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## CLINICAL STUDY OF PUSHYANUGA CHURNA AND YONI PRAKSHALANA WITH TRIPHALA KWATHA IN MANAGEMENT OF KAPHAJA YONIVYAPADA W.S.R. VULVOVAGINITIS

Ankur Maurya<sup>1</sup>\*, Basant Kumar Parashar<sup>2</sup> and Pratap Rao Ighe<sup>3</sup>

<sup>1</sup>M. S. (Ayu.) MS (Ayu)-Batch202 P.G. Deptt. of Prasuti Tantra and Stri Roga Shri Dhanwantri Ayurvedic Medical College Research Centre, Mathura- 281401.

<sup>2</sup>MD (Ayu.) Principal Shri Dhanwantri Ayurvedic Medical College Research Centre, Mathura-281401.

<sup>3</sup>M.S. (AYU.) Associate Professor P. G. Deptt. of Prasuti Tantra And StriRoga Shri Dhanwantri Ayurvedic Medical College Research Centre, Mathura- 281401.

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\*Corresponding Author
Dr. Ankur Maurya

M. S. (Ayu.) MS (Ayu)-Batch202 P.G. Deptt. of Prasuti Tantra And Stri Roga Shri Dhanwantri Ayurvedic Medical College Research Centre, Mathura- 281401.

#### **Need of study**

- The prevalence & incidence rate occurrence of Vulvovaginitis is widespread due to unhealthy habits and lack of hygienic conditions. The majority of cases of Vaginitis are Bacterial Vaginosis.
- The onset of the infection is not known as 50% of the women are asymptomatic. Though it is projected to be 40 to 50% in the age group of childbearing women, the second most common type of genital Candidiasis around 20-25% in women, and the incidence of Trichomonas infection is about 10-15%.
- According to WHO, every year 333 million new cases of curable Vulvovaginal infections are registered. 75% women experience vaginal yeast infection at least once during their life time.
- So, there is a great scope to find out a safe, potent, effective and cost-effective Ayurveda remedy for the management of Vulvovaginitis.
- With the use of external treatments like, Yoni Prakshalana, Uttar
   basti and internally administered medicines such as Pushyanuga

Churna, Triphala Guggulu, Ashokarishta, Lodhrasava, etc., many patients get symptomatic relief with minimal or no side effects.

#### INTRODUCTION

- In Ayurveda classics, majority of the gynecological disorders have been described under the heading *Yonivyapada*. Abnormal diet, Abnormal mode of life causing *Pradushta Artava* and *Beej Dushti* are common factors that give rise to these disorders. *Kaphaja Yonivyapada* is one of them. Among twenty *Yonivyapada*, *Shleshmala* (by Sushruta), *or Shleshmiki* (by *Charaka* and *Vagbhatt*a) is explained in different criteria as a cause of *Kapha Dosha Dushti* in the vagina leading to discoloration of the skin and mucosal lining. Vaginal discharge, i.e., *Yoni Strava* is seen as a symptom in case of this disease. The symptoms of *Kaphaj Yonivyapada* mentioned in Ayurveda literature appear similar to the clinical features of Vulvovaginitis.
- Vulvovaginitis is an inflammatory condition of vulva and vagina and characterized by vaginal discharge, pain, itching, which are its most common symptoms and is accompanied by sign of vulval irritation such as erythema and excoriation of the vulval skin. As a part of natural protection, estrogen accumulates Doderlein"s bacilli in the vagina that convert the glycogen into lactic acid. Thus, the acidic vaginal Ph is maintained. There is occurrence of different types of vaginal infection due to organisms such as trichomonas.
- Disturbed Menstrual cycle signs and symptoms explained by *Chakrapani*, which may be evident to chronic trichomonas, have significant characters like vaginitis. In this condition, the vaginal canal is covered with strawberry-coloured patches and white or yellowish thick curdy discharge, and the vaginal canal appears as yellowish/pale discoloration. Considering all such symptoms mentioned by various Ayurveda texts, the *Kaphaja Yonivyapada* can be closely compared with vulvovaginitis. As mentioned before, the *Kaphaja Yonivyapada* or vulvovaginitisis characterized by *Yonigata Shwetastrava* (White discharge) and *Yonikandu* (Vaginal itching). If these signs and symptoms remain neglected, they may lead to significant infections that harm the overall health and responsible for psychological disturbances.
- The treatment modality in the allopathic medicines include Antifungal, Antibacterial, Antiprotozoal, etc. drugs. But all have unsatisfactory results. They also have some side effects like local burning, irritation, rashes and hypersensitivity.
- In Ayurveda, *Yoni Prakshalana* is a procedure which is quite similar to vaginal douching.

It is a method of Ayurvedic cleansing of the vaginal area with *Kwatha* (Decoctions) and medicated oils. This procedure is prescribed for gynecological disorders, inflammations, erosion, infertility. It also provides strength to vaginal muscles. In addition to treatment of pathological conditions it can also beused as a general cleansing measure of genital organs to avoid bacterial or fungal infections. *Pushyanuga Churna* is a potent medicine useful in treating many gynecological disorders.

#### Kaphaja yonivyapada

Excessive consumption of foods and substances which cause oozing and serous effusion in the body and other *Kapha* aggravating foods and activities on regular basis by woman causes aggravation of *Kapha*.

*Kapha Dosha* is composed of earth and water elements. It has coolness and Heaviness as its basic qualities. Any diet or activity that causes in crease of coolness and heaviness naturally increases *Kapha Dosha*.

#### Factors that aggravate kapha dosha are

- *Guruahara*–Excessive consumption of heavy to digest foods
- *Madhura*–Excessive consumption off oods which haves sweet taste
- Atisnigdha Excessive consumption of unctuous or oily foods (Fried foods). Oiliness (Unctuousness) is a Kapha Dosha quality. Hence, any thing that is oily and fatty aggravates Kapha Dosha.
- Dugdha-Excessive consumption of milk. Cow milk, beings sweet in taste and heavy to digest, increases Kapha Dosha.
- *Ikshu*-Excessive consumption of sugar cane and its derivatives like sugar, jaggery (Molasses) etc.
- *Bhakshya*—High caloric foods
- Coconut milk—Being sweet and heavy to digest increases *Kapha Dosha*.
- *Drava*–Excessive consumption of liquid foods. This is due to increase of water elements.
- *Dadhi*–Excessive consumption of curds, especially sweet curds.
- *Atinidra*–Excessive sleeping.
- *Apupa*–Excessive consumption of stuffed foods.
- *Sarpi*–Excessive consumption of ghee, ghee foods. Ghee is known to calm down *Vata* and *Pitta Dosha*. In higher doses, due to its unctuousness, it increases *Kapha Dosha*.
- **Divasaadau**—early part of the day. If we divide day time into three parts, the first part of

- the day is dominated by Kapha Dosha.
- *Bhuktamatre*—immediately after the consumption of the food. If we divide the digestion process into three parts, the first part of the digestion is dominated by *Kapha Dosha*.

#### Etiology of kaphaja yonivyapada

- Intake of *Kaphakara* (Muco-genic) and *Abhishyandi Ahara* (Obstructive/congestive foods) causes *Shleshmala* (*Kaphaja*) *Yoni Vyapada. Abhishyandi Ahara* leads to qualitative aggravation of *Kapha dosha* and *Srotomalinyakara Ahara* (Systemic pollutants) leads to *Kapha vriddhi*.
- *Mithyachara* includes both the *mithyaahara* (Abnormal diet)—intake of excessive, non-congenial, unwholesome, unhygienic, and incompatible food and *mithya*.
- *Vihara* (Abnormal mode of the life, coitus in abnormal body postures, stressful life) which also leads to *Vata Vriddhi*.
- Vata is the prime dosha for the manifestations of diseases pertaining to female reproductive organs. In Kaphaja Yonivyapada, intake of Abhisyandhi Ahara leads to Agnimandya leading to Rasadhatu dushti. Thus, Snigdhatwa, Guru, Picchila Guna of abnormal Kapha along with that the Chala guna of Vata (excessive secretory activity) results in manifestation of Kaphaja Yonivyapada characterised by Snigdha, Sheeta, Picchila Srava in Yoni.

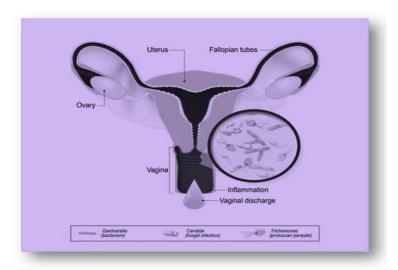
#### Samprapti ghatak

Dosha	Vata + Kapha
Dushya	Rasa, Rakta & Mamsa
Srotas	Rasavaha, Artavavaha, Raktavaha
Srotodusti Lakshana	Atipravritti
Adhisthana	Yoni
Rogamarga	Abhyantara
Sthanasamsraya	Yonimarga & Garbhashaya

#### Vulvovaginitis

- Vulvovaginitis, Vulvitis and Vaginitis are inflammation or infection of the vulva and vagina (External genital organs of woman). Vulvovaginitis is a frequently observed condition in pregnancy, which may sometimes emerge as dangerous outcome.
- Vulvo-vaginal infections can cause discomfort, discharge with itching, redness, sometimes burning and soreness. The area around the entrance to the vagina (vulva) can also become irritated. Infection is the most clearly recognized and more widely studied and responsible for between 20 to 40% of all cases of preterm birth and other

complication like premature rupture membranes Chorio amnionitis, spontaneous abortion etc.



#### **Causative factor for vulval infection**

The vulval and perineal tissue is usually resistant to common infection. But the defence is lost following constant irritation by the vaginal discharge or urine (Urinary incontinence). Further more, there may be atrophy or degenerative changes either in disease. It is indeed too difficult to classify the vulval infection but the following etiological classification can be of help.

- A. Vulvitis due to specific infection-Bacterial, fungal, moniliasis, pyogenic (Non Gonococal), Sexually transmitted disease, Tubercular, Viral, Herpes genital is and Herpes Zoster, Condylomata accuminata, and Ring worm induced.
- B. Vulvitis due to sensitive reaction- The vulval skin is very much sensitive to many agents (mostly chemical) which may produce contact dermatitis .Such agents include drugs used locally to cure purities –douche, soap, and powder; detergent etc. the vulva is intensely inflamed and swollen.
- C. Vulvitis due to urinary contamination (Vaginal discharge)- Constant vaginal discharge makes the area moist, irritation, scratching, trauma. This favors growth of the organisms like Candida albicans or Trichomonas vaginalis. This growth is favoured by glycosuria.
- D. Diabetic Vulvitis-This is the Vulvitis due to diabetes mellitus but is caused by Monilia albicans and pyogenic infection.

#### General Signs and Symptoms of Vulvovaginitis

Vulvovaginitis is characterized by one or more of the following signs and symptoms-

Increased volume of discharge: - Local congestive state is responsible cause of an

increased vaginal secretion. Discharge is by an increased transudation from the vaginal wall.

- **Abnormal colour of discharges:** Discharge are white, thick, and cheesy inconsistency in Candidiasis, grayish in bacterial Vulvovaginitis and yellowish or greenish in colour in Trichomoniasis.
- **Vulvalitching (Pruritis vulvae):-** The discharge causes irritation of the vulva and patients complain of itching or irritation.
- **Dyspareunia:-** Due tos evere Vulvo-vaginitis vagina is very sore. Also because of severe itching Vulva and vagina is ulcerated and tender. The patient's experiences severe pain during coitus.
- Vaginal walls becomes oreandred.
- Irritation and burning on the vulva (Inner and Outer lips around the vagina) and in the vagina, including around the urethra.

#### Clinical features

#### **Symptoms**

- Vaginal discharge:- The vaginal discharge is a main complaint in Candida. The vaginal discharge is typically thick, white, and cheesy tending to from plaques which are lightly adherent to the vaginal wall. If they pull away, they leave multiple hemorrhagic spots. Many times, discharge is atypical and may be watery or purulent.
- Pruritus vulvae:- The discharge causes severe itching of the vulva, it is worst at night.
- Dyspareunia: Severe Candida infection may causes Dyspareunia due to local soreness. Non offensive and odorless discharge and sometimes foul smells. Constant vulval irritation.
- Dysuria: Pain in the vulval area is known as vulvodynia.

#### Signs

- On speculum examination the vaginal walls appear diffusely reddened and edematous. The thick white cheesy or curdy vaginal discharge is seen. The peeling of discharge from vaginal wall, small petechial hemorrhage sere seen underneath. Sometime the discharge may be watery and yellowish.
- Excoriation and fissures may present in severe cases. Perianal area is often involved.

#### **Diagnosis**

The Ph of the discharge tends to be less than 4.5 the diagnosis is often confirmed by a

vaginal swab.

#### Microscopicexamination

- Wet mount or preparation of vaginal discharge should be done. In 10% KOH we mount preparations, we can identify the fungal elements either budding yeast forms or mycelia will appear within as many as 80% of cases.
- In KOH preparation, Candida hyphae and buds stands out in prominence and easily diagnosed. The results of saline preparation of the vaginal secretion are usually
- normal, although there may be a slight increase in the number of inflammatory cells in severe cases.

#### Culturesensitivity

 The vaginal swab is take nursing Sabouraud brother Nickerson 's and medium prepared for reliable results.

#### Gram or methylene blue staining

The Candida stains poorly so that after staining of vaginal discharge the mycelia and spores may be seen retractile areas in background of stained and epithelial cells. The whiff test is negative.

#### Management of vulvovaginitis

#### **Preventive aspects**

- Advice given regarding to the personal and local hygiene.
- Use only warm water to wash the vulva. Dry thoroughly with a clean towel.(If the vulva is very irritated, you can try drying it with a blow dryer set on cool.)
- Wash new under clothes before wearing.
- Use a mild soap for washing underclothes. Do not use detergents. Use soft toilet tissue.
- Control predisposing condition
- Reduce predisposing medication(e.g. corticosteroid)
- Use only white, 100% cotton under wear and Avoid moisture, Retaining products near vagina, Nylon underwear, Panty liners, Vaginal lubricants etc.
- Avoidance of contamination of vulva with a blution water after bowel action. Treat sexual partner also.
- Finger nails should be clipped short.
- Physical and emotional stress of ten precipitates attacks; hence attention should be paid to

this and treatment started immediately.

Improvement of general health.

#### **Curative aspect**

- Treatment of vaginal discharge is mainly based on the causative factor.
- Pelvic lesions producing vaginal discharge requires appropriate therapy for the pathology.

#### **Candidiasis**

- Oral antifungal medication (Fluconazole) can cause side effects such as headache, nausea,
   and abdominal pain, while vaginal treatment is unlikely to cause these side effects.
- Oral antifungal medications are also not recommended for use during pregnancy.
- Azole cream that include, 2% butaconazole, 1% clotrimazole, 2% Miconazole and
- 0.4 to 0.8% Terconazole.
- Topical treatment is recommended, although oral azoles are generally considered safe.
- Clotrimazole, Miconazole, Nystatine, and Terconazole are also available as vaginal tablets.

#### **Bacterial vaginosis**

- Orally Metronidazole 500 mg twice daily for 7days.
- 2% Clinidamycin cream, one applicator dose inserted intra vaginal at bed time for 7 days.

#### **Trichomoniasis**

 Orally Metronidazole is effective ineradicating T.vaginal is administered orally in a single 2gm dose.

#### Chlamydia vaginitis

- Treatment with tetracycline 500 mg 4times a day for one week to both partners is very effective.
- Erythromycin base 500 mg orally four times a day for 7 days is the primarily recommended regimen during pregnancy (curerate 85%)
- Alternatively, the Amoxicillin 500 mg orally three times daily for 7 days may be given (curerate 82%)

#### Non-specific bacterial vaginitis

 Treatment during pregnancy is critical because data suggest an association of adverse maternal and fatal outcome with bacterial vaginitis. Patients with recurrences should be screened for other STD's.

#### **Drugs**

#### Pushyanuga churna

Pushyanuga churna is used in gynecological disorders such as, Asrigdhara (Menorrhagia), Shwetpradara (Leucorrhoea), Rajodosha Yonidosha etc. according to classics. It is indicated in the classical text "Bhaisajya ratnavali" under Striroga Adhikara. Pushyanuga Churna is a classical Aurvedic preparation. Drugs present in this preparation has Sthambhan, antifungal and anti-bacterial actions. It is used in different Rogas with specific Anupanas.

Sr. No.	Content	Latin/CommonName	Proportion	Part Used
1	Patha	Cyclea peltata	1 part	Root
2	Jambu	Eugenia jambolana	1 part	ВеејаМајја
3	Amra	Mangifera indica	1 part	ВеејаМајја
4	Pashanabheda	Aerua lanata	1 part	Rhizome
5	Rasanjana	Berberisaristata	1 part	Root
6	Ambashthaki	Cissampelospareria	1 part	Root
7	Mocharasa	Salmalia malabarica	1 part	Gum
8	Lajjalu	Mimosapudica	1 part	Root
9	PadmaKeshara	Nelumbonucifera	1 part	Seed
10	Kumkuma	Crocussativus	1 part	Stamen
11	Ativisha	Aconitum heterophyllum	1 part	Root
12	Bilva	Aegle marmelos	1 part	Root
13	Lodhra	Symplocosracemosa	1 part	Stembark
14	Katphala	Myric anagi	1 part	Stembark
15	Maricha	Pipernigrum	1 part	Seed
16	Shunthi	Zingiberofficinalis	1 part	Rhizome
17	Draksha	Vitisvinifera	1 part	Dried fruit
18	Raktachandana	Pterocorpussantalinum	1 part	Heartwood
19	Araluka	Oroxylumindicum	1 part	Stembark
20	Kutaja	Holarrhena antidysenetrica	1 part	Stembark
21	Shweta Sariva	Hemidesmusindicus	1 part	Root
22	Madhuka	Glycyrrhizaglabra	1 part	Root
23	Arjuna	Terminalia arjuna	1 part	Stembark
24	Ghrita Shodhita Gairika	RedOchre	1 part	-

#### Pharmacological information of ingredients of pushyanuga churna

Sr. No.	Content	Rasa	Guna	Veerya	Vipaka
1	Patha	Tikta	Laghu Teekshna	Ushna	Katu
2	Jambu	Kashaya, Madhura, Amla	Laghu, Ruksha	Sheeta	Sheeta
3	Amra	Madhura, Amla Kashaya	Laghu, Ruksha	Sheeta	Katu
4	Pashanabheda	Tikta, Kashaya	Laghu, Snigda	Sheeta	Katu

5	Rasanjana	Tikta, Kashaya	Laghu, Ruksha	Ushna	Katu
6	Ambashthaki	Tikta	Laghu, Teekshna	Ushna	Katu
7	Mocharasa	Madhura,Kashaya	Laghu, Snighda	Sheeta	Madhur
8	Lajjalu	Tikta, Kashaya	Laghu, Ruksha	Sheeta	Katu
9	PadmaKeshara	Tikta, Katu	Snighda	Ushna	Katu
10	Kumkuma	Tikta,Katu	Snighda	Ushna	Katu
11	Ativisha	Tikta,Katu	Laghu, Ruksha	Ushna	Katu
12	Bilva	Tikta, Kashaya	Laghu, Ruksha	Ushna	Katu
13	Lodhra	Kashaya	Laghu, Ruksha	Sheeta	Katu
14	Katphala	Tikta, Kashaya	Ruksha	Sheeta	Katu
15	Maricha	Katu	Laghu, Ruksha	Ushna	Katu
16	Shunthi	Katu	Guru, Ruksha	Ushna	Madhura
17	Draksha	Madhura	Guru, Snighda	Sheeta	Madhura
18	Raktachandana	Madhur, Tikta	Laghu, Ruksha	Sheeta	Katu
19	Araluka	Katu, Tikta, Kashaya	Laghu, Teekshna	Ushna	Katu
20	Kutaja	Tikta, Kashaya	Laghu, Ruksha	Sheeta	Katu
21	Shweta Sariva	Madhura, Tikta	Guru	Sheeta	Madhura
22	Madhuka	Madhura	Guru, Snigdha	Sheeta	Katu
23	Arjuna	Kashaya	Laghu, Ruksha	Ushna	Katu
24	GhritaShodhita Gairika	Madhur,	Kashaya	Sheeta	Katu

#### Method of preparation

- Each ingredient was powdered and weighed separately.
- All ingredients were then mixed together to form homogeneous mixture of *Pushyanuga Churna*.

#### **Drug administration details**

**Drug:** Pushyanug a Churna

**Frequency:** Twice a day

**Duration:** 21days (after cessation of menses for 2 consecutive Cycle)

#### Yoni Prakshalana / Dhawana/Parisheka

It is a procedure in which the vagina, vaginal passage, and mouth of uterus is washed with medicated decoction or other liquids. *Dhavana* means cleaning or purification of wound with water or other medicated material, *Kwatha, Kshirapak, Siddha jala, Taila* have aseptic, wound healing, pain alleviating, and bactericidal action. They prevent growth of bacterial organism and restore the altered pH of vaginal cavity. It gives quality to vaginal muscles. This is general purifying measures of genital organs to maintain a strategic distance from parasitic or yeast diseases. Absorption of drug through the mucus and blood circulation also help sto have beneficial effect on the uterus it should performed in *Ritukala* from 6<sup>th</sup> day of menses

for 8 days and duration is 1-1.5min. For example, *Prakshalana* with decoction of *Lodhra* and *Trikatu* is used in *Kaphaj aartava dushti*. *Prakshalana* with decoction of *Triphala* is used in *Kunapgandhi artavadushti*. It is also indicated in *Yonikandu*, *Yoni paicchilya*, *Yoni strava*, *Yoni arsha*, *Pradara etc*.

#### Materials required

- Enema Pot
- Sterile Catheter
- Cotton
- Mackintosh cloth
- Hand Gloves

#### **Procedure**

- Proper aseptic precaution should be taken before starting the procedure.
- Patient is given lithotomy position.
- The rubber mackintosh is placed underneath patient"swaist, one end of which lies in the bucket. Sterile rubber catheter is inserted into vagina.
- Enema pot filled with decoction is kept at 5feet distance with lukewarm decoction prathamavarta (Vagina) is washed out.
- After the procedure the vulva is dried with cotton.
- Then procedure is repeated on the respective days.

#### Pharmacological study of triphala kwatha

- The *Triphala* includes three herbs, viz. *Haritaki*, *Bibhitaki* and *Amalaki*.
- Synonyms of Triphala: Phalatrika, Vara.
- Properties of Triphala: Kapha pittahara, Chakshushya, Dipani, Vrishya, Sara.
- Uses of *Triphala*: *Meha*, *Kushtha*, *vishamajwara* etc

#### Haritaki

Latin name: - Terminalia chebula Retz. Family - Combrataceae

**Chemistry:-** Fruits contain about 30% of astringent substance. The astringency is due to a characteristic principle, tannin, also contains chebulic acid, digalloy glucose, diabasic acid, ellagic acid and free tannic acid etc.

#### Guna karma

- Rasa- Kashaya pradhana Tikta, Katu, Madhura, Amla
- Guna Laghu, Ruksha
- Virya Ushna
- Vipaka-Madhura
- Prabhava Tridoshahara.

#### **Action and Uses**

Medhya, Rasayana, Brimhana, Anulomana, Ayushya, Chakshushya etc. It is used in diseases like Svasa, Kasa, Prameha, Shopha, Arsha, Grahani, Hridroga, Eye diseases, Tvakroga and Kamala etc.

#### **Pharmacology**

Terminalia chebula have cytoprotective effect on gastric mucosa.

- Myrobalans are a safe and effective purgative (Gentle laxative), astringent and alterative.
   Unripe fruits are more purgative and the ripe are astringent.
- Rangari harade are alterative, stomachic, laxative and tonic.
- Survari harade is a valuable purgative,
- Bala harade is a mild and safe aperients and antibilious, though astringent. Ripe fruit is considered as purgative removing bile and phlegm and the adjust bile.



Bibhitaki

**Latin name:-** *Terminalia bellerica* Roxb. Family – Combrataceae

**Chemistry:-** B-sitosterol, gallicacid, ellagicacid, chebulicacid, galloylglucose, Mannitol, galactose, ethyl gallate, fructose, rhamnose, a new cardiac glycoside, belliricanin, kernels

yielded yellow fatty oil.

#### Guna karma

- Rasa:-Kashaya (Pradhana), Tikta, Katu, Madhura, Aamla
- Guna:- Ruksha, Laghu
- Virya:- Ushna
- Vipaka:- Madhura
- *Doshaghnata:- Tridosha, mainly Kaphahara.*

#### **Action and Uses**

Dipana, Anulomana, Grahi, Chakshushya, Kanthya, Swasa-kasahara, Rakta shodhana. It is used in Kapharoga, Shotha, Pratishyaya, Kasa, Swasa, Swarabheda, Vatavyadhi, Arsha etc.



Bibhitaki

#### Amalaki

**Latin name:-** *Emblica officinalis* Linn(syn. *Phylanthus emblica* Linn) Family – Euphorbiaceae.

**Chemistry:-** Crystalline vitamin C is olated form the fruit pericarp in a yield of 70 – 72 % of the total. Seeds contain fixed oil, phosphatids and essential oil. Fruit contains mineral matter (0.7%), fibre (3.4%), carbohydrate (14.1%), Calcium (0.05%), phosperous (0.02%), ferrous (91.2mg/100gm), nicotinicacid (0.2mg/100gm). Phyllemb in from the fruit pulp is identified as ethyl gallate.

#### Guna karma

Rasa:- Amla (Pradhana), Kashya, Tikta, Katu, Madhura.

Guna:- Guru, Ruksha

Vipaka:- Madhura

Virya:- Seeta

Doshaghnata:- Tridoshaghna

#### **Action and Uses**

Rasayana, Vrishya, Vajikara, Chakshushya etc.

Used in Svasa, Kasa, Raktapitta, Grahani, Arsha, Kamala etc.



**Amala** 

#### Method of preparation

Triphala kwatha (Bhaishajya Ratnavali Shotha Rogadhikara-10)

Sr. No.	Ingredients	Name Botanical	PartUsed	Ratio
1	Haritaki Churna	Terminalia chebula	Driedfruit	1Part
2	Amalaki Churna	Emblica officinalis	Driedfruit	1Part
3	Bibhitaki Churna	Terminaliabelirica	Driedfruit	1Part

#### Method of preparation

 Alltheingredientswereaddedto16timesofwater, boiledandreducedto 1/4th part, the mixture was filtered and for medication purpose.

#### **Drug administration details**

- **Drug:** Yoni Prakshalan with Triphala Kwatha
- **Frequency:** once a day
- Duration:7days (After cessation of menses for 2 consecutive Cycles)

#### Method of yoni prakshalana

Proper aseptic precautions were taken before starting the procedure.

- Patient was given the lithotomy position.
- The rubber Macintosh was placed underneath patient"s waist, one end of which lay in the bucket.
- Sterile rubber catheter was inserted into the vagina.
- Enema pot filled with decoction was kept at 5 feet height with lukewarm decoction.
- Prathamavarta (Vagina) was washed out
- After the procedure, the vulva was dried with cotton.
- Then procedure was repeated on the respective days. The drugs used for *Yonidhawana* were antiseptic.

#### MATERIALS AND METHODS

The study entitled, "Clinical Study of Pushyanuga Churna and Yoni Prakshalana With Triphala Kwatha in Management of Kaphaja Yonivyapada w.s.r. Vulvovaginitis" was carried out in following ways –

#### Clinical study

- **Study design:** Single Arm Open Clinical Study
- Study centre: OPD & IPD of Shri Dhanwantari Ayurved College & Research Centre
- Ethical clearance: Institutional Ethics Committee (IEC approval letter attached in the annexure)
- **Duration of study:** 18 months
- Medium of dissertation: English supported by Ayurveda terminology and literature wherever necessary in Sanskrit.
- Diagnosed Patient as Kaphaj Yoni and after appropriate Counselling by Complaints, Examination. Patient will be selected for Study from OPD & IPD of Shri Dhanwantari Ayurved College & Research Centre with the informed consent for participation in the clinical trial will be done. These patients will be randomly selected.

#### **Selection of cases**

#### **Inclusion criteria**

- Age Group above 18 and below 40 years, having Kaphaja Yonivyapada.
- Diagnosed the patient as Kaphaja Yonivyapada.

#### **Exclusion criteria**

- Pregnancy.
- Unmarried Women

- Systemic Disorder like HTN, DM, IHD etc.
- Sexually Transmitted Disease System (STD's).
- Benign & malignant Tumors related to Female Reproductive System.
- Congenital abnormalities related to Female Reproductive

Criteria for withdrawal:- During the course of trial treatment, if any serious condition or any serious adverse events which required urgent treatment or if patients themselves want to withdraw from the study, such subjects were withdrawn from the trial.

#### Follow up

- **During clinical trial:** 7<sup>th</sup> day, 14<sup>th</sup> day and 21<sup>th</sup> day
- After trial: 1month
- **Total duration of study:** 90Days
- Sample size: 50Patients
- **Duration of clinical trial:** 2month

#### Criteria for assessments

#### Subjective criteria

- Vaginal white discharge (Srava)
- Itching (Kandu)
- Backache (Kati Shool)
- Burning of Vulva(Yoni Daha)

#### **Objective criteria**

- Vulval-Oedema, Scratch marks (Evidenceofpruritus)
- Picchila Yoni (Stickiness)
- Atisheetataa (Coldness)
- Panduvarna (Colour of Vaginal mucosa)
- Pandupicchila Artava Srava (Colour and consistency of menstrual blood)

#### **Investigations**

#### **Before trial**

- Complete Blood Count, VDRL, ESR, RBS
- Urine Routine & Microscopic Examination.
- Vaginal Swab Culture (If necessary)

- Pap Smear (If necessary)
- HIV, HBsAG, HCV
- USG Abdomen & Pelvis (if necessary)

#### After trial

- Complete Blood Count, ESR
- Urine Routine & Microscopic Examination

#### **Assessment Chart and Gradation**

#### **Subjective parameters**

**Srava:-** (Vaginal white discharge)

No vaginal discharge	
Occasionally wetting the under garments	1
Moderate Discharge, Wetting her undergarments	2
Heavy Discharge which needs the pads	3

#### *Kandu:-*(Vaginal itching)

No itching	
Occasionally Itching at Morning Or in night	1
Regular itching disturbing routine Work	
Regular severe itching with disturbing routine work	

#### Katishool :- (Back pain)

No Pain	0
Pain during Menses intercourse, no interference with routine work	1
Continuous pain interference with routine subsides after	
Continuous pain interference with routine work no relief with medication	3

#### Burning of vulva :- (Yoni daha)

No Burning	0
Occasional Burning	1
Frequent Burning	2
Continuous Burning	3

#### **Objective parameters**

No evidence of pruritis	
Reddish Discoloration	1
Edematous-Reddish Discolouration	2
Rashes & Edematous of vulva, vagina, in thigh	3

#### (Examination of external genitalia i.e. P/V & P/S)

#### **Evidence of puritis**

#### Picchila yoni (Stickiness)

No Stickiness	0
Mild Stickiness	1
Moderate Stickiness (Seen on Vaginal wall)	2
Severe Stickiness (Sticky discharge on the speculum)	3

#### Ati sheetataa (Coldness)

Coldness Not felt	0
Coldness felt	1
Romaharsham	2
Ushna kamitvam	3

#### Panduvarna (Color of vaginal mucosa)

Reddish	0
Light red	1
Yellowish	2
Paleyellow	3
Pale	4

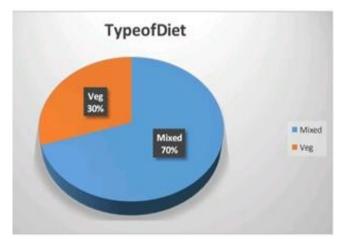
#### Pandu picchila Artava Srava (Color and Consistency of menstrual blood)

Normal	0
LightredMildStickiness	1
YellowishModerateStickiness	2
PaleYellowSevereStickiness	3

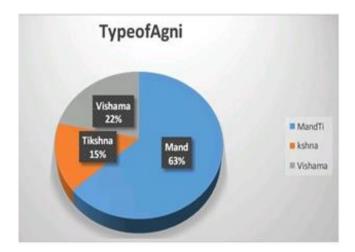
#### Plan for statistical analysis

- The study data generated through clinical study were subjected to statistical analysis to reach to the final results and conclusions.
- The demographic data were presented in tables and graphs. The data obtained in the studies were subjected to tests of significance. Results were expressed as mean value ± standard deviation (SD) and/or Median (Inter-quartile range).
- Graph Pad in Stat (www.graphpad.com) software was used for statistical analysis of data.
- For Intra-Group Comparison: Friedman test (Non-Parametric Repeated Measures ANOVA) for more than two observations
- For discrete variables: Chi–Square test was applied.
- P value <0.05was considered significant.</li>

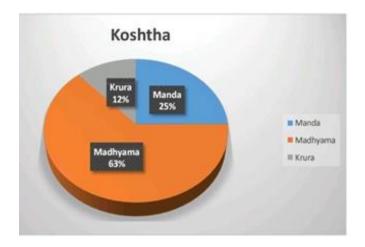
#### **Demographic presentation**



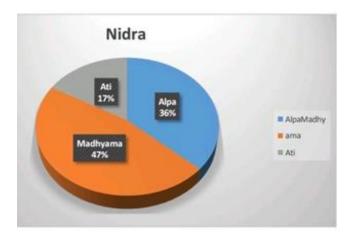
Sr. No.	Type of diet	No. of Patients	Percentage
1	Mixed	42	70
2	Veg	18	30



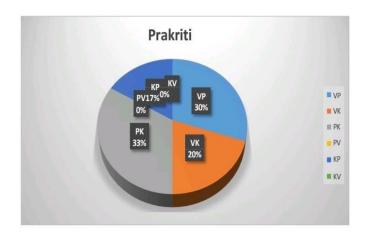
Sr. No.	Type of <i>Agni</i>	<b>No.of Patients</b>	Percentage
1	Mand	38	63
2	Tikshna	9	15
3	Vishama	13	22



Sr. No.	Koshtha	<b>No.of Patients</b>	Percentage
1	Manda	15	25
2	Madhyama	38	63
3	Krura	7	12



Sr. No.	Nidra	No. of Patients	Percentage
1	Alpa	22	37
2	Madhyama	28	47
3	Ati	10	17

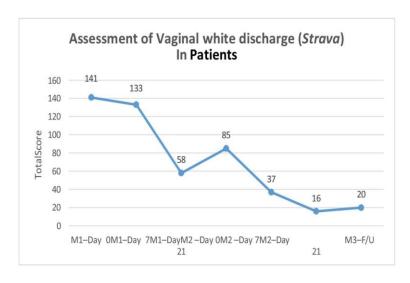


Sr. No.	Prakriti	No. of Patients	Percentage
1	VP	18	30
2	VK	12	20
3	PK	20	33
4	PV	0	0
5	KP	10	17
6	KV	0	0

#### **Assessment of parameters**

#### Assessment of vaginal white discharge (Strava) in patients

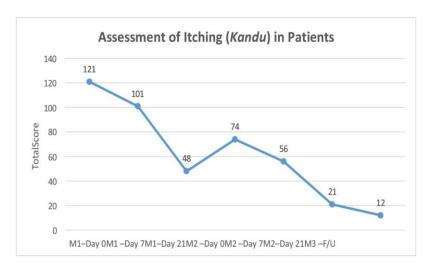
Visit	<b>Total Score</b>	Percentage Relief	Median (Range)	<b>Sum of Ranks</b>	
M1– Day 0	141		03(02-03)	335.00	
M1– Day 7	133	19.86%	02(01-03)	293.50	
M1– Day 21	58	58.87%	01(00-02)	182.00	
M2– Day 0	85	39.72%	02 (01–02)	243.50	
M2– Day 7	37	73.76%	01(00-02)	142.50	
M2– Day 21	16	88.65%	00 (00-02)	97.500	
M3- F/U	20	85.82%	00 (00-02)	106.00	
Intra-Group Comparison	Friedman Test (Non parametric Repeated Measures ANOVA)				
	Friedman Statistic Fr = 256.49(corrected forties)				
Pvalue	The P v	value is < 0.0001, cons	sidered extremely si	gnificant.	



#### Assessment of Itching (Kandu) in Patients

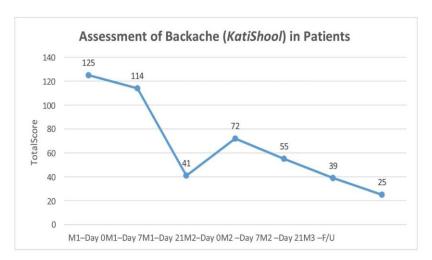
Visit	Total Score	Percentage Relief	Median (Range)	Sum of Ranks
M1– Day 0	121		02 (02–03)	328.50
M1– Day 7	101	16.53%	02(01-03)	288.00
M1– Day 21	48	60.33%	01(00-02)	169.00
M2– Day 0	74	38.84%	01(01-03)	229.00
M2– Day 7	56	53.72%	01(00-02)	190.50
M2– Day 21	21	82.64%	01(00-01)	107.50

M3-F/U	12	90.08%	01(00-01)	92.500	
Intra-Group Comparison	Friedman Test (Non parametric Repeated Measures ANOVA)				
	Friedman Statistic Fr =230.68(corrected forties)				
Pvalue	The P value is <0.0001, considered extremely significant.				



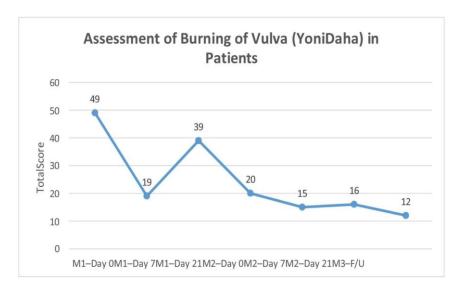
#### Assessment of backache (Kati shool) in patients

Visit	TotalScore	Percentage Relief	Median (Range)	Sum of Ranks
M1– Day 0	125	-	2.5 (02–03)	324.50
M1– Day 7	114	08.80%	02(02-03)	309.50
M1– Day 21	41	67.20%	01(00-02)	138.50
M2- Day 0	72	42.40%	01(01-03)	214.00
M2– Day 7	55	56.00%	01(00-02)	172.00
M2- Day 21	39	68.80%	01(00-02)	134.50
M3-F/U	25	80.00%	0.5 (00–01)	107.00
Intra-Group Comparison	Friedman Test (Non parametric Repeated Measures ANOVA)			
	Friedman Statistic Fr = 235.58 (corrected forties)			
P value	The P value	e is < 0.0001, c	onsidered extre	mely significant.



#### Assessment of Burning of Vulva (Yoni Daha) in Patients

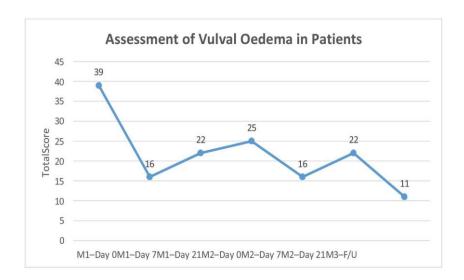
Visit	<b>Total Score</b>	Percentage Relief	Median (Range)	<b>Sum of Ranks</b>	
M1–Day 0	49	1	01(00-02)	279	
M1–Day 7	19	61.22%	00 (00-01)	182.5	
M1–Day 21	39	20.41%	01(00-02)	250	
M2–Day 0	20	59.18%	00(00-02)	186	
M2–Day 7	15	69.39%	00(00-02)	169	
M2–Day 21	16	67.35%	00(00-01)	172.5	
M3- F/U	12	75.51%	00(00-01)	161	
Intra-Group Comparison	Friedman Test (Non parametric Repeated Measures ANOVA)				
	Friedman Statistic Fr = 105.26 (corrected forties)				
Pvalue	The P	value is <0.0001, consi	idered extremely sig	gnificant.	



#### Assessment of vulval edema in patients

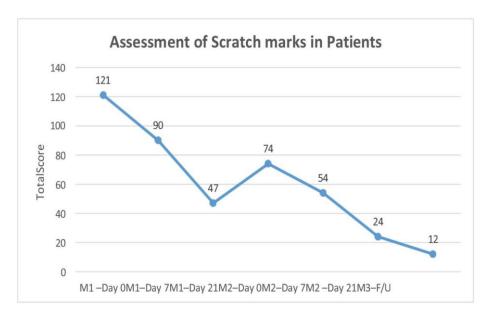
Visit	Total Score	Percentage Relief	Median (Range)	Sumof Ranks
M1–Day 0	39		01(00-02)	259.5
M1–Day 7	16	58.97%	00(00-02)	181
M1–Day 21	22	43.59%	00(00-02)	201.5
M2–Day 0	25	39.90%	00(00-02)	212
M2–Day 7	16	58.97%	00(00-02)	181
M2–Day 21	22	43.59%	00(00-02)	201.5
M3- F/U	11	71.79%	00(00-01)	163.5
Intra-Group Comparison	Friedman Test (Non parametric Repeated Measures ANOVA)			
	Friedman Statistic Fr =64.954 (corrected forties)			
Pvalue	TheP value is < 0.0001, considered extremely significant.			

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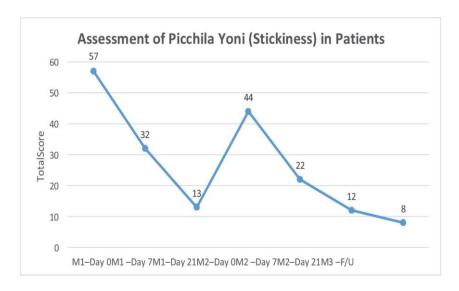
#### Assessment of scratch marks in patients

Visit	Total Score	Percentage Relief	Median (Range)	Sumof Ranks
M1–Day 0	121		02(02-03)	330.5
M1–Day 7	90	25.62%	02(01-03)	270
M1–Day 21	47	61.16%	01(00-02)	170
M2–Day 0	74	38.84%	01(00-03)	235
M2–Day 7	54	55.37%	01(00-02)	188
M2–Day 21	24	80.17%	00(00-01)	116
M3- F/U	12	90.08%	00(00-01)	90
Intra-Group Comparison	Friedman Test (Non parametric Repeated Measures ANOVA)			
	Friedman Statistic Fr =226.73 (corrected forties)			
P value	The P value is <0.0001, considered extremely significant.			



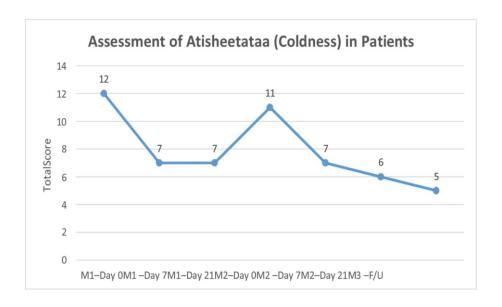
#### Assessment of picchila yoni (Stickiness) in patients

Visit	Total Score	Percentage Relief	Median (Range)	Sumof Ranks
M1–Day 0	57		01(00-02)	288.5
M1–Day 7	32	43.86%	00(00-02)	209.5
M1–Day 21	13	77.19%	00(00-01)	159
M2–Day 0	44	22.81%	01(00-02)	261.5
M2–Day 7	22	61.40%	00(00-01)	184
M2–Day 21	12	78.95%	00(00-01)	155.5
M3- F/U	8	85.96%	00(00-01)	142
Intra-Group Comparison	Friedman Test (Nonparametric Repeated Measures ANOVA)			
	FriedmanStatisticFr =140.12(corrected forties)			
Pvalue	TheP value is <0.0001, considered extremely significant.			



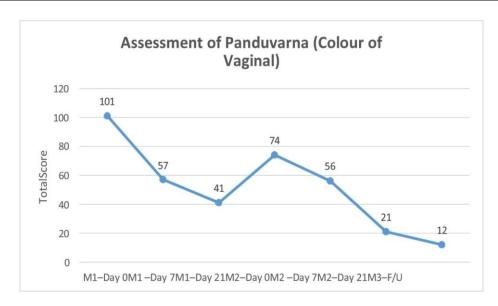
#### Assessment of atisheetataa (Coldness) in patients

Visit	Total	Percentage	Median	Sumof
	Score	Relief	(Range)	Ranks
M1–Day 0	12	-	00(00-01)	214.5
M1–Day 7	7	41.67%	00(00-01)	197
M1–Day 21	7	41.67%	00(00-01)	197
M2–Day 0	11	8.33%	00(00-01)	211
M2–Day 7	7	41.67%	00(00-01)	197
M2–Day 21	6	50.00%	00(00-01)	193.5
M3- F/U	5	58.33%	00(00-01)	190
Intra-Group Comparison	Friedman Test (Non parametric Repeated Measures ANOVA)			
	Friedman Statistic Fr =22.00(corrected forties)			
Pvalue	The P value is 0.0012, considered very significant.			



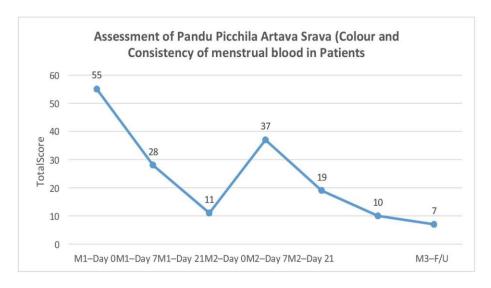
#### Assessment of panduvarna (Color of vaginal mucosa) in patients

Visit	Total Score	Percentage Relief	Median (Range)	Sumof Ranks
M1–Day 0	101	-	02(01-03)	319.5
M1–Day 7	57	43.56%	01(00-02)	214.5
M1–Day21	41	59.41%	01(00-02)	172
M2–Day 0	74	26.73%	01(01-03)	259.5
M2–Day 7	56	44.55%	01(00-02)	215
M2–Day 21	21	79.21%	00(00-01)	119.5
M3- F/U	12	88.12%	00(00-01)	100
Intra-Group Comparison	Friedman Test (Non parametric Repeated Measures ANOVA)			
	Friedman Statistic Fr = 200.58(corrected forties)			
Pvalue	The P value is <0.0001, considered extremely significant.			



Assessment of pandu picchila artava srava (Color and Consistency of menstrual blood in	n
Patients	

Visit	Total Score	Percentage	Median	Sumof
VIDIC	Total Score	Relief	(Range)	Ranks
M1–Day 0	55		01(00-02)	293
M1–Day 7	28	49.09%	00(00-02)	208.5
M1–Day 21	11	80.00%	00(00-01)	161
M2–Day 0	37	32.73%	01(00-01)	247.5
M2–Day 7	19	65.45%	00(00-01)	185
M2–Day 21	10	81.82%	00(00-01)	157.5
M3- F/U	7	87.27%	00(00-01)	147.5
Intra-Group	Esiadman Tast(Nan nanamatria Danastad Massauras ANOVA)			
Comparison	Friedman Test(Non parametric Repeated Measures ANOVA)			
	Friedman Statistic Fr =12.04(corrected forties)			
Pvalue	The P value is <0.0001, considered extremely significant.			



#### DISCUSSION

#### Probable mode of action of drugs

Pushyanuga Churna and Triphala possesses mainly Kashaya Rasa.

Acharya Charaka has mentioned that Kashaya Rasa is having pharmacological properties like Samshmana, Soshana, Sangrahi, Stambhana and Kaphanashaka. It has also quality of drying Kleda. So, by virtue of Kashaya Rasa it stops Srava. 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. These conddominant Rasa are Tikta, Amla & Madhura Rasa. Tikta Rasa is having Kandughna, Kleda, Puya and Kapha shoshna pharmacological properties. Tikta Rasa is a combination of Vayu and Akasha Mahabhuta. These two

Mahabhuta is are having qualities opposite to Kapha. While Amla Rasa possesses Laghu and Ushna Guna which quash the Kapha. Some of the ingredients also possess Madhura Rasa which is Vata and Pitta Shamaka and also has Prinana, Jeevana property etc. Hence, Tikta, Amla and Madhura Rasa alleviate Srava.

- Triphala destroys micro-organisms, repairs damaged tissue and also increases immunity by its rejuvenated nature and exhibits antiviral, antibacterial, anti- fungal, immunomodulatory and antioxidant properties
- The menstrual blood in patients with Kaphaja Yonivyapad also exhibits features of Kapha
   Dushti, both Sthanika and Sarvadaihika.
- This is seen by whitish and excessively sticky nature of menstrual blood. As the treatment was completed, most of the patient"s reported normalization of menstruation and it was statistically very significant.
- The combined therapy of *Pushyanuga Churna* with *Triphala Yoni Prakshalana* helped in pacification of vitiated *Kapha Dosha*.

#### **CONCLUSIONS**

- 1) Vaginal discharge, i. e. *Yoni Strava* is seen as asymptom incase of this disease. The symptoms of *Kaphaja Yonivyapada* mentioned in Ayurveda literature appear similar to the clinical features of vulvo-vaginitis.
- 2) Treatment modalities in the Allopathic medicine comprise of antifungal, antibacterial, antiprotozoal, etc. drugs. But all have unsatisfactory results. They also have some side effects like local burning, irritation, rashes and hypersensitivity. So, there is a great scope for research to find out a safe, potent, effective and less costly remedy of Ayurveda for the management of Vulvovaginitis.
- 3) The intervention of *Yoni Prakshalana* (*Triphala Kwatha*) and *PushyanugChurna* for two total study duration showed statistically significant results in subjective parameters such as Vaginal white discharge (Strava), Itching (Kandu), Backache (Kati Shool) and Burning of Vulva (Yoni Daha).
- 4) Yoni Prakshalana (Triphala Kwatha) and Pushyanug Churna for two total study duration also showed statistically significant results in objective parameters as Vulval-Oedema, Scratch marks (Evidence of pruritus), *Picchila Yoni* (Stickiness), *Atisheetataa* (Coldness), *Panduvarna* (color of vaginal mucosa) and *Pandu picchila Artava Srava* (color and consistency of menstrual blood).
- 5) Out of total 50 patients, 39 patients showed marked improvement in subjective as well as

- objective assessment parameters, 09 patients showed moderate improvement whereas only 02 patients showed mild improvement in subjective as well as objective assessment parameters. The alternative hypothesis of significant difference was accepted.
- 6) No Adverse drug reaction (ADR) and side effects were reported in the present study.
- 7) The drugs of *Pushyanuga Churna* and *Triphala Kwath* have *Kashaya Rasa, Ruksha Guna, Kapha Dosha Nashaka, Sravahara, Kanduhara, Shothahara* and *Krimighana* etc. properties. They have been reported to exert astringent, analgesic, anti-inflammatory, anti-microbial, anti-protozoal and anti-fungal properties which help to relieve the signs and symptoms of the disease. Both the drugs showed almost equal and highly significant respond in the cardinal features.
- 8) It can be concluded that "The *Yoni Prakshalana* with *Triphala Kwath* along and *Pushyanug Churna* is effective in the Management of *Kaphaja Yonivyapada* with reference to Vulvo-Vaginitis".

#### **Recommendations for further studieo**

- Since the study has shown interesting results, it is recommended that the study should be carried out in large number of patients to evaluate and analyze the results.
- The dose and duration can be increased to see the result of the drugs in chronicity.
- Further study can be planned for the survey of the prevalence of Vulvovaginitis especially for asymptomatic microorganism.

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