

INTERNATIONAL AYURVEDIC MEDICAL JOURNAL



Research Article

ISSN: 2320 5091

Impact Factor: 5.344

A CLINICAL STUDY ON UPAPLUTA YONIVYAPAD W.S.R TO VULVOVAGINITIS DURING PREGNANCY AND ITS MANAGEMENT WITH PANCHAVALKALADI VARTI

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https://doi.org/10.46607/iamj08062020

(Published online: June 2020)

Open Access © International Ayurvedic Medical Journal, India 2020 Article Received: 08/05/2020 - Peer Reviewed: 13/06/2020 - Accepted for Publication: 26/06/2020

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ABSTRACT

Vulvovaginitis is the common problem of the pregnant woman that challenges the obstetrician today. It is estimated that 75% of women will experience at least one infection during their childbearing years. It is the most clearly recognized and more widely studied, responsible for between 20-40% of all cases of preterm birth. On the basis of the textual description, it seems that *Upapluta Yonivyapad* can be compared to Vulvovaginitis during pregnancy. In this study 52 patients were randomly divided in to two groups i.e. 27 patients in Group A treated with *Panchavalkaladi Varti* and 25 patients in Group B treated with *Trida* vaginal Suppository for local application. Aim of this study to assess the efficacy of trial drug *Panchavalkaladi Varti* in the management of Vulvovaginitis during pregnancy. The results of this study indicate that the patients of both the groups obtained highly significant relief in almost all the signs and symptoms of Vulvovaginitis during pregnancy.

Keywords: Vulvovaginitis, Upapluta Yonivyapad, Panchavalkaladi Varti, Trida vaginal Suppository

INTRODUCTION

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. Pregnancy induced changes may predispose the development of lower genital tract infection.

Bacterial and fungal infections of the genital track are increased due to increase in cell glycogen and reduced pH under influence of higher blood level oestrogen¹. Due to increased vaginal acidity & increased glycogen content pregnancy favours infections of the lower genital track². If these infections are not treated, then they may spread to the choriodecidual tissue through the cervical canal resulting in the premature rupture of membrane, premature labour, spontaneous abortion and post pregnancy infection³.

The percentage of causative agent of vulvovaginitis during pregnancy is as follows-

- Yeast infection 20-40%⁴.
- Bacterial vaginitis 15-20%⁵.
- Trichomonas vaginitis 20 %⁶.

Upapluta Yonivyapad is described by *Acharya Charaka*⁷, both *Vagbhattas*^{8,9}, and *Sharangadhara*¹⁰. *Upapluta Yonivyapad* is caused by vitiation of *Vata & Kapha* and it is characterized by yellowish or white mucoid vaginal discharge associated with pricking pain, itching etc. in vagina.

In the present study **Panchavalkaladi Varti** is selected for the local application¹¹. Most of the drugs of this *Varti* have *Kashaya Rasa, Ruksha Guna* and *Kapha Dosha Nashaka, Vedanasthapana, Shothahara, Dahaprashamana, Vranasodhana and Vranaropana* etc. properties. They have been reported to exert astringent, analgesic, anti-inflammatory, antimicrobial, antiprotozol and antifungal properties¹². 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 in pregnancy.

Aim and Objectives

- 1. To study the etiopathogenesis of vulvovaginitis during pregnancy as per *Ayurvedic* and Modern concept.
- 2. To assess the efficacy of trial drug *Pan-chavalkaladi Varti* in the management of Vulvo-vaginitis during pregnancy.

Materials and Methods

A. Patients

Patients attending the O.P.D. of *Stree Roga* and *Prasooti Tantra* Department of I.P.G.T. & R.A., G.A.U., Jamnagar.

Criteria for Inclusion criteria

- After completion of first Trimester.
- Age 19 to 40 years with different parity.
- White discharge present during examination.
- Inflammation present in vulva and vagina.
- Pathogens present in wet vaginal smear study.

Criteria for Exclusion criteria

- Age below 19 years or above 40 years, with nonspecific vulvovaginitis.
- Hypersensitivity to drug and inability to confirm the protocol.
- Women with severe physical illness, any organic pathology, hepatic, cardiac, renal disease any acute infection of any system.
- Women suffering from any systemic disease like Diabetes, T.B, S.T.D and HIV.

B. Drugs

Content of Panchavalkaladi Drugs: Vata (Ficus bengalensis Linn), Udumber (Ficus racemosa Linn.), Ashvatha (Ficus religiosa Linn.), Plaksha (Ficus lacor Buch), Parisha (Thespesia populnea Linn), Jambu (Syzygium cumini Linn), Shallaki (Boswellia serrata Roxb), Dhava (Anogeissus latifolia Wall), and Jingini (Odina woodier Roxb).

Dry extract of *Panchavalkaladi* was prepared in the Pharmacy of Gujarat Ayurved University, Jamnagar.

Panchavalkaladi Varti prepared in the Institute of Ayurved Pharmaceutical Sciences, Gujarat Ayurved University, Jamnagar.

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Investigations:

Haematological: Routine Haematological investigations like Hb%, BGRh, TC, DC, ESR. **Urine:** Routine and microscopic urine examination.

Ultrasonography: for confirming normal growth etc. Specific investigations like vaginal pH, wet vaginal smear study. Vaginal swab culture if required. Method of Study:

• The present study is a single blind, randomized clinical trial with Trida vaginal suppository as a standard control.

- The study had due clearance from the Institutional Ethics Committee.
- Informed consent was taken from the patient before including them in the clinical trial.

Management of Patients

(1) Selection of the drugs for the study:

For the present study *Panchavalkaladi Varti* and *Trida* vaginal suppository were selected for locally administration.

Table 1: Grouping and Posology

Group	Drugs	Method	Duration					
А.	Panchavalkaladi Varti form - Panchavalkaladi kwath-53%	Locally (in vagina). 1varti (1gm) B.D.	15 days					
	+ Glycerine-36% + Gelatin-11%							
В.	Clotrimazole-200mg, Tinidazole-500mg Lactic acid ba-	Locally (in vagina). 1 tab (1gm) O.D	7days					
	cillus-150 million spores. (Trida, vaginal suppository)							

Method of administration of Yoni Varti:

Patient was advised to empty the bladder and clean the vaginal area. Then asked to lie on her back with flexed thighs and *Yoni Varti* was inserted deep in vagina (Posterior Fornix).

Pathyapathya: Patients were advised to take light, nutritious easily digestible and congenial diet and avoid Excessive use of *Guru*, *Snigdha*, *Kaphavardhaka and Vishtambhi Ahara*. They were also advised for *Harsha*, *Prasannata*, light work and avoid excessive Divasvapna, *Ratrijagarana*, *Vega Vidharana and Ativyavaya*.

Follow Up: After stopping the administration of the drugs under trial patients were advised to report every 7 days for follow up study, which was carried out up to two weeks after delivery. During the follow up study, further improvement or deterioration or no change in the signs & symptoms were recorded.

Criteria for Assessment

Subjective Criteria: All symptoms and signs taken for the assessment of clinical improvements were thoroughly examined and the severity of each symptoms and signs were rated before and after the trial for clinical assessment. Efforts were made to give numerical values to all symptoms and signs depending upon their severity before and after the treatment.

Objective Criteria:

- Changes in the pH
- Vaginal wet smear study
- Criteria for overall assessment of therapy:

The total effect of therapy was assessed considering the overall improvement in signs and symptoms.

Pre-Observations: Total 52 patients registered in the present study, out of which 51 completed the treatment and 01 patient had to be discontinued in between the treatment.

In the present study, majority i.e. 55.88% of patients belonged to age group of 19-24 years. 38.46% patients were seen in 26 to 32 weeks of gestation. 51.92% patients belonged to rural area, 65.38% patients were living in unhygienic condition, 65.38% of patients were having burning Micturation. *Yoni Srava, Yoni kandu and Yoni Vedana were* found in 100% of patients, *Yoni Daha in 96.15%*, and *Yoni Daurgandhya* was found in 65.38% of patients. 26.92% patients were having pH - 4, On the basis of wet vaginal smear examination fungal hyphae was found in 100% of patients, pus cells 92.31% and Trichomonas vaginalis was found in

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13.46% patients and Vulvitis, vaginitis, local tender-

ness was seen in 100% patients respectively.

Results of Clinical Study:

Effect of therapy on signs and symptoms of Upapluta Yonivyapad

Table- 2: Effect on Cardinal features- Group A

ʻn'	Chief complaints	Mean Score		% of re-	S.D. (±)	S.E.	ʻt'	Р
		B.T.	A.T.	lief		(±)		
27	Yoni Srava	2.74	0.30	89.19	0.48	0.09	26.29	< 0.001
27	Yoni Kandu	2.03	0.11	94.54	0.32	0.06	31.64	< 0.001
26	Yoni Daha	1.96	0.11	94.12	0.32	0.06	29.77	< 0.001
18	Yoni Daurgandhya	1.89	0.17	91.17	0.41	0.10	17.89	< 0.001
27	Yoni Vedana	1.71	0.45	73.17	0.53	0.11	11.61	< 0.001

Table 3: Effect on Cardinal features- Group B

ʻn'		Mean Score		% of re-	S.D. (±)	S.E.	't'	Р
		B.T.	A.T.	lief		(±)		
24	Yoni Srava	2.65	0.38	85.71	0.33	0.68	33.07	< 0.001
24	Yoni Kandu	2.25	0.25	88.89	0.33	0.068	29.39	< 0.001
23	Yoni Daha	1.83	0.17	90.47	0.44	0.09	17.96	< 0.001
16	Yoni Daurgandhya	1.81	0.18	89.65	0.5	0.13	13	< 0.001
24	Yoni Vedana	1.70	0.58	65.85	0.5	0.10	11.02	< 0.001

Table 4: Effect on Vaginal pH & Wet vaginal smear - Group A

'n'		Mean Score		% of re-	S.D. (±)	S.E.	't'	Р
		B.T.	A.T.	lief		(±)		
27	Vaginal pH	4.96	4.14	19.40	1.03	0.20	4.84	< 0.001
27	Fungal hyphae	1.85	0.15	92	0.52	0.10	17.14	< 0.001
3	T. vaginalis	2	0	100		-	-	< 0.001
27	Vaginal pus cells	2.33	0.48	80.95	0.92	0.18	10.68	< 0.001

Table 5: Effect on Vaginal pH & Wet vaginal smear - Group B

'n'		Mean Score		% of re-	S.D. (±)	S.E.	't'	Р
		B.T.	A.T.	lief		(±)		
24	Vaginal pH	4.58	0.83	18.18	0.97	0.19	4.20	< 0.001
24	Fungal hyphae	1.87	0.25	82.22	0.5	0.10	15.1	< 0.001
2	T. vaginalis	1.5	0	100	-	-	-	< 0.001
18	Vaginal pus cells	2.38	0.66	72.09	0.67	0.15	10.96	< 0.001

Follow-Up:

- In follow up study, no patient had complaint of recurrence of symptoms within 2 weeks.
- But after 2 to 3 months of follow up, 2 patients in Group A & after 1 to 2 months of follow up, 7 Patients in Group B had complaint of recurrence.

DISCUSSION

Vulvovaginitis during pregnancy is one of the most discomforting, commonly seen conditions by practitioners. Increased lower genital tract infection causes complications like premature rupture of membrane, spontaneous abortion, preterm labour¹³. Excessive use of unwholesome edibles or unhygienic diet may initiate nutritional deficiency¹⁴. In *Garbhini* excessive *Divasvapna, Ratrijagarana Vegavidharana* and *Garbhopaghatakara Bhavas* etc. are prohibited by *Acharyas*¹⁵. These Bhavas cause *Kapha prakopa* and *Vata prakopa* which reaches to *Yoni* and produces the disease. According to modern science also increased sexual intercourse during pregnancy can make the woman more prone to ascending infections which results in various complications. Beside this *Manasika Bhavas like Chinta, Bhaya* and *Shoka* etc., also leads to various *Yonirogas*. In modern science, it is believed that excessive stress (as excess stress can lead to an outbreak) also causes Yeast infection¹⁶.

Effect of therapy on Cardinal features: Trial drug, *Panchavalkaladi Varti* provided relief in all the cardinal features of *Upapluta Yonivyapad*. The results observed were highly significant statistically (<0.001). All the cardinal features of *Upapluta Yonivyapad* were relieved in group B with *Trida* vaginal suppositories also. The results were highly significant statistically (<0.001).

Effect on wet vaginal smear and vaginal pH: Trial drug provided highly significant results (<0.001) in the wet vaginal smear of Fungal hyphae, T. vaginalis, Vaginal pus cells and Vaginal pH. The standard control, *Trida* vaginal suppositories also provided highly significant results (<0.001) in the wet vaginal smear of fungal hyphae, T.vaginalis, vaginal pus cells and vaginal pH.

Effect on Local pathology: Vulvitis, Vaginitis and Local tenderness in Group A was improved 90%, 87.03% and 94.64% respectively, which was highly significant (p<0.001), while Vulvitis, Vaginitis and Local Tenderness in Group B was improved 86.95%, 84.44% and 83.67% respectively, which were highly significant (p<0.001).

On comparing the effect of both the therapies no statistically significant difference was found. Though in Group A percentage improvement was more in comparison to group B.

Overall effect of therapy:

In Group A, out of 27 patients none of the patients got complete remission, 85.98 % patients got marked improvement, 14.11% patients got moderate improvement. None of the patients got mild improvement and no patients remained unchanged.

In Group B out of 24 patients none of the patients got complete remission, 79.65 % patients got marked improvement, 20.35% patients got moderate improvement, none of the patients got mild improvement and no patients remained unchanged.

Probable Mode Of Action Of Drugs:

Acharya Charaka has mentioned Kashaya Rasa as having pharmacological properties like Stambhana, Sangrahi, Shoshana, Kledashoshaka and Kaphanashaka¹⁷. So, by this way also Kashava Rasa decreases the Srava. The second dominant Rasa in Panchavalkaladi Varti is Madhura Rasa. Balya, Poshana Karma of Madhura Rasa helped in promotion of healing by Dhatuvardhana (re-growth of the epithelium) leading to minimal inflammation. Some of the ingredients possess Katu Rasa. Katu Rasa itself has Krimighna and Kanduhara properties. Hence, it is useful in reducing the symptoms. Majority of ingredients possess Shothahara Properties and Pharmacological action of anti-inflammatory which also prevent the inflammatory process like redness, tenderness and pain etc. Local causative organisms like Candida albicans, T. vaginalis etc. may be destroyed by Krimighna property or antimicrobial, antifungal and antibacterial properties of the most of ingredients¹⁸. Panchavalkaladi Varti was made from Panchavalkaladi Ghanasatva, Glycerin and Gelatin. Glycerin is used for local congestion and inflammation. Gelatin is very popular as a binder, Vehicle for suppositories (Varti) and also recommended as an emulsifying agent¹⁹.

CONCLUSION

Both the drugs showed almost equal and highly significant respond in the cardinal features. On comparing the effect, *Panchavalkaladi Varti* has provided better relief than Trida Vaginal suppository. It suggests that the effect of *Panchavalkaladi Varti* is more prolonged and long lasting as compared to *Trida* vaginal suppositories. *Panchavalkaladi Varti* can be used effectively in infections and delaying the recurrence. Thus, in nutshell we can say that, *Panchavalkaladi Varti* is

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effective in management of Vulvovaginitis during pregnancy without having any adverse effect.

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Source of Support: Nil **Conflict of Interest: None Declared**

How to cite this URL: Sunita et al: A Clinical Study On Upapluta Yonivyapad W.S.R To Vulvovaginitis During Pregnancy And Its Management With Panchavalkaladi Varti. International Ayurvedic Medical Journal {online} 2020 {cited 2020Available June, from. http://www.iamj.in/posts/images/upload/3628_3633.pdf