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Research Article

CLINICAL EVALUATION OF *BRIHAT SHATAVARI GHRITA* LOCALLY AND ORALLY IN *PITTAJ YONIVYAPAD* WITH SPECIAL REFERENCE TO PELVIC INFLAMMATORY DISEASES Mulla Iram Bano^{1*}, Dongre Rupali¹, Prasad Lomate³

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KEYWORDS: Pittaja Yoni	ABSTRACT
Vyapad, Brihat Shatavari ghrita, Intra vaginal drugs.	<i>Yoni Vyapad</i> is a compilation of various disorders of the genital tract ranging from vulva till the uterus. Local infectious conditions like vulvo vaginitis, pelvic inflammatory diseases have also been described. Among the various treatment modalities described for <i>Yoni Vyapad</i> , the emphasis given to <i>Sthanika Chikitsa</i> is noteworthy. The mode of approach through local route (with or without oral treatment) is with the aim to give instantaneous relief to the suffering woman. <i>Pichu Prayoga</i> is one such intervention among which <i>"Shatavari ghrita pichu"</i> has been specifically mentioned in the context of <i>Pittaja Yoni Vyapad</i> . The symptoms which are seen in the stubborn vulvo vaginitis conditions need effective treatment procedures. The use of a topical medicine like <i>Pichu</i> will act directly on the vaginal mucosa and enable easier and target specific action. Therefore it helps to combat the local disease causing agent and simultaneously strengthen the vagina as well as prevent recurrence. Simultaneous oral ingestion of the drug alongside, takes care of the complete eradication and relief of the
*Address for correspondence	disease symptoms. Since Ghrita is the best Pitta Shamaka, Shatavari Ghrita is
Vd. Mulla Iram Bano	chosen for our study in <i>Pittaj Yonivyapad</i> which is a <i>Pitta pradhan vyadhi</i> seen
P.G Final yr in PTSR.	frequently these days. A Clinical Trial was carried out on 60 patients detected with <i>Pittaj Yonivyapad</i> with a trial group of 30 patients undergoing oral
Room No 14, Sector A, E -line, Near Gulshan-e-Baghdad Masjid,	treatment of Shatavari Ghrita orally and Shatavari Ghrita Pichu vaginaly for 7
Church Road, Cheetah Camp,	days in comparison with same number of patients taking oral tablets of
Trombay, Mumbai-400088	Clindamycin with Clindamycin pessaries kept vaginally for equal number of
Ph: 09594162992	days. The drugs were prepared in the College Pharmacy and the Research
Email:	conducted in the PTSR OPD of Loknete Rajaram Bapu Ayurvedic College,
theshanghaishores@ymail.com	Hospital and PG Institute, of which we got satisfactory results of 50 – 75% in
	comparison with the allopathic drugs for Pelvic Inflammatory Disease.

INTRODUCTION

A healthy woman is a promise of a healthy family and a woman's health status is a complex arrangement controlled by a wide range of factors headed by her reproductive system. The significance of a healthy *Yoni* has been asserted in various phases of a woman's life from puberty to marriage to child birth and thereafter.^[1] The word *Yoni* has been mentioned with reference to female reproductive system at various levels especially with reference to the vagina, uterus and sometimes the reproductive tract as a whole.^[2]

Pittaj Yonivyapad is one of the frequently seen gynecological disorder remains one among those which cause considerable morbidity affecting both physical as well as psychology of the women. It is observed that physiological state of body changes throughout the life span. As per *Ayurveda, Tridoshas* should be at *Prakrut avastha*. With the technological development social life has undergone huge changes. With change in lifestyle people adapted new habits like *Mithya aahara vihara* like eating spicy food, fast food, travelling in hot polluted atmosphere, for spacing the family usage of various types of contraceptives like OC pills and Cu-T insertion etc,. which are harmful to women's health. A detailed description of the disease of female genital tract is described in *Ayurveda*^[3] under the chapter on *Yonivyapads*. Charak has described 20 different types of disease of the genital tract and *Pittaj Yonivyapad* is one of the common and important *Yonivyapads*.

In Rajaswala stage i.e. (Reproductive age 20-40 years) Pitta dosha pradhanyata is seen and if woman indulges in Pittakara aahar vihar in this stage it causes Pitta dushti and can cause Pitta pradhan vyadhis. Pittaj Yonivyapad is one among this due to excessive intake of Katu, Amla, Lavana, Kshara aahara, Pitta gets vitiated and reaches Tryavarta yoni and leads to Daha, Paka, Ushna, Raja adhikya, Neel peeta rajasrava, and many times Jwara is seen as Sarvadehik lakshan.

Based on the characteristics of *Pittaj Yonivyapad* it has been observed that features mimic Pelvic inflammatory disease. Throughout the world there is increasing rate of pelvic infection due to rise in STDs.

According to CDC (Centers for Disease Control) incidence of Pelvic Inflammatory Disease 24-32% women in India in 2013-14.From 1995-2001, 769,859 cases of Pelvic Inflammatory Disease were reported in The United States annually. The Center For Disease Control And Prevention has estimated that more than 1 million women experience an episode of Pelvic Inflammatory Disease every year. The disease leads to approximately 2.5 million OPD visits and 125,000-150,000 hospitalization yearly. Some are identified and treated whereas most are overlooked.^[4]

Increased incidence of STDs and correspondingly PID is due to.

- Increased permissive sexual attitude together with the ready availability of contraception.
- The incidence varies from 1% -2% per year among sexually active women. About 85% are spontaneous infection in sexually active females of reproductive age.
- The remaining 15% follow procedures which favors the organisms to ascend up. Such iatrogenic procedures include – Endometrial biopsy,
- Uterine curettage
- Insertion of Intra uterine device & Hysterosalpingogram.

Keeping in view all these factors, a woman who is afflicted with *Pittaj Yonivyapad*^[5,6,7,8], if not properly intervened in right time, in long run she may come out with various complications in the form of infertility etc.

In modern system of medicine antimicrobials, analgesic, NSAID's are often prescribed in the treatment of Pelvic Inflammatory Disease. Gastrointestinal upset which are increased by analgesics and anti-inflammatory drugs, which also produce headache, dizziness, drowsiness. The aim of this study is to find out a safe, potent, nonsurgical management for Pelvic Inflammatory Disease.

Management of *Pittaj Yonivyapad* in classics has been described as being treated by using *Raktapittahara Chikitsa Sheetaveerya Dravyas*, therapies like *Seka*, *Abhyanga* and *Pichudharana* etc.

AIMS

To evaluate clinical efficacy of *Brihat Shatavari Ghrita* orally and locally (In the form of *Pichu*) in *Pittaj Yonivyapad*

OBJECTIVES

To study the *Pittaj Yonivyapad* in detail.

- Conceptual study of Pelvic Inflammatory Disease in detail
- To study the properties and actions of *Shatavari Ghrita* in detail.
- Comparative study of *Pittaj Yonivyapad* & PID.

NIDANA FOR PITTAJ YONIVYAPAD

Vishesha nidanas for Pittaj Yonivyapad are as follows :

These are mainly Pitta prakopaka factors. Katu,

Amla, Lavana, Kshara padartha atisevana. Along with this other factors are: *Teekshna, Vidahi* and *Ushna padartha Atisevana*, other articles of food include :

- Kulatha
- Sarshapa
- Takra
- Amla phala
- Sura vikara
- Shukta sevana
- Dhanyamla sevana
- Tila anna sevana etc.
- *Vihara* include: *upavasa, bhaya, ayasa, irsha* and shoka.

SAMPRAPTI OF PITTAJ YONIVYAPAD

Pittaprakopaka ahara and vihara

↓ Vitiates *pitta dosha* ↓ Enters *yoni* ↓

Produces Pittaj Yonivyapad

SAMPRAPTI GHATAKAS

Dosha - Pitta, Vata. Dushya - Rasa, Rakta Srotas – Artavavaha Udabhava sthana - Amashaya Roga marga - abhyantara Adhisthana – Yoni, Garbhashaya Srotodushti prakara - Sanga Vyakta sthana - Yoni, Garbhashaya

LAKSHANAS:

According to Charaka

- Daha
- Paka
- Jwara
- Ushna kamita
- Artava is Neela, Peeta and Asita.
- Srava which is Bhrusha, Ushna and Kunapa.
- According to Sushruta
- Daha
- Paka
- Jwara
- Acharya Dalhana mentions there may be manifestations of *Lakshanas* like *Osha*,^[7] *Chosha*, *Paridaha*, *Dhoomayana* etc.
- According to Vagbhata
- Daha
- Paka
- Jwara

VYAVACHEDAKA NIDANA:

The conditions from which *Pittaj Yonivyapad* can be differentiated are:

- 1. Pittaja artava dushti
- 2. Raktaja artava dushti
- 3. Pittaja rakta pradara

PITTAJ YONIVYAPAD CHIKITSA

1. In all *Yonivyapad*^[8] caused due to *Pitta dosha, Sheetala* Chikitsa should be done or *Raktapittahara* measures should be adopted.

2. Therapies like *Seka, Abhyanga* and *Pichu kriya* must be performed with the drugs having *Sheetala* properties.

3. Uttarabasti should be given with Ksheera prepared from Madhura drugs or Madhuka. (Charak samhita chiktsa 30/85)

4. Kalkadharana

Panchavalkala kalkadharana should be done in Pittaj Yonivyapad. (Charak Samhita Chikitsa 30/62)

Preparation of ghrita kalpana

Sneha kalpana ^[9,10,11,12] is prepared by taking *Sneha* in one *Matra*, drug *Kalka* in 1/4th of *Sneha* and adding *Drava* (liquid) four times of *Sneha*. Heating the given combination till following characters are observed gives the *Sneha kalpana*.

- 1. The drug *Kalka* could be melted in *Varti* with two fingers.
- 2. If the *Kalka* is exposed to fire no sound is observed.
- 3. "*Phen shanti*"^[13], that means no further bubbles are observed over *Ghrita* while heating it.
- 4. *Ghrita* gets all the characters of crude drug by which it was medicated, such as smell, taste, color and its medicinal properties.

Thus when this *Sneha* gets prepared finally, it could be used for massaging the body, taking it orally, for the purpose of *Nasya, Gandush, Basti*, oiling the eyes, *Vrana chikita, Pichu dharan* etc.

Indication for Ghrita sevan

Intake of *Ghrita* is prescribed for those whose bodily constitution is dominated by *Vata* and *Pitta*, who is suffering from disease due to vitiation of *Vata* and *Pitta*, those desirous of strength, good complexion, voice, nourishment, progeny, tenderness, luster, *Ojas*, memory, intelligence, power of digestion, wisdom, proper functioning of sense organs and those afflicted with injuries due to burns, by weapons, poison and fire.

Absorption of drug through vagina- Vagina is preferred as a route for drug delivery because of its anatomical position which favors secure retention of vaginal formulation. The vaginal defense (i.e. epithelium, flora, immune cells and pH), microbiology and vascularity make it ideal for absorbing drugs. Now, potential for systemic delivery through vagina was explored due to its large surface area, high vascularity and permeability to a wide range of compounds including peptides and proteins.

MATERIALS AND METHODS

Source of data

- 1. 60 patients diagnosed as *Pittaj Yonivyapad* (PID) attending O.P.D. of our institution and fulfilling criteria was taken for the study.
- 2. A special Performa was prepared with all points of history taking, physical sign and symptoms and lab investigations. The parameters were scored on the basis of standard methods of statistical Analysis.
- 3. Selected patients were divided into two groups of 30 patients each.

Inclusive Criteria

- Married females

- Patients within the age group of 20-40 years.
- Diagnosed cases of *Pittaj Yonivyapad* (PID)
- Written informed consent and voluntary willing patients were taken for this study.

Exclusive Criteria

- Pregnant females
- H/o DM, HTN, Asthma.
- Patients who require surgical interventions in cases like pelvic Abscess, Tubo ovarian mass etc.
- Patients with PID when seen associated with prolapsed uterus.
- PID associated with tubercular infections.
- Patients with exclusively vulvitis and bartholinitis.
- PID when complicated with Diabetes.
- HIV, HBsAg, VDRL Positive
- Patients with benign and malignant tumors of the uterus.
- STD, IUCD disease.

Investigations

- CBC
- HIV, VDRL, HBsAg
- Urine Routine and Microscopic
- Pap smear
- USG (if required)

PARAMETERS FOR ASSESSMENT

Subjective Parameter

1) Daha

1) Daha	
Absent :	0
Mild :	1
Moderate (Subsides on its own) :	2
Severe (Needs medicines to subside) :	3
2) Srava – praman	
No discharge	: 0
Occasional discharge	: 1
Discharge sufficient to wet the	
undergarment	: 2
Heavy discharge	: 3
3) Mutradaha	-
Absent	: 0
Occasional	: 1
Moderate relief by cold water wash	: 2
Severe	: 3
4) Backache	
No pain	: 0
Pain during menses, intercourse,	: 1
No interference with routine work	• •
continuous pain interferes with routine	2
subsides after medication	: -
Continuous pain interferes with routine	: 3
work no relief with medication	
5) Ruja (Adhodar Shoola)	
No pain : 0	
Mild : 1	
Moderate : 2 Severe : 3	
Objective parameters	
1) <i>Paka</i> of Vulva	
Normal (Pink color) :	0
Mild (Slight deviation towards red)	1
Moderate (red)	2
Severe (Bright red)	3
Severe (Dright reu)	5

0

1

2

3

2) Tenderness			
No Adnexal tenderness			:
Adnexal tenderness			:
Cervical motion tender	ness		:
Mass felt through fornio	ces		:
3) Fever			
Absent	:	0	
Mild (97.6°-99°f)	:	1	
Moderate (99º-100ºf)	:	2	

Severe(100⁰-101⁰f) : Level of Percentage of Relief

Difference between pre and post treatment symptom score

3

Cured:All symptoms Disappeared-100%Remarkable.improvement:Relief in between 50-75%Improved:Relief in between 25-50%Unchanged:Relief < 25%</td>

STUDY DESIGN

Group A (Trial Group)

30 diagnosed patients of *Pittaj Yonivyapad* were administered *Shatavari Ghrita* orally for 7 days and *Shatavari Ghrita Pichu Dharan* (Vaginally) for 7 days.

✓ Shatavari Ghrita (orally)

Dose: - 12gm once a day (approximately 3 tsf.)

Anupana:-Go dugdha

Kala:-Pratah kala on empty stomach (between 6 to 8 am.)

Duration:-7 days.

Follow up:-daily for 7 days.

Next follow up:-on 14th day

✓ Method of Pichu Dharan

Brihat Shatavari Ghrita Pichu Dharan (vaginally) Procedure

- Patient was advised to come after her menstruation. **OBSERVATIONS**

- After evacuation of the bladder patient was made to lie in lithotomy position
- Vulva and surrounding area was cleaned with antiseptic lotion.
- *Pichu* was prepared with *Shatavari Ghrita* and inserted deep into the vagina touching the cervix
- Patient was asked to retain it for 4 hours.
- Same Procedure was continued for 7 days.

Kala :- Day time (for 4 hours) once in a day

Duration :- 7 days

Follow up:- daily for 7 days.

Next follow up:- on 14th day

Group B (control group)

30 diagnosed patients of *Pittaj Yonivyapad* (PID) were administered.

Tab. Clindamycin 450 mg qid (4 times in a day) for 7 days. Followed by Clindamycin 100 mg vaginal pessary HS for 7 days.

Follow up :- daily for 7 days.

Next follow up :-on 14th day

METHOD OF PREPARATION OF DRUG:

- Raw drugs required were authentically identified and preparation was done in College Pharmacy.
- *Ghrita* was prepared according to *Sharangdhara samhita*.^[14]

Method of Preparation of Brihat Shatavari Ghrita

Brihat Shatavari Ghrita was prepared according to Sarangdhara Samhita. Jeevak, Rishbhak, Meda, Mahameda, Kakoli, Kshirkakoli drugs are not available therefore their Pratinidhi drugs i.e. Vidari, Ashwagandha & Shatavari were taken in double quantity. Rests of the ingredients of the compound were taken in one-one part. The quantity of Ghrita was taken twice the whole drugs. The quantity of milk was taken four times to Ghrita.

Table 1: According to Change in Daha Daha Day-0 Day-14 Wilcoxon Signed Sd % Relief Ranks Test Z Р **Mean score** Sd Mean score 1.97 .711 4.594 < 0.001 HS Group-A 1.066 .67 66.1 1.83 .675 78.2 Group-B .874 .40 4.651 < 0.001 HS

In trial group-A: The mean score for B.T. was 1.97 & had changed to. 711 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

In Control group-B: The mean score for B.T. was 1.83 & had changed to. 40 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Table 2: According to Change in Srava

Srava	Day-0		Day-14		%	Wilcoxon Signed			
praman	Mean score	Sd	Mean score	Sd	Relief	Ranks Test Z	Р		
Group-A	2.03	.809	.77	.626	62.3	4.597	<0.001 HS		
Group-B	1.83	.747	.40	.621	78.2	4.667	<0.001 HS		

In trial group-A the mean score for B.T. was 2.03 & had changed to. 77 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

In Control group-B the mean score for B.T. was 1.83 & had changed to. 40 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Table 3: According to Change in Mutradaha

	Day-0		Day-14		%	Wilcoxon Signed	
Mutradaha	Mean score	Sd	Mean score	Sd	Relief	Ranks Test Z	Р
Group-A	2.00	.947	2.00	.699	58.3	4.419	<0.001 HS
Group-B	1.63	.890	1.63	.606	79.6	4.481	<0.001 HS

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In trial group-A the mean score for B.T. was 2.00 & had changed to. 69 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

In Control group-B the mean score for B.T. was 1.63 & had changed to. 60 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Table 4: According to Change in Backache

	Day-0		Day-14	ŀ	%	Wilcoxon Signed	
Backache	Mean score	Sd	Mean score	Sd	Relief	Ranks Test Z	Р
Group-A	2.03	.765	.80	.761	60.7	4.604	<0.001 HS
Group-B	1.40	.675	.73	.583	47.6	4.472	<0.001 HS

In trial group-A the mean score for B.T. was 2.03 & had changed to. 80 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

In Control group-B the mean score for B.T. was 1.40 & had changed to. 73 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Table 5: According to Change in *Ruja*

	Day-0		Day-14		%	Wilcoxon Signed Ranks	
Ruja	Mean score	Sd	Mean score	Sd	Relief	Test Z	Р
Group-A	2.23	.817	.73	.521	67.2	4.755	<0.001 HS
Group-B	1.80	.847	.40	.498	77.8	4.584	<0.001 HS

In trial group-A the mean score for B.T. was 2.23 & had changed to. 73 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

In Control group-B the mean score for B.T. was 1.80 & had changed to. 40 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Table 6: According to Change in *Paka* of Vulva

	Day-0		Day-14		%	Wilcoxon Signed			
<i>Paka</i> of vulva	Mean score	Sd	Mean score	Sd	Relief	Ranks Test Z	Р		
Group-A	2.00	.587	.60	.621	70.0	4.752	<0.001 HS		
Group-B	1.53	.819	.33	.547	78.3	4.512	<0.001 HS		
	C	D M	0 0 0 0 1 1 1	101	() ()				

In trial group-A the mean score for B.T. was 2.00 & had changed to. 60 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

In Control group-B the mean score for B.T. was 1.53 & had changed to. 33 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001

Table 7: According to Change in Tenderness

	Day-0		Day-14		%	Wilcoxon Signed	
Tenderness	Mean score	Sd	Mean score	Sd	Relief	Ranks Test Z	Р
Group-A	1.93	.583	.77	.626	60.3	4.882	<0.001 HS
Group-B	1.60	.814	.57	.774	64.6	4.625	<0.001 HS

In trial group-A the mean score for B.T. was 1.93 & had changed to. 77 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

In Control group-B the mean score for B.T. was 1.60 & had changed to. 57 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Table 8: According to Change in Fever

	Day-0		Day-14		%	Wilcoxon Signed	
Fever	Mean score	Sd	Mean score	Sd	Relief	Ranks Test Z	Р
Group-A	.80	.551	.13	.346	83.3	4.264	<0.001 HS
Group-B	.50	.509	.03	.183	93.3	3.742	<0.001 HS

In trial group-A the mean score for B.T. was. 80 & had changed to. 13 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

In Control group-B the mean score for B.T. was. 50 & had changed to. 03 after treatment, by Wilcoxon Signed Rank test it was found that change from B.T. to A.T. was highly significant as P value <0.001.

Table 9: Percentage Relief								
Symptoms	Group-A (Trial Group)	Group-B (Control Group)						
Daha	66.1	78.2						
Srava-Praman	62.3	78.2						
Mutradaha	58.3	79.6						
Backache	60.7	47.6						
Ruja	67.2	77.8						
Paka Of Vulva	70.0	78.3						
Tenderness	60.3	64.6						
Fever	83.3	93.3						

AYUSHDHARA, 2016;3(2):652-658 Table 10: Percentage Relief

Overall Effect	No. of sy	No. of symptoms				
	Group-A	Group-B				
No change (<25%)	0	0				
Mild change (25% – 49.9%)	-	1				
Moderate change (50% -74.9%)	8	3				
Good change (75% +)	2	6				

Above distribution shows that there is<25 to no change, improved in zero symptom, where as there is 25 to 49.9% cured in 1 symptom i.e. backache, 50 to 74.9% cured in 8 symptoms i.e. *Daha, Sravapraman, Mutradaha, Ruja, Paka* of vulva and tenderness. 75% cured in 2 symptoms i.e. *Srava* and Fever.

DISCUSSSION

The etiologies given for *Pittaj Yonivyapad* are mainly the dietetic factors like *Kshara, Amla, Lavana, katu* etc which are mainly the *Pitta* vitiating factors.

CONCLUSION

- The conclusions that have been drawn from the study are
- Features of *Pittaj Yonivyapad* have close resemblance with Pelvic Inflammatory Disease.
- The treatment which includes *Brihat Shatavari Ghrita* locally (*Pichu Dharan* vaginally) and orally has been used based on their properties like *Sheeta veerya*, *Madhura rasa*, *Daha prashamana*, *Srava hara* and *Vedana shamaka* all these objectives are fulfilled to a greater extent.
- Among the available treatment for *Pittaj Yonivyapad*, *Brihat Shatavari Ghrita pichu* and taken orally is beneficial in curing the vitiated *Pitta dosha*.
- Total effect of the combined therapy on *Daha* contributes about 66.1% after treatment and 70.0% for *Paka*.
- So it can be concluded that *Brihat Shatavari Ghrita* is preparable, effective, potent, easily administrable type of treatment.
- It is also noted that, *Brihat Shatavari Ghrita* orally and locally (*Pichu Dharan*) i.e.-A (trial drug) has shown mild better results in some symptom of *Pittaj Yonivyapad* i.e. *Srava* and Backache.
- Since the clinical study was conducted on a limited number of patients it may not be claimed as final. More detailed study may be needed in this regard to establish the efficacy of *Brihat Shatavari Ghrita* orally and locally (*Pichu*).

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