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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *KASISADI* VAGINAL PESSARY AND *UDUMBARADI TAIL PICHU* IN MANAGEMENT OF *SHWETA PRADAR* (ABNORMAL VAGINAL DISCHARGE): A DOUBLE ARM RANDOM CONTROL STUDY

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ABSTRACT

Shwetapradara, a symptom of many gynaecologic disorders, develop due to vitiation of *Kapha* predominant *Doshas*. *Laghutriya* described *Shwetapradar.* In *Charak Samhita* management of *Shwetpradar* is described under the description of *Pandurasrigdara*. C*hakrapani* has explained *Pandura-Asrigdara* as *Shwetapradar* in his commentary. **Objectives:** To draw Ayurvedic management to the disease with effective cure and no or minimal side effects, that can be easily administered and accepted by the patient. **Materials & Methods:** After obtaining Ethics Committee approval and informed consent, 210 patients were randomized into two groups. In one group, *Kasisadi* vaginal pessary in the night followed by *Udumbaradi Taila Pichu* for 2 hours in the morning was given while in another a vaginal pessary (clotrimazole+tinidazole+clindamycin) was given for 7 days. From baseline to 7th day on the bases of assessment criteria per-speculum examination was done. A comparison of categorical variables was done using an appropriate statistical test. **Results:** *Uduambaradi Taila* and *Kasisadi* vaginal pessary exhibited potentially comparable effects to the conventional treatment but the recurrence rate was found more in conventional treatment. **Conclusion:** *Uduambaradi Taila pichu* and *Kasisadi* vaginal pessary combination is an effective, side effects-free, patient-compliant herbal alternative for the management of abnormal vaginal discharge.

INTRODUCTION

All women have experienced some sort of vaginal discharge in their life span. Normally, vaginal discharge happens in regular variations in amount and consistency during the course of the menstrual cycle. Physiological excess of vaginal discharge may not require specific treatment. However pathological conditions involving infections like Candida, Trichomonas, and gram-negative, gram-positive bacteria may necessitate its management.[1] Pathological discharge may also result due to non-infective diseases such as genital tract tumors or fistula and chemical vaginitis as a result of the use of perfumed soaps, bath additives, spermicides, or antiseptic douche, and foreign bodies in the vagina.

In *Samhita,* all gynecological disorders come under the heading of *Yonivyapad. No* description of *Shweta Pardara* has been described by scholars of *Brihatrayee*. Commentator *Chakrpani* has explained the word *Pandur Asrigdara* (pale vaginal discharge) as *Shweta Pradara*. However, the word "*Shwetapradar*" was first mentioned by *Acharya Vrinda Madhava* in the 9th century A.D.

However, collecting scattered direct or indirect references and by kneeling observation, it can be compared with the following modern diseases by the similarity of signs and symptoms:

Chronic infection, most probably tuberculosis (*Parisruta jataharini*), senile/atrophic vaginitis (*Vataj Yonivyapa*), acute infection of reproductive organs (*Pittala yonivyapad*), trichomonas vaginitis or monilial vulvovaginitis (*Sleshmala Yonivyapad*) mixed type of

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severe genital tract infections (*Sannipatki Yonivyapad*), genital tract infection (*Acharna, Atyananda Yonivyapada*), monilial vulvovaginitis especially in pregnant women (*Upapluta Yonivyapad*), acute genital tract infection (*Paripluta Yonivyapada*), second-degree uterine prolapse (*Prasramsinee Yonivyapad*), prolapse of the vaginal wall *(Phalinee Yonivyapada*).[2] In all these gynecological conditions vaginal discharges may be present directly or may be present with other symptoms. But it doesn't mean that all these symptoms should be present in *Shweta Pradra*. Hence all these conditions may not cause *Shweta Pradra* but may be one of the causative factors of *Shweta Pradra*.

Though *Kapha* and *Vata* seem to be leading *Doshas* responsible for *Shwetapradar,* the role of *Pitta* cannot totally be neglected here, as it is said to be responsible for *Paka*. So, *Shwetapradar* can be considered a *Vata-Kapha Pradhana Tridoshaja Vyadhi.*[3] As in *Madukosha* commentary on *Madhava Nidana a* few scholars consider the indigested and improperly formed essence of food (*Apakava Ahara Rasa*) as *Ama*, while others assume it to be the accumulation of waste products in the body (*Mala*) and a few others consider it as an early stage of *Dosha* vitiation. Here as *Shwetapradara* is a local symptom with disturbing normal flora thus we can consider *Dosha* vitiation as *Ama* and *Agnidushti.*

In this study, *Shweta Pradara* is selected for study as it is one of the most common presentations seen in gynecology OPD. It may not be present as a disease but is a symptom of various diseases so it is important to know about *Shweta Pardara* so that it can be treated by giving consideration to its cause as well. Ayurveda is rich in pharmaceutical preparations. But only a few preparations are being used in today's Ayurvedic practice because of inconvenient forms. In the management of *Shwetapradara,* many *Kalpana* like *Yoni Prakshalana, Yoni Avachurnana, Yoni Pichu, Yoni Varti,* etc. are mentioned. Out of them this clinical trial of the *Kasisadi Yoni Varti* and *Udumbaradi Yoni Pichhu* has been carried out to evaluate the efficacy in *Shwetapradara* (leucorrhea).

MATERIALS AND METHODS

Study Design

A double-arm randomized case control, Open, Comparative clinical study conducted at R.G.G.P.G. Ayu. Hospital, Paprola.

Study Participants

From March 2021 to May 2022, a total number of 210 cases from the participating centre suffering from *Shweta Pradara* (abnormal vaginal discharge) were enrolled as per the protocol specifically designed for this clinical trial and divided into two groups. All the participants were recruited from the OPD level and were screened in accordance with the inclusion and exclusion criteria mentioned in the protocol. Before initiation of the recruitment of the participants, approvals of the Institutional Ethical Committees were obtained. Written consent of the participants was obtained in the IEC-approved consent form. The study was registered in India's Clinical Trial Registry CTRI/2021/03/041812 Dated 04/03/2021

Inclusion and Exclusion Criteria

The sexually active female patient complained of *Shewtapradar* (abnormal vaginal discharge) as a major symptom, and willing for the trial and ready to give consent were included in the study.

Patients who have certain gynaecological pathologies like CA cervix, fibroid polyp, etc., HIV positive patients, diabetic and with severely anaemia patients (Hb level =7 or <7) were excluded from the study.

Study Interventions

The enrolled patients of group one were administered with *Kasisadi* vaginal pessary at night followed by *Udumbaradi Taila Pichu* in the morning for 2 hours as study interventions for a period of 7 days. After necessary quality checks, both drugs were procured and prepared by an institutional pharmacy, *Charak* Pharmacy. In the standard care group, vagina pessary of a combination of clindamycin+ clotrimazole + tinidazole was used for 7 days.

Outcome Measures

The primary outcome measure was the difference in overall symptoms of *Shweta Pradara* at baseline and at the end of the treatment.

The secondary outcome measures were changes in difference in individual symptoms associated with white discharge i.e., *Yonigata lakshana, Srava lakshana*, and on objective criteria, physical function, pain, and change in quality of life assessed at baseline and at the end of the treatment.

Sample Size and Treatment Protocol

A total of 210 patients of *Shweta Pradara* were enrolled. The recruited patients were randomly divided and 105 patients were allotted to group 1 i.e., the study group, and 105 were allotted to group 2. A total of 10 patients discontinued the trial because of menstrual flow during the trial period.

Assessment Criteria

The assessment was done based on subjective as well as objective criteria by using MS Excel. Subjective criteria include Gradation on *Yonigata Lakshana,* associated symptoms, and per speculum examination, while objective criteria included gradation based upon wet vaginal smear, vaginal pH, and micro-organisms in vaginal discharge as shown in following table.

	0	1	2	3
Yonigata lakshana				
Yoni Srava (Amount of vaginal discharge)	Normal moistening	Moderate	profuse	
Yoni dorgandhya (Offensiveness)	Absent	Present		
Gramyedharama Ruja (Dyspareunia)	Absent	Pain on superficial penetration	Pain on deep penetration	Tries to avoid coitus d/t pain
Gramyedharama Ruja (Dyspareunia)	absent	occasional	Mild feeling of irritability	Constant intolerable itching and excoriation
Maithunottra raktsrava (Post coital bleeding)	Absent	Spotting	Mild	Moderate
Gr**adation on Associated Symptoms**				
Katishula (Backache)	No pain	Pain on exertion and relieved by rest	Pain on exertion and relieved by rest	Severe pain interference in routine activities and no relief after medicine
Artava Chakra (Menstrual cycle)	Regular cycle	Irregular cycle with scanty to moderate bleeding	Irregular cycle with heavy bleeding	
Udarshula (Pain in lower abdomen)	absent	Mild pain throughout day but relieved by rest	Moderate pain interfering physical activity and not relieved by rest	Pain interfering physical activity and need to take analgesic
Mutradaha (Burning micturition)	Absent	Mild	Moderate	Severe
Gradation on Per speculum examination				
Yonisrava Samhana (Consistency of vaginal discharge)	*Jalabha* (watery discharge)	*Pichhila* (Mucoid)	*Singdha* (Creamy)	*Dadhivata* (Curdy)
Yonisarav varana (Colour of discharge	*Shetabha* (Whitish)	*Peetabha* (Yellowish)	*Haritabha* (Greenish)	*Raktabha* (Brownish / Blood stained)
Size of cervix	Normal	Atrophic	Hypertrophoid	
Garbhashyagrivamukha Raktabhta (Congestion of cervix)	Absent	Mild	Moderate	Severe
Garbhashyagrivamukhagatavrana (Cervical Erosion)	Absent	At upper lip/ lower lip	Around OS	Whole cervix
Objective criteria				
Vaginal discharge pH	3.5-4.5	4.5-5.5	5.5-6.5	6.5-7.5
Gradation on Wet vaginal smear				
Pus cell and Epithelial cells each	0-5	6-25	26-50	50-100
Trichomonas vaginalis	Absent	Present		

Statistical Methods

The obtained data were analyzed statistically and expressed in terms of median, mean, standard deviation (±SD), and standard error (±SE). The patients in each group were statistically analyzed on standard parameters by using Wilcoxon's Sign rank test for intragroup comparison and Mann Whitney U test was used for intergroup comparisons.

The level of significance was noted and interpreted accordingly at least up to 5% level of significance or 95% confidence limits.

RESULTS

A total of 210 participants were enrolled in the study, among which 200 completed the study. On statistical analysis with an appropriate test on each criterion, it was found that the study drug and the conventional drug had highly significant results in *Yonigata* symptoms as shown in Table 1 But in intergroup comparison, no significant difference was found as shown in figure 1, associated symptoms as shown in table 2, and intergroup comparison shown in figure 2, per speculum examination as well as objective as shown in table 3, and intergroup comparison of drugs shown in figure 3. Thus the drugs had no significant difference in action.

Table 1: Effect of therapy *Yonigata* Symptoms

Intergroup comparison by Wilcoxon sign rank test								Intergroup comparison by Mann Whitney test		
Symptom		**Mean score**		**Mean Diff.**	**%**	**P**	**Result**			
	Group	**B.T**	**A.T**					U	P	result
Yoni Srava	Study	1.53	0.29	1.24	81.68	<0.001	H.S.	4753.5	.477	N.S
	Control	1.4	0.29	1.11	78.2	<0.001	H.S			
Yonidorgandhya	Study	0.33	0.05	0.28	84.84	<0.001	H.S.	4766.5	.467	N.S
	Control	0.29	0.06	0.23	80.00		H.S.			
Gramyedharma Ruja	Study	0.65	0.22	0.43	72.22	0.005	S	4804.0	.412	N.S
	Control	0.16	0.07	0.09	60	.033	S			
Yonikandu	Study	1.33	0.27	1.06	79.69	<0.001	H.S.	3848	0.003	S
	Control	0.94	0.19	0.75	80.2		H.S.			
Maithunouttra Raktasrava	Study	0.25	0.07	0.18	72	<0.001	H.S.	4684.5	0.248	N.S
	Control	0.14	0.04	0.1	73.33	0.012	S			

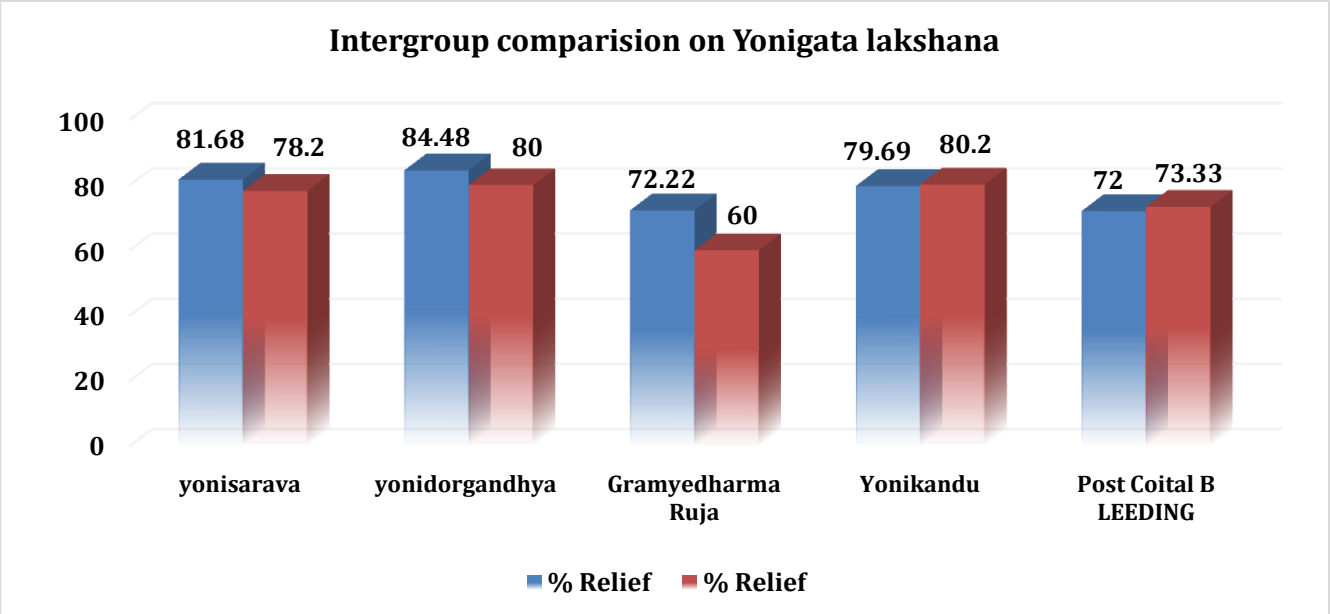

Figure 1: *Yonigata Lakshana*

Table 2: Results on Associated Symptoms

Symptom		Mean score		Mean Diff.	%	P	Result	Intergroup comparison by Mann Whitney test u		
	Group	B.T,	A.T.					U	P	Result
Katishula	Study	1.53	0.29	1.24	81.68	<0.001	H.S.	4803	0.580	N.S
	Control	1.4	0.29	1.11	81.17	<0.001	H.S			
Artavadushti	Study	0.33	0.05	0.28	84.84	<0.007	H.S.	4746.5	0.296	N.S
	Control	0.29	0.06	0.23	80.00		H.S.			
Udarshula	Study	0.65	0.22	0.43	72.22	<0.001	H.S.	4233.5	0.027	S
	Control	0.16	0.07	0.09	60	.033	S			
Mutradaha	Study	1.33	0.27	1.06	79.69	<0.001	H.S.	4883.5	0.717	N.S
	Control	0.94	0.19	0.75	80.2		H.S.			

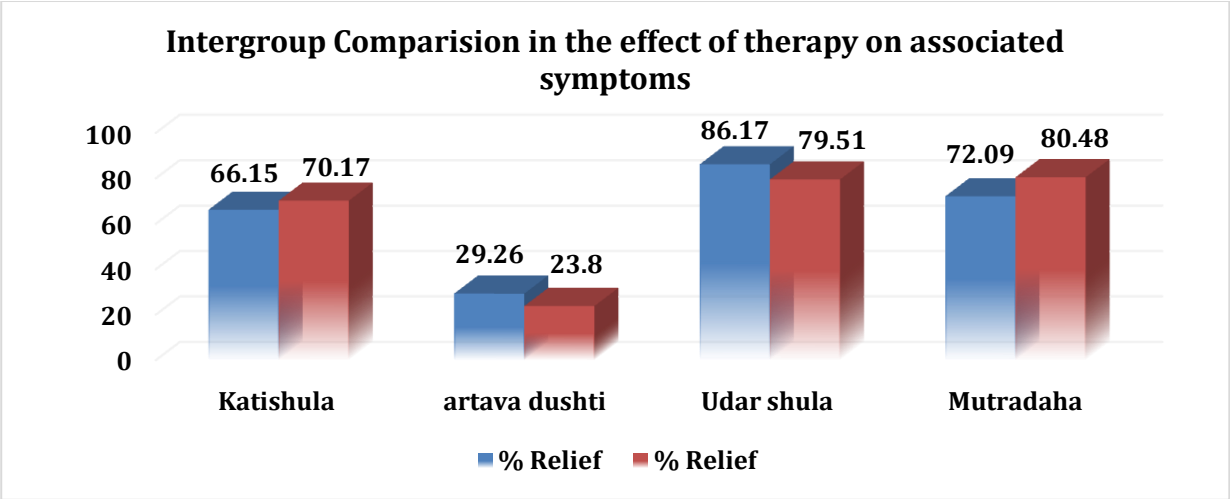

Figure 2

Table 3: Effect of therapy in per-speculum examination

Symptom		Mean score		Mean Diff.	%	P	Result	Intergroup comparison by Mann Whitney test u		
	Group	B.T	A.T					U	P	Result
Yoni Srava Samnhana	Study	1.53	0.29	1.24	81.68	<0.001	H.S.	4451.5	0.155	N.S
	Control	1.4	0.29	1.11	81.17	<0.001	H.S			
Yoni Srava Vrana	Study	0.33	0.05	0.28	84.84	<0.001	H.S.	4209.5	0.14	N.S
	Control	0.29	0.06	0.23	80.00	<0.001	H.S.			
Garbhashyamukha Raktabhata	Study	0.25	0.07	0.18	72	<0.001	H.S.	3970.5	0.005	H.S
	Control	0.14	0.04	0.1	73.33	<0.001	H.S.			
Garbhashyamukha Gatavarna	Study	0.25	0.07	0.18	72	<0.001	H.S.	4593.0	0.220	N.S
	Control	0.14	0.04	0.1	73.33	<0.001	H.S.			

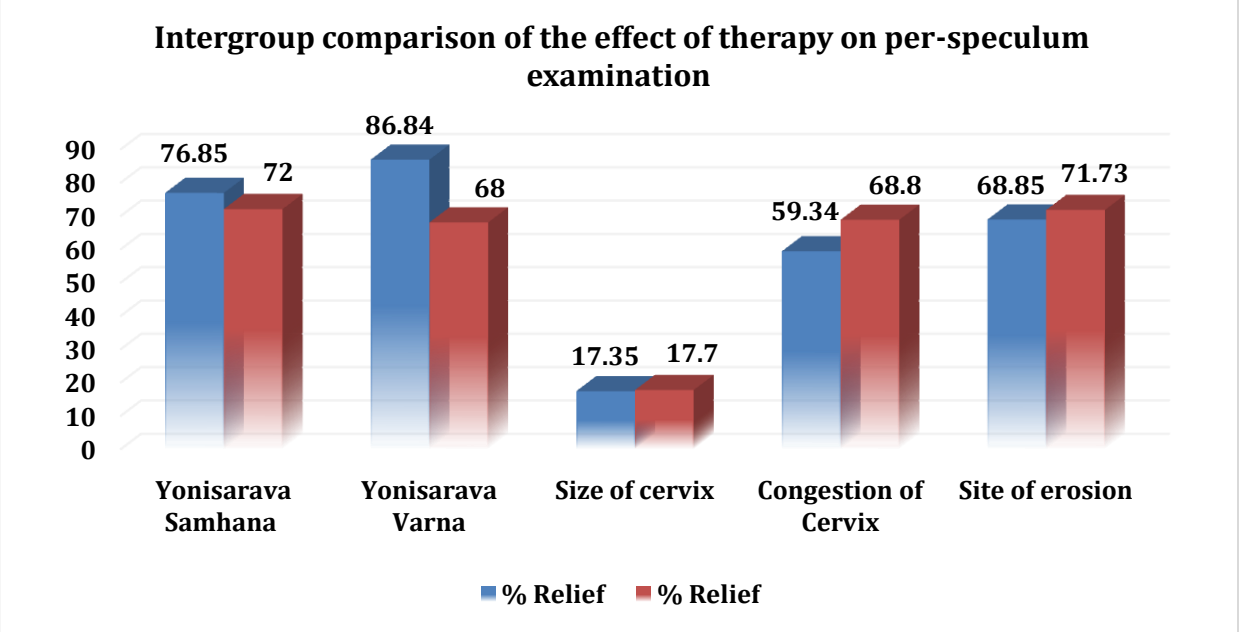

Figure 3

Table 4: Effect of therapy on objective criteria

Symptom		Mean score		Mean Diff.	%	P	Result	Intergroup comparison by Mann Whitney test u		
	Group	B.T	A.T					U	P	Result
Ph of vaginal Discharge	Study	1.53	0.29	1.24	81.68	<0.001	H.S.	4684.5	.019	S
	Control	1.4	0.29	1.11	81.17	<0.001	H.S			
Wet Smear										
Pus cell	Study	0.33	0.05	0.28	84.84	<0.001	H.S.	4863.5	.728	N.S
	Control	0.29	0.06	0.23	80.00		H.S.			
EPC	Study	0.65	0.22	0.43	72.22	0.005	S	4862.5	.602	N.S
	Control	0.16	0.07	0.09	60	.033	S			

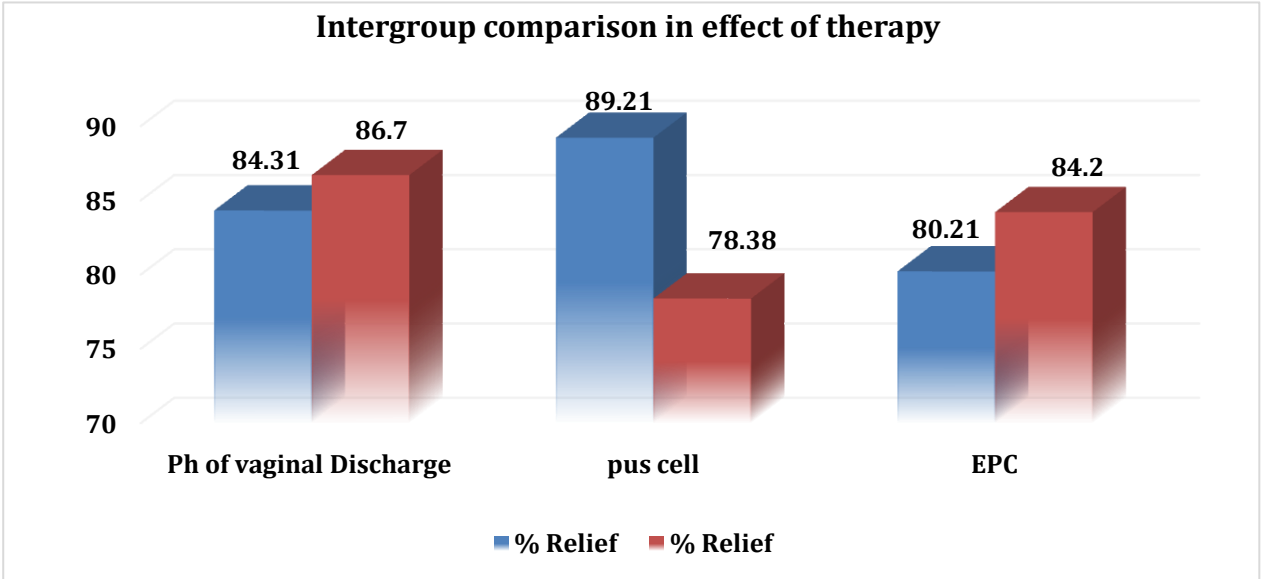

Figure 4

Here we also keep a photographic record of the local symptoms of the patient so we can also compare the before and after treatments and found drastic relief in symptoms as shown in figure 5 of some patients in the study group.

Study Related Drug Photo

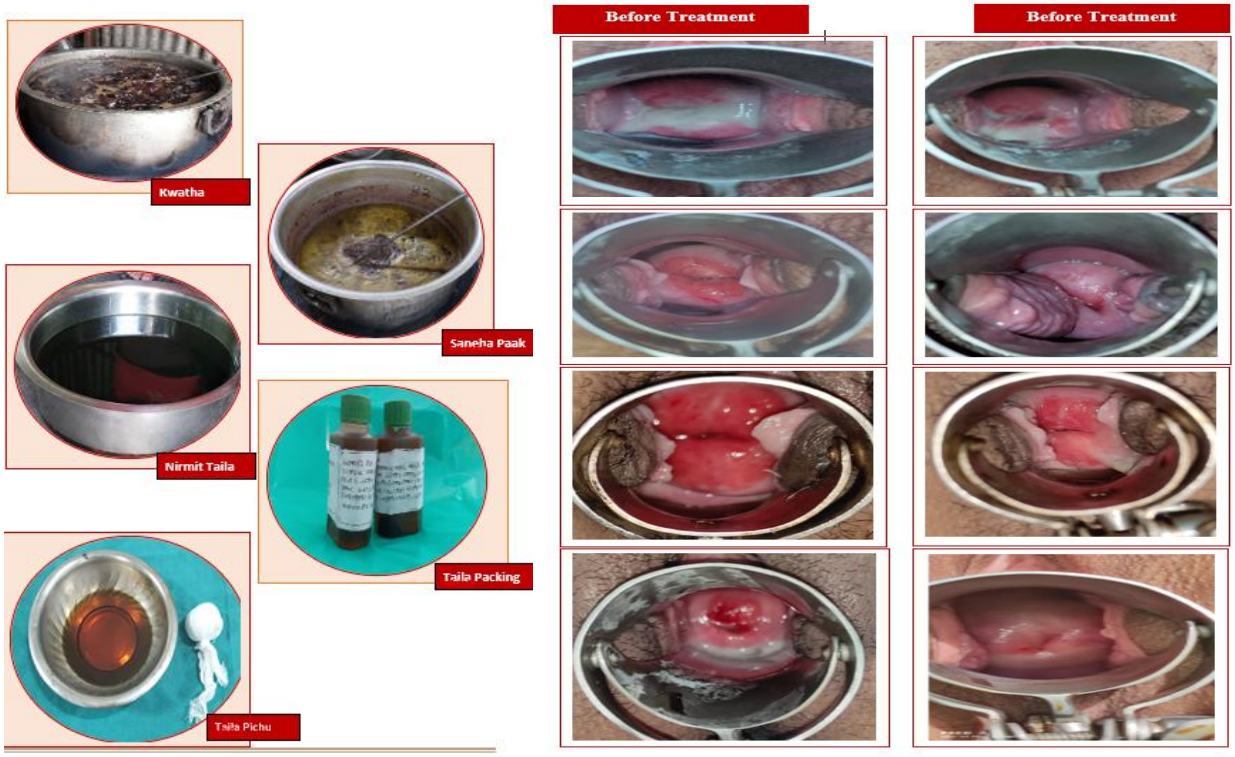

Figure 5

Overall Therapy Effect in Both Groups

At the end of the study, it was found that maximum patients (46%) markedly improved and 36.5% of patients had moderate improvement as shown in table 5.

Table 5: Overall Effect of Therapy

% Relief	Group I	Group II	Total	Total %
No improvement (<25%)	6	7	13	6.5
Mild improvement (26-50%)	10	12	22	11
Moderate improvement (51-75%)	42	31	73	36.5
Marked improvement (>75%)	42	50	92	46
	100	100	200	100

Assessment of Safety

None of the subjects in the study reported any major local adverse effect due to the use of the intervention in either of the two groups. Also, no significant change in safety-related laboratory parameters was observed in the study groups. It was observed that these parameters remained within the normal range at both baseline and final visits.

Treatment Compliance

Patients were asked about the immediate effect that they experienced post-application of medicines. It was observed that the application was comfortable without any burning or irritation in both groups.

DISCUSSION

The drugs used for the study were *Kassiadi Yoni Varti* and *Udumbradi Taila Yoni Pichhu.* Ayurvedic classics have an exceptional approach to clarifying the method of medication i.e., the mode of action of drugs. The action of every drug is determined by the dominant pharmacodynamic factors in that particular drug and that may be *Rasa, Guna, Veerya, Vipaka,* and *Prabhava*. The dominant rasa in *Uduambaradi Tiala* is *Kashaya rasa*, *Tikta, Madhura*, and *Katu* respectively in decreasing order. In *Kasisadi Varti* the predominant *Rasa* is *Kashaya* and *Amla* and *Katu, Tiikta,* and *Madhur* all find in equal ratio. *Acharya Charaka* has mentioned that *Kashaya Rasa* is having pharmacological properties like *Samshmana*, *Soshana*, *Sangrahi*, *Stambhana, Kaphanashak,* and *Kledahara,*

and formed by the conjugation of *Vayu* and *Prithvi Mahabhuta*.[4] *Vayu* is *Ruksha* in quality[5] 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 *Sarva*. *Tikta Rasa* is having *Kandughna, Krimighna* property, *Kleda, Puya* and *Kaphashoshna* pharmacological properties.[6] *Guna Laghu* and *Ruksha* are predominant in the ingredients of study drug. *Laghu Guna* has the property of *Varna Ropna* and *Lekhana* property and *Ruksha* has the property of *Stambhana* thus they diminish *Yoni Sarva*. The drugs are both *Ushana* and *Sheeta virya* thus they pacify *Tridosha.* Most of the content of both study drugs *Yonisravahara/ Yonirogahara, Yonisodhana, Stambhana,* and *Krimighana* by *Prabhava. Shwetapradara* is *Kapha Vata* predominant *Tridoshaja Vyadhi* and both study drugs most of ingredients (10 content in *Udambaradi Taila*) had *Kaphapittashamka* and also some content *Vatakapha Shmamka* and *Tridoshanashaka*. As a formulation act by the combined effect of all its gradients. Thus, the *study* drugs alleviate the *Tridosha* by their *Tridoshahara* properties. Probable mode of action of *Yoni Varti* and *Yoni Pichu* was shown in following figures 6 and 7.

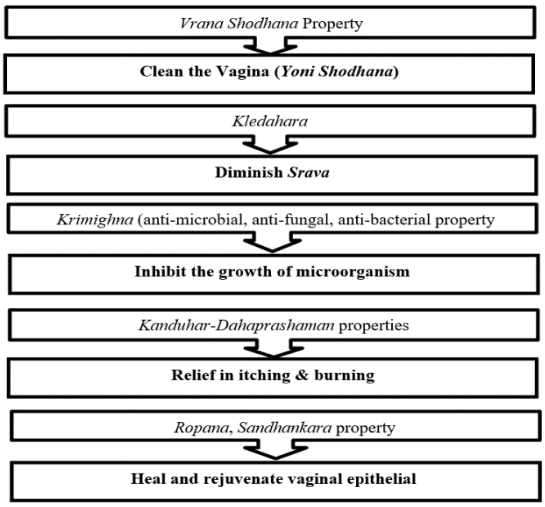

Figure 6: Mode of Action of *Yonivarti*

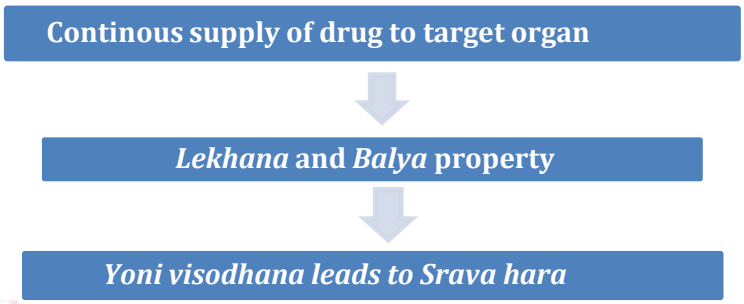

Figure 6: *Samprpati vighttana* by *Yoni varti*

The formulations had properties like anti-inflammatory, antimicrobial, hypoglycemic activity, immunomodulatory effect, and anti-oxidant activity. Thus, by *Samprapti Vighattana* drugs helps in the cure of *Shweta Paradara* both in Ayurvedic as well as modern terminology as shown in the following figure 8 and 9.

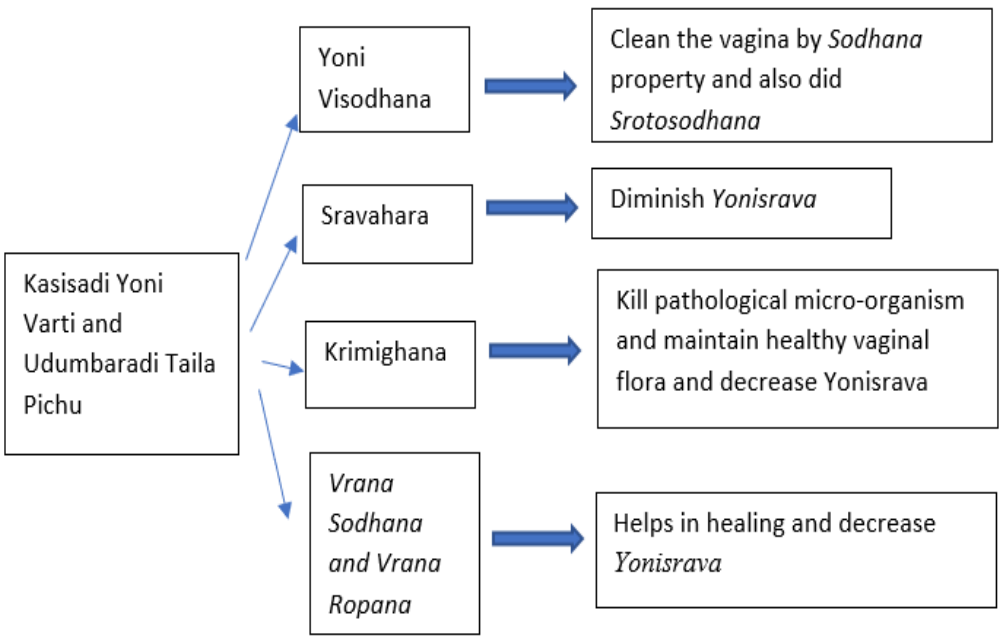

Figure 7: mode of action of drug in Ayurvedic Terminology

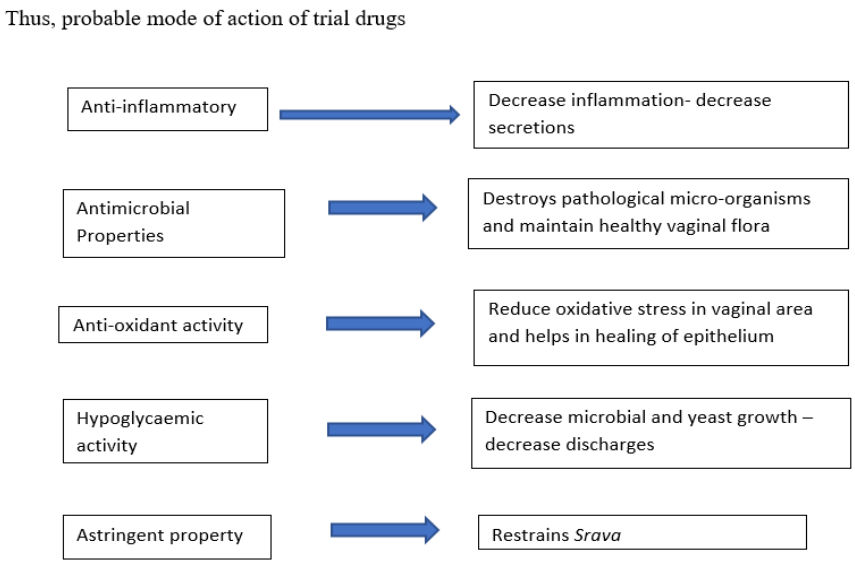

Figure 8: Mode of Action in Modern Terminology

CONCLUSION

The present study concludes that the action of *Udumbaradi Taila Pichu* and *Kasisadi* vaginal pessary have potentially comparable effect to the currently used conventional treatment of *Shweta Pradar*. The exact mode of action of these drugs with respect to their anti-microbial action needs to be further evaluated.

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