ayurvedic Medical College, Ron. Patients were administered *Pippalyadi taila yonipichu* for 7 days and were assessed before and after the treatment and followed up on the 14th day. **Results:** This pilot study showed statistically significant changes in reduction of *Katishoola* ($p<0.001$), *Kandu* ($p<0.001$), consistency of the *srava* ($p<0.001$) and *Srava pramana* (quantity of the discharge) ($p<0.001$) showing the effectiveness of *Pippalyadi taila yoni Pichu* in the management of *Kaphaja yonivyapad*. **Conclusions:** *Pippalyadi taila yonipichu* showed significant changes in the management of *Kaphaja* yoni *Vyapad* with the reduction of *Katishoola, Kandu*, consistency of the *Srava* and *Srava pramana* after the treatment.

INTRODUCTION

Normally, a healthy vaginal environment maintains a balance between the protective organisms (Lactobacillus) and other anaerobic and aerobic flora, with Lactobacillus as the majority organism. The adversely altered balance between protective organisms and potential pathogens in the microenvironment of genital tract results in gynecological disease, such as non-specific vaginitis (NSV)[1,2]. Large number of women in their reproductive ages is diagnosed with NSV.[3]

Non-specific vaginitis is an abnormal discharge with altered vaginal pH, clue cells and absence of inflammatory response.[4] The common conditions associated with abnormal vaginal discharge are bacterial vaginosis (50%), mycotic vulvovaginitis (20-25%) and trichimoniasis (15-20%).[5] Bacterial vaginosis is the cause in 40% to 50% of cases in which a cause is identified, with vulvovaginal candidiasis accounting for 20% to 25% and trichomoniasis for 15% to 20% of cases. Noninfectious causes, including atrophic, irritant, allergic, and inflammatory vaginitis, are less common and account for 5% to 10% of vaginitis cases.[6]

Their vaginal discharge gives out a fishy odor, which is intensified after intercourse and during menstruation. NSV is diagnosed on the basis of the presence of at least three out of the following four parameters: presence of thin grey homogeneous discharge, vaginal pH 4.7, release of fishy odor after adding 10% potassium hydroxide (KOH), and the presence of "clue cells"[7].

Vaginitis causes various pregnancy complications like preterm labour, premature

rupture of membranes and chorioamnionitis.[8,9] The secret of successful management of vaginal discharges or infections is in the diagnostic approach. If a proper diagnosis is made treatment follows easily.[10] The therapy for specific vaginitis rest on specific drugs, depending on the etiology (e.g. metronidazole for trichomoniasis), while the treatment for the vaginosis should be focused in restoring the local physiological homeostasis. Nevertheless, it has to be noted that, except in clearly defined cases, such as candida infections, the initial clinical picture of the two types of vaginitis is virtually the same (presence of symptoms such as local itching and burning, leukorrhea, dysuria, and dyspareunia). Whereby, the first line therapeutic approach, which is frequently subject to self-medication[11], should be focused on rebalancing the flora and not on antimicrobials, reserving the latter to persistent cases that are properly characterized by appropriate microbiological tests. A new medical device (Damor Pharmaceuticals, Naples, Italy) is available in different formulations for the local treatment of vaginitis and, in addition, of irritative-dystrophic states of the vaginal area.[12]

In Ayurvedic medical science, gynecological disorders have been detailed under the name *Yoni vyapads* or the *Yoni rogas* which are twenty in numbers. One such disorder is *Kaphaj yoni vyapad*, which exhibits the *Lakshanas* such as *Picchila yonisrava* and *Yoni kandu*. This disorder affects both the physical and psychological health of the women. For the successful treatment of these *Yonivyapads*, Ayurveda Acharyas have described various treatment methods and yoni *Pichu* is one of its kinds that have shown its effectiveness in managing *Yonivyapads*. In the present study, an effort has been made to evaluate the effects of *Yonipichu* with *Pippalyadi taila* in the management of *Kaphaja yonivyapad*, one of the 20 *Yonivyapad* affecting most women due to the present lifestyle and improper dietary habits.

Methodology

This pilot study included twenty female patients with the complaints of *Kaphaja yoni vyapad fulfilling* the inclusion criteria from the O.P.D, Dept of Prasooti Tantra & Streeroga, Rajiv Gandhi Educational Society's Ayurvedic Medical College & PG Research Center, Ron. Patients with the complaints of *Srava* or vaginal discharge, kandu or itching and *Picchilata* or stickiness were included for the study and those with cervical or uterine malignancy, cervical erosion, candidiasis, bacterial, pregnant and lactating women and patients with systemic diseases like HTN, DM, tuberculosis and afflicted with infections like HIV, Syphilis, Herpes Genitalis, PID and Endocrinal abnormalities like hyper and hypo gonadism and hyper prolactinaemia were excluded. A special protocol was followed to collect all the necessary details pertaining to the study. Ethical clearance was obtained from the Institutional Ethical Committee and Informed consent was obtained from all the patients.

Study Design

This was a pilot study with single group, pre and post-test design with 20 patients of *Kaphaja yoni vyapad* or the non specific vaginitis.

Intervention

This study was conducted for 14 days in which *Pippalyadi taila yoni pichu* was administered for 7 days and follow up was done on 14th day. Patients were explained in detail about the treatment and assurance was given.

Poorva Karma

Pichu and *Pippalyadi taila* was sterilized with the help autoclave. After voiding the urine, patient was advised to lie down comfortably in the lithotomy position with the help of nursing staff. Perineal region was cleaned with savlon and betadine solution and draped.

Pradhana Karma

Under aseptic precaution sterile *Pichu* soaked in *Pippalyadi taila* was inserted in the vaginal canal with the help of index finger and thumb and with the help of swab holding forceps in such a way that the thread of *Yoni Pichu* was made lying out of vagina which will facilitate its easy removal.

Paschat karma

Yoni Pichu was retained till patient gets the urge of micturition or 3-4 hours after insertion. It was removed by the patient herself by pulling out the tampon of *Taila* by sitting in squatting position.

Assessment Criteria

Both the subjective and objective parameters were assessed before and after the treatment.

Subjective Parameters

Katishoola, Consistency of *Srava, Kandu.*

Objective Parameters

Srava pramana (quantity of the vaginal discharge)

Table 1: Showing the Grading of the Parameters

Sl.No		Parameters	Grading	Scoring
1.	**Subjective Parameters**	*Katishoola*	Absent	0
			Mild	1
			Moderate	2
			Severe	3
2.		Consistency of *Srava*	Watery	1
			curdy	2
3.		*Kandu*	Mild	1
			Moderate	2
			Severe	3
4.	**Objective Parameters**	*Srava pramana*	1 pad/day	1
			2-3 pad/day	2
			More than 3 pads	3

Formulation

Pippalyadi taila was prepared by collecting all the required ingredients from GMP certified store under the supervision and assistance of Department of Dravyaguna, Rasashastra & Bhaishajya kalpana of Rajiv Gandhi Educational Society's Ayurvedic Medical College & PG Research Center, Ron.

Table 2: Ingredients of *Pippalyadi taila*

S.No.	Sanskrit Name	Botanical Name	Family	*Rasa*	*Virya*	*Vipaka*	Part used
1	*Pippali*	*Piper longum*	Piperaceae	*Madhur, Katu, Tikta*	*Anusna*	*Madhura*	fruit
2	*Marich*	*Piper nigrum*	Piperaceae	*Katu, Tikta*	*Ushna*	*Katu*	*Beej*
3	*Mash*	*Amaranthus tricolor*	Amaranthaceae	*Madhura Tikta*	*Sheet*	*Katu*	*Beej*
4	*Shatpushpa*	*Anthem sowa*	Umbelliferae	*Madhur*	*Sheet*	*Madhur*	*Panchang*
5	*Kushtha*	*Saussurea lappa*	Compositae	*Katu, Tikta*	*Ushna*	*Katu*	Stem bark
6	*Saindhav*	Rock salt		*Madhur*	*Ushna*	*Madhur*	
7	*Tila tail*	*Sesamum indicum*	Pedalaceae	*Madhur, Kashay*	*Ushna*	*Madhur*	

Preparation of *Pippalyadi taila*

Preparation of Coarse Powder

Equal parts of the ingredients were taken and made into coarse powder separately. The ingredients were mixed methodically to make a homogeneous mixture and used to prepare *Kalka* and *Kwatha*.

Preparation of *Kwatha* (decoction)

Kwatha was prepared by following the general rule of text. One part of coarse powder was added with 4 parts of potable water and subjected to heat on medium temperature, until the volume was reduced to 1/4th of its initial quantity. The contents were filtered and the filtrate was used as liquid media in the preparation of *Taila*.

Preparation of *Kalka* (paste)

The coarse powder was taken and mixed with sufficient quantity of water to prepare the *Kalka*.

Taila Paka

For *Taila Paka*, as per Samhita, *Kalka* (Paste): *Sneha* (*Tila Taila* – Sesame oil): *Kwatha* (Decoction) were taken in proportion of respectively. *Tila Taila* was made warm in vessel and then vessel was taken out from flame and increments of *Kalka* was added to *Tila Taila* and heated for some time. *Kwatha* was added to these contents and heating was continued on medium flame till the *Samyak Snehapaka Siddhilakshanas* of

Mridupaka were obtained. *Udumbaradi taila* thus obtained was filtered while hot and preserved in an airtight container.

RESULTS

In the present study, twenty patients suffering from *Kaphaja yonivyapad* aged between 25 to 30yrs were administered *Pippalyadi taila yonipichu* for 7 days and follow up was carried out on the 14th day. Demographic data of the patients has been represented in Table 3.

Among the twenty patients, 10 (50%) patients were aged between 21-30yrs and 10 (50%) between 31 to 40yrs, regarding the socio-economic background, 6 patients (30%) were from lower background, 10 (50%) of middle and 4 (20%) from upper background. 13 (65%) were from urban and 7 (35%) were from rural areas, 12 (60%) were of mixed diet, 6 (30%) vegetarians and 2 (10%) eggetarian. 15 (75%) patients had disturbed sleep and 5 (25%) had undisturbed sleep, 11 (55%) were of *Vatapitta prakruti*, 5 (25%) of *Pittakapha prakruti* and 4 (20%) were of *Kaphapitta prakruti*. Assessments were made before and after the treatment and subjected to statistical analysis. (Table 4)

Table 3: Showing Demographic data

Sl. No			
1.	**Age group (years)**	**Number**	**Percentage**
	21-30	10	50%
	31-40	10	50%
2.	**Socio-economic background**		
	Lower	6	30%
	Middle	10	50%
	Upper	4	20%
3.	**Habitat**		
	Urban	13	65%
	Rural	7	35%
4.	**Diet**		
	Mixed	12	60%
	Vegetarians	6	30%
	Eggetarian	2	10%
5.	**Sleep**		
	Disturbed	15	75%
	Not disturbed	5	25%
6.	***Prakruti***		
	Vatapitta	11	55%
	Pittakapha	5	25%
	Kaphapitta	4	20%

Table 4: Results

Symptoms	**Mean (BT)**	**Mean (AT)**	**Difference**	**%**	**SD**	**SE**	**t - test**	**p - value**
Katishoola	3.1	0.85	2.25	56.25%	1.5909	0.3560	4.46	<0.001
Consistency of *Srava*	3.35	1.5	1.85	46.25%	1.3081	0.2927	4.46	<0.001
Kandu	3.1	0.85	2.25	56.25%	1.5909	0.3560	4.46	<0.001
Sravapramana	3	0.75	2.25	56.25%	1.5909	0.3560	4.46	<0.001

Katishoola

The changes in mean from 3.1 to 0.85 after the treatment with p<0.001 showed that the *Pippalyadi taila yonipichu* was effective in reducing *Katishoola* in patients suffering from *Kaphaja yonivyapad*.

Consistency of *Srava*

The changes in mean from 3.35 to 1.5 after the treatment with p<0.001 showed that the *Pippalyadi taila yonipichu* was effective in changing the consistency of the *Srava* (discharge) in patients suffering from *Kaphaja yonivyapad.*

Kandu

The changes in mean from 3.1 to 0.85 after the treatment with p<0.001 showed that the *Pippalyadi taila yonipichu* was effective in reducing *Kandu* in patients suffering from *Kaphaja yonivyapad.*

Srava Pramana

The changes in mean from 3.0 to 0.75 after the treatment with p<0.001 showed that the *Pippalyadi taila yonipichu* was effective in reducing the quantity of *Srava* in patients suffering from *Kaphaja yonivyapad.*

DISCUSSION

Irrespective of wealth of recent advances in diagnosis and treatment facilities, symptoms of vaginitis form the major complaint of patients attending the Gynaecology outpatient department.[10]

A healthy woman is a promise of healthy family. The concept of healthy *Yoni* has been asserted in various phases of woman's life from puberty to marriage to child birth and thereafter. *Kaphaja yonivyapad* is one of the problems which ruin both physically and psychologically. Due to change in lifestyle, modern food habits of fast food, junk food women is unable to follow the rules of *Dincharya, Rutucharya, Rajaswala, Rutumati and Sutikaparicharya* which are explained by Aacharyas for women's health. Thus she is prone to various *Yonirogas* one of which is *Yonigat shewta picchilsrava, Yonikandu, Yonigata Alpavedana* which are the features of *Kaphaja yonivyapada* and is neglected by women as minor symptoms.[13] In *Kaphaja yoni vyapad*, intake of *Mithya ahara*, *Ati snighda* and *Abhishyandi ahara* vitiates *Yoni pradesha* leading to excess *Sweta srava* which is *Snigdha* (unctuous), *Pandu varna* (whitish in colour) and *Picchila* (sticky in nature) associated with *Kandu* (severe itching). Acharya sushruta has described *Atisheeta srava*, *Pandu varna* and *Kandu* as the *Lakshanas* of *Kaphaja yoni vyapad.* Whereas, Acharya Vagbhata adds yellowish discharge per vagina with or without mild pain in addition.

Ayurveda emphasizes more on the preventive treatment rather than symptomatic methodology. It provides unique therapies, medications and disease specific *Ahara* and *Vihara* to manage the disease effectively and to avoid the recurrence. Major maladies affecting the female reproductive system are the *Yoni vyapads* or the *Yonirogas* which are said to be caused due to the indulgence of *Mithya ahara vihara*, *Artava dusti*, *Shukra dushti* and influence of *Daiva. Kaphaja Yonivyapad* is one of the twenty *Yonivyapads* as opined in Ayurvedic literature. Based on the features, *Kaphaja yoni vyapad* can be considered as non specific vaginitis.

Regarding the management of *Kaphaja yoni vyapad*, various unique therapies have been mentioned in Ayurveda, among which *Yoni pichu* is one. In the present study, *Pippalyadi taila* has been used for *Yoni pichu* for the management of *Kaphaja yonivyapad*. This study included 20 female patients with the complaints of *Kaphaja yoni vyapad* who were administered *Pippalyadi taila yonipichu* for the management of the disease. Patients were examined and assessed before and after the treatment for *Katishoola*, consistency of *Srava*, *Kandu* and *Srava pramana* and showed significant results in all the outcome measures with p<0.001. Among the 20 female patients, both the age groups had (50%) of patients, middle socio-economic status (50%), most of them were from urban areas (65%), mixed diet (60%), having disturbed sleep (75%) and of *Vatapitta prakruti* (55%).

Sthanika chikitsa or local treatment plays very crucial role in the management of various gynaecological disorders. Ayurveda has described many therapies for the management of common gynecological disorders (*Stree Roga*) and *Sthanika Chikitsa* is one of them. *Sthanika Chikitsa* (local therapies) helps to relieve itching, burning pain, discharge and bad smelling. In Ayurveda there are various forms of local treatments such as *Yoni Pichu, Yoni Dhupana, Yoni Dhavana, Yonilepana, Yoni Varti*, *Kshar Karma* and *Agnikarma* have been mentioned for the management of various gynaecological and obstetrical disorders. Although it is more of local treatment but its effect is systemic too and capable of preventing complications of diseases. *Yoni Pichu* is one of the types of *Sthanika chikitsa* where sterile medicated *Pichu* is kept inside the vagina for a specific period of time. "*Vatartanam cha yoninam sekabhyanga pichu kria*".[14]

This is one of the simplest para surgical procedures that ensures the continuous drug delivery to the target organ, another advantage is that there is no need of sophisticated instruments and trained expert rather than patient can do itself after a little instruction. *Pichu* (Tampon) is made up of cotton swab wrapped with gauze piece and tied with long thread. It should be immersed in medicated oil or liquid. Oils are mostly preferred due to its retention ability. Circular and elongated *Pichu* is used for shallow and deep insertion in side vagina respectively *Pichu* should be kept for 5 to 6 hour up to retention of urine.[15,16]

One study which studied probiotic vaginal tampons showed that they are more natural with better compliance, significantly effective in relieving vaginal symptoms and discharge and had non-significant higher cure rate for patients with bacterial vaginosis than metronidazole oral therapy.[17]

Ayurveda classics describe the action of medicines in three ways i.e., *Dravyaprabhava*, *Gunaprabhava* and *Dravyaguna prabhava*. According to Sushruta, *Pichu* helps in *Lekhana* karma and thus, removes slough. In *Yonipichu*, mostly medicated *Kashaya, Sarpi* and *Taila* are used. These preparations have two main functions i.e., *Shodhana* (purification) and *Ropana* (healing). Its various mode of action will depend upon the various types of medicine that used, as different medicines have different action. Depending on the drugs *Yonipichu* can act as an antibacterial, controls vaginal discharges, helps in wound healing. *Pichu* helps the medicine to remain at that particular site for a longer period for better action. It improves the musculature tone of vaginal canal.[18] The present study showed significant changes in the reduction of the complaints of *Kaphaja yoni vyapad* with the *Pippalyadi taila* administration for 7 days.

CONCLUSION

This pilot study with *Pippalyadi taila yonipichu* in twenty patients showed significant changes in the management of *Kaphaja yoni vyapad* with the reduction of *Katishoola, Kandu*, consistency of the *Srava* and *Srava pramana* after the treatment. Cost effective, affordable and a very easy treatment that could be carried out on OPD basis without any adverse effects. Studies with larger sample size and randomized controlled studies needs to be conducted to further evaluate the effects of the *Pippalyadi yonipichu*.

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