RESEARCH PAPER

Effect Of *Khadira* Suppository In The Management Of *Upapluta Yoni Vyapad* Vis-A-Vis Vulvovaginitis In Pregnancy – An Open Label Standard Controlled Clinical Study

Dr Sudharani [1], Dr Usha D T [2], Dr Laxmi Iranna Benur [3], Dr Suma Patil[4], Dr. Prathap. T[5], Dr Hemalatha H K[6]

1, 3, 4, 6 Final year PG Scholar, 2- Professor And HOD
Department of PG studies in Prasuti Tantra and Stree Roga, JSSAMCH, Mysuru, Karnataka, India.
[5]Associate professor (JSS Academy Of Higher Education And Research –College in Mysuru)
Corresponding Author
Dr Usha D T
Email:ID: sudharampure1997@gmail.com

ABSTRACT

Background: Vulvovaginitis is one of the most common gynecological infections encountered during pregnancy due to physiological, hormonal, and immunological changes that alter the vaginal flora. It presents with symptoms such as abnormal vaginal discharge, itching, burning sensation, pain, and foul smell, and may contribute to adverse pregnancy outcomes including premature rupture of membranes and preterm labour. In the clinical features of vulvovaginitis during pregnancy can be correlated with *Upapluta Yonivyapad,* a condition predominantly involving vitiated *Kapha* and *Vata Dosha.* Contemporary treatment mainly includes antimicrobial agents. However, recurrence and drug-related limitations necessitate exploration of safe and effective Ayurvedic alternatives. *Khadira* known for its antimicrobial, antifungal, anti-inflammatory, and wound-healing properties, may offer therapeutic benefits in the management of this condition.

Aims and Objectives: To Evaluate The Efficacy Of *Khadira* Suppository In The Management *Upapluta Yoni Vyapad.* To Evaluate The Efficacy Of Clingen Forte (Clotrimazole 100mg, Clindamycin 100mg, Tinidazole 100mg) Vaginal Capsule In The Management Of Vulvovaginitis In Pregnancy. And to Compare The Efficacy Of *Khadira* Suppository With Clingen Forte Vaginal Capsule In Vulvovaginitis In Pregnancy.

Materials and Methods: The trial was registered prospectively under CTRI on 23/04/2025 with CTRI Number CTRI/2025/04/085360. Randomized standard controlled clinical study was conducted in JSS Ayurveda Medical Hospital to evaluate the effectiveness of *Khadira* suppository n *Upapluta Yonivyapad*. The medicine was prepared at JSS College of Pharmacy, Mysuru. 40 patients were screened based on Inclusion and Exclusion Criteria and subjects who fulfilled the inclusion criteria of *Upapluta Yoni Vyapad* vis-a-vis Vulvovaginitis during pregnancy and were taken into study.

Results: When the comparative effect of *Khadira* suppository (group A) with that of Clingen forte vaginal capsule (group B) is done by applying the Wilcoxon's Sign Rank test, both groups showed significant improvement in vulvovaginitis during pregnancy. Comparative analysis of the overall effect of the treatments in both the groups is done by statistically with Man-Whitney U test. The test shows statistically no significant difference between the groups indicating both are equally effective in managing *Upapluta Yoni Vyapad*/Vulvovaginitis during pregnancy.

Conclusion: Both *Khadira* suppository and Clingen forte vaginal suppository are equally effective in the management of *Upapluta Yoni Vyapad* vis-à-vis Vulvovaginitis during pregnancy. However, Khadira suppository showed clinically more efficacy when compared to clingen forte vaginal suppository

Keywords: *Khadira* Suppository, Pregnancy, *Upapluta Yonivyapad*, Vulvovaginitis

How to cite this article: Sudharani, Usha DT, Benur LI, Patil S, Prathap T, Effect Of *Khadira* Suppository In The Management Of *Upapluta Yoni Vyapad* Vis-A-Vis Vulvovaginitis In Pregnancy – An Open Label Standard Controlled Clinical Study, Int J Drug Deliv Technol. 2026;16(70s): 1502-1512. DOI: 10.25258/ijddt.16.70s.161

Source of support: Nil.

Conflict of interest: Nil.

INTRODUCTION

Upapluta Yoni Vyapad is one among 20 *Yoni Vyapads* occurs due to vitiation of *Vata* and *Kapha Dosha* explained by *Acharya Charaka*[1], *Acharya Vagbhata*[2] and *Acharya Sharangadhara*[3]. The classical symptoms described in *Upapluta Yoni Vyapad* resemble the clinical presentation of vulvovaginitis during pregnancy.

During pregnancy, the female body undergoes significant endocrine alterations, particularly increased secretion of estrogen and progesterone[4]. The hormonal changes are necessary for maintenance of pregnancy, uterine growth, and preparation for lactation. However, they also alter the physiology of various organ systems and predispose pregnant women to several disorders and infections. Increased blood volume, altered vascular resistance, suppression of cell-mediated immunity, and changes in vaginal glycogen content create a favourable environment for the occurrence of many systemic and local disorders during pregnancy. Pregnancy is a state of immunological

**Author for Correspondence: sudharampure1997@gmail.com*

weakness and therefore of increased susceptibility to infectious diseases.

Vulvovaginitis is one of the most common gynaecological complaints encountered during pregnancy and is characterized by abnormal vaginal discharge, vulvar itching, irritation, burning sensation, foul smell, and discomfort. Pregnancy predisposes women to vulvovaginal infections due to increased hormonal levels, increased glycogen deposition in vaginal epithelial cells, altered vaginal pH, and changes in local immunity, which facilitate the growth of pathogenic microorganisms such as Candida albicans, Gardnerella vaginalis, and other bacteria. If such conditions are left untreated, vulvovaginitis may adversely affect maternal health and has been associated with complications such as preterm labour, premature rupture of membranes, chorioamnionitis, and low birth weight[5].

According to *Acharya Charaka*, when a pregnant woman indulges in *Kapha* and *Vata* vitiating diet or regimen and suppresses vomiting and inspiration leading to aggravation of *Vayu* which in turn withholds *Kapha* reaches *Yoni* producing abnormalities. There is yellowish discharge or mucoid white discharge per vagina with pain. There is prevalence of *Kapha* and *Vata Rogas*, termed as *Upapluta Yoni Vyapad.*

Among women of reproductive age, bacterial vaginosis is considered the most common vaginal infection and affects nearly 30% of pregnant women worldwide. Yeast infections, mainly caused by Candida species, are also frequently seen during pregnancy, with approximately 70% of pregnant women being affected. Trichomoniasis, which is a sexually transmitted infection, is another important cause of vulvovaginitis in pregnancy. During pregnancy, the prevalence varies (3.9% to 24.6%) depending on the diagnostic method used and the population evaluated.[6]

Although modern medicine provides antifungal and antimicrobial therapy, recurrence and discomfort remain common concerns. *Sthanika Chikitsa*, or local therapy, plays a significant role in the management of various gynecological disorders. Classical *Ayurvedic* texts mention different modalities of local treatment including *Yoni Pichu, Yoni Prakshalana, Yoni Lepana, and Yoni Varti* for the management of gynecological and obstetrical conditions. Although these therapies act locally at the site of disease and thereby help in preventing further complications.

Among the drugs mentioned in *Ayurveda, Khadira* is known for its *Kandughna, Krimighna, Kashaya, and Shothahara* properties which may help in reducing abnormal vaginal discharge, itching, and inflammation associated with vulvovaginitis. Hence, the present study is undertaken to evaluate the effect of *Khadira* suppository in the management of *Upapluta Yonivyapad* (vulvovaginitis during pregnancy).

AIMS AND OBJECTIVES:

- To Evaluate The Efficacy Of *Khadira* Suppository In The Management *Upapluta Yoni Vyapad.*
- To Evaluate the Efficacy of Clingen forte (clotrimazole 100mg, clindamycin 100mg, tinidazole 100mg) vaginal capsule In The Management Of Vulvovaginitis in Pregnancy.
- To Compare The Efficacy Of *Khadira* Suppository With Clingen Forte Vaginal Capsule In Vulvovaginitis In Pregnancy.

MATERIALS AND METHODS:

Selection of patients: Subjects fulfilling the criteria for diagnosis and inclusion visiting OPD and IPD of Dept of *Prasuti Tantra and Stree Roga*, JSS Ayurveda Medical Hospital, JSS Medical Hospital, Mysuru, camps and other referrals with written informed consent were selected for the study.

Drug source:

1. Clingen forte vaginal capsule was purchased from Aristo Pharmaceuticals.
2. *Khadira* bark and heartwood powder was purchased from S A Herbals.

METHOD OF PREPARATION OF *KHADIRA* SUPPOSITORY:

The suppositories were prepared at JSS Pharmacy College Mysore, based on fusion or melt moulding method.

Ingredients are: drug (Khadira-1 Part), coconut oil (1.5 part) and base(1 part)

Finely sieved *Khadira* bark and heartwood catechin rich extract powder was triturated with coconut oil and incorporated into liquefied cocoa butter. The homogenous mixture was poured into lubricated suppository moulds, refrigerated for 30 minutes, removed from the moulds, wrapped individually in aluminium foil, and stored under refrigeration. Methyl paraben and propyl paraben were used as preservatives.

The prepared suppositories were bullet-shaped, smooth, homogeneous, firm, non-gritty, light brownish-white in colour, and possessed a characteristic odour. Quality control tests showed satisfactory physicochemical properties, with a mean weight of 1.37 ± 0.02 g, pH of 4.5 ± 0.1, mean hardness of 0.37 ± 0.03 kg/cm², and mean disintegration time of 9 minutes 40 seconds ± 30 seconds.

METHOD OF COLLECTION OF DATA:

Study Design: An Open Label standard, controlled, clinical study.

Sample Size: 40 subjects fulfilling the diagnostic criteria were selected for the study.

Diagnostic criteria: Diagnosis was done based on, Symptoms- *Yoni Srava*(abnormal vaginal discharge), *Yoni Kandu*(itching vulva), *Yoni Daha*(burning sensation in vagina), *Yoni Vedana*(pain in vagina), and *Yoni Dourgandhya*(foul smell in vagina).

Laborartory tests:

Vaginal pH >4.5

Vaginal swab gram staining

Vaginal swab culture

Inclusion criteria:

Pregnant women between the age group of 19 to 35year, having clinical features such as *Yoni Srava*(abnormal vaginal discharge), *Yoni Kandu*(vulvar itching), *Yoni Daha*(burning sensation in vulva and vagina), *Yoni Vedana*(pain in vagina), and *Yoni Dourgandhya*(foul smell of discharge).
Pregnant women with irrespective of parity between 8 to 28 weeks of gestation recruited to the study.
On pelvic examination presence of discharge and inflammation of vulva and vagina.

Exclusion criteria:
Pregnant Women with known case of medical disease such as diabetes mellitus, hypertension, thyroid abnormalities, any organic pathology or hepatic, cardiac, renal disease.
Known case of Obstetric complications such as placenta previa, cervical insufficiency and twin pregnancy.
History of previous abortion and known case of threatened abortion.
History of sexually transmitted diseases and known case of Human Immunodeficiency Virus (HIV).
Known case of congenital vaginal anomalies.

ASSESSMENT CRITERIA:
Subjective parameters:
The improvement in the patient was assessed on the basis of relief in the symptoms of the disease such as *Yoni Srava, Yoni Kandu, Yoni Vedana, Yoni Daha and Yoni Dourgandhya* through a special scoring pattern.
Objective parameters:
Assessment of the therapy was done by comparing the before treatment, after treatment and follow-up changes in discharge from the vagina, vaginal pH, vaginal smear and vaginal swab culture.

INTERVENTION:
40 subjects fulfilling the diagnostic criteria were selected and divided into two groups - Group A and Group B with 20 subjects in each group by simple randomization method.
Group A: *Khadira* Suppository 1.3g per vagina at bed time for 7 days.
Group B: Clingen forte vaginal capsule, 1 capsule per vagina at bed time for 7 days.
Intervention period: 7 days
Assessment schedule: Assessment was done before treatment, 7th day after treatment.
Follow up: After completion of course, patients were advised to report after 15 days.
Total Duration of intervention: 22 days.
Subjective parameters:

Yoni Srava/Abnormal vaginal discharge

No complaints of abnormal vaginal discharge	0	BT	AT	FU
Mild discharge, only vulvar moistness	1			
Moderate discharge, staining of undergarments	2			
Severe discharge, staining undergarments and patient needs use of pads	3			

Yoni Kandu/ vaginal itching

No itching	0	BT	AT	FU
Mild itching(feeling of irritability)	1			
Moderate itching (disturbs daily routine)	2			
Severe(affects routine activity and disturbs sleep)	3			

Yoni Dourgandhya/foul smell of vaginal discharge

No foul smell of vaginal discharge	0	BT	AT	FU
Mild (Foul smell is felt only while performing P/S)	1			
Moderate (Foul smell felt from a short distance)	2			
Severe (the observer unable to stand near the patients)	3			

Yoni Daha/ Burning sensation of vulva or vagina

No burning sensation of vulva and vagina	0	BT	AT	FU
Mild (little, localized, sometime feeling of burning sensation)	1			
Moderate (more, localized, & often burning sensation which doesn't disturbs sleep)	2			
Severe (continuous, disturbs daily activity and sleep)	3			

Yoni Vedana/Vaginal pain

No vaginal pain	0	BT	AT	FU
Mild (Localized feeling of pain during movement only but no feeling of pain during rest)	1			
Moderate (Localized feeling of pain during movement only but not disturbing the sleep)	2			
Severe (Localized continuous feeling of pain, radiating & not relieved by rest)	3			

Objective parameters:

Abnormal vaginal discharge on per speculum examination

No abnormal vaginal discharge	0	BT	AT	FU
Mild discharge(Mild discharge present only on examination)	1			
Moderate discharge(visible at introitus)	2			
Severe discharge(Profuse discharge soaking undergarments)	3			

Vaginal pH

<4.5	0	BT	AT	FU
4.6- 5.0	1			
5.1-5.5	2			
>5	3			

Vaginal swab gram staining

Pathogens	A/P	category	BT	AT	FU
Bacteria	Present	1			
Fungal	Present	2			

Vaginal swab culture

Pathogens	A/P	category	BT	AT	FU
Staphylococcus aureus	Present	1			
Gardnerella vaginalis	Present	2			
Candida albicans	Present	3			

CRITERIA FOR OVERALL ASSESSMENT:

Improvement	**Result**	**Grade**
Less than 25% changes were found in symptoms	No change	4
26-50% changes	Mild improvement	3
51-75% changes	Moderate improvement	2
76-99% changes	Marked improvement	1
100% changes	Complete response	0

OBSERVATIONS AND RESULTS:

Distribution of patients based on age:

Age	Group A	Group B	Grand Total
19-20years	2 (10.00%)	0 (0.00%)	2 (5.00%)
21-25years	2(10.00%)	(0.00%)	2(5.00%)
26-30years	10 (50.00%)	18 (90.00%)	28 (70.00%)
31-35years	6 (30.00%)	2 (10.00%)	8 (20.00%)

Distribution of subjects based on presenting symptoms:

Symptom	Group A	Group B	Total
Vaginal Discharge	20 (100.00%)	20 (100.00%)	40 (100.00%)
Itching	18 (90.00%)	18 (90.00%)	36 (90.00%)
Foul smell	18 (90.00%)	16 (80.00%)	34 (85.00%)
Burning Sensation	3 (15.00%)	7 (35.00%)	10 (25.00%)
Pain	0	0	0

Distribution of subjects based on Period of gestation:

POG	Group A	Group B	Grand Total
18-22 weeks	3(15.00%)	13 (65.00%)	16(40.00%)
23-28weeks	8 (40.00%)	7 (35.00%)	15 (37.50%)
13-17 weeks	7 (35.00%)	0.00%	7 (17.50%)
8-12weeks	2 (10.00%)	0.00%	2 (5.00%)
Grand Total	20 (100.00%)	20 (100.00%)	40 (100.00%)

Distribution of subjects based on gravida:

Gravida	Group A	Group B	Grand Total
Primigravida	13 (65.00%)	11(55.00%)	24(60.00%)
Multigravida	7 (35.00%)	9 (45.00%)	16 (40.00%)
Grand Total	20 (100.00%)	20 (100.00%)	40(100.00%)

Distribution of subjects based on personal hygiene:

Personal Hygiene	Group A	Group B	Grand Total
Well maintained	12(60.00%)	6(30.00%)	18(45.00%)
Not aware	8(40.00%)	14(70.00%)	22(55.00%)
Grand Total	20(100.00%)	20(100.00%)	40(100.00%)

Distribution of subject based on vaginal pH:

Vaginal PH	Group A	Group B	Grand Total
4.6-5.5	7 (35.00%)	6(30.00%)	13(32.50%)
3.5-4.5	13(65.00%)	14(70.00%)	27(67.50%)
Grand Total	20(100.00%)	20(100.00%)	40(100.00%)

Distribution of subject based on organisms present on gram staining:

Vaginal Swab Gram Staining	Group A	Group B	Grand Total

Bacteria	10(50.00%)	8(40.00%)	18(45.00%)
Fungal	10(50.00%)	12(60.00%)	22(55.00%)
Grand Total	20(100.00%)	20(100.00%)	40(100.00%)

Distribution of subjects based on organism growth present on culture

Vaginal Swab Culture	Group A	Group B	Grand Total
Gardnerella vaginalis	7(35.00%)	5(25.00%)	12(30.00%)
Staphylococcus aureus	3(15.00%)	7(35.00%)	10(25.00%)
Candida albicans	10(50.00%)	8(40.00%)	18(45.00%)
Grand total	20(100.00%)	20(100.00%)	40(100.00%)

RESULTS:

Result of Wilcoxon signed rank test- *Yoni Srava*

Yoni Srava	**Mean**		**% of improvement**	**Negative rank**	**Positive rank**	**Ties**	**W**	**P value**
	BT	**AT**						
Group A	1.6	0.3	81.3	19	0	1	**-3.963**	**<0.001**
Group B	1.9	0.4	78.9	19	0	1	**-3.946**	**<0.001**

Both groups demonstrated statistically significant improvement in *Yoni Srava* following treatment. Although Group A showed a slightly higher percentage improvement (81.3%) compared to Group B (78.9%), both interventions were effective in reducing abnormal vaginal discharge.

Result of Mann Whitney U test- *Yoni Srava*/abnormal vaginal discharge

***Yoni Srava*/abnormal discharge**	**Mean Rank**		
	BT	**AT**	**FU**
Group A	17.5	19.5	20.5
Group B	23.5	21.5	20.5
Test Statistic	**140**	**180**	**200**
P value	**0.031**	**0.513**	**1**

A significant difference was observed between the groups at baseline, no significant differences were found after treatment or at follow-up. This suggests that both treatments were similarly effective in reducing abnormal vaginal discharge and maintaining improvement over time.

Result of Wilcoxon signed rank test- *Yoni Kandu*

Yoni Kandu	**Mean**		**% of improvement**	**Negative rank**	**Positive rank**	**Ties**	**W**	**P value**
	BT	**AT**						
Group A	1.1	0.15	86.4	18	0	2	**-4.146**	**<0.001**
Group B	1.05	0.25	76.2	16	0	4	**-4.000**	**<0.001**

Both groups demonstrated statistically significant improvement in *Yoni Kandu* following treatment. However, Group A showed a greater percentage improvement (86.4%) compared to Group B (76.2%), suggesting comparatively better relief from *Yoni Kandu* in Group A.

Result of Mann Whitney U test- *Yoni Kandu*

Yoni Kandu	**Mean Rank**		
	BT	**AT**	**FU**
Group A	20.95	19.5	20.5
Group B	20.05	21.5	20.5
Test Statistic	**191**	**180**	**200**
P value	**0.756**	**0.435**	**1**

No statistically significant differences were observed between Group A and Group B at baseline, after treatment, or at follow-up. This suggests that both treatments were equally effective in reducing *Yoni Kandu* and maintaining the improvement over time.

Result of Wilcoxon signed rank test- *Yoni Dourgandhya*/foul smell of vaginal discharge

Yoni Dourgandhya	**Mean**		**% of improvement**	**Negative rank**	**Positive rank**	**Ties**	**W**	**P value**
	BT	**AT**						
Group A	1.1	0	100	19	0	1	**-4.119**	**<0.001**
Group B	0.85	0	100	16	0	4	**-3.900**	**<0.001**

Before and after treatment result- *Yoni Dourgandhya*
Both groups demonstrated statistically significant improvement in *Yoni Dourgandhya* following treatment, with complete resolution of the symptom after treatment in both groups. Since both groups achieved 100% improvement, the treatments appeared equally effective in relieving *Yoni Dourgandhya*.

Result of Mann Whitney U test- *Yoni Dourgandhya*

Yoni Dourgandhya	**Mean Rank**		
	BT	**AT**	**FU**
Group A	22.72	20.5	20.5
Group B	18.28	20.5	20.5
Test Statistic	**155.5**	**200**	**200**
P value	**0.099**	**1**	**1**

No statistically significant differences were observed between Group A and Group B at baseline, after treatment, or at follow-up. This suggests that both treatments were equally effective in reducing *Yoni Dourgandhya* and maintaining the improvement throughout the follow-up period.

***Yoni Daha*/burning sensation of vulva or vagina**

Groups	Grades	*Yoni Daha* (Number and percentage of cases)					
		BT		AT		F1	
		N	%	N	%	N	%
Group A (n = 20)	No	17	85	20	100	20	100
	Mild	3	15	0	0	0	0
	Moderate	0	0	0	0	0	0
	Severe	0	0	0	0	0	0
Group B (n = 20)	No	13	65	20	100	20	100
	Mild	7	35	0	0	0	0

	Moderate	0	0	0	0	0	0
	Severe	0	0	0	0	0	0

In Group A, most of the subjects 85% (n = 17) were symptom free, only 15% (n = 3) of the subjects had *Yoni Daha*. After treatment complete improvement was observed, with 15% (n = 3) of patients showing no *Yoni Daha.*

In Group B, 65% (n = 13) of the subjects were symptom free, only 35% (n = 7) of the subjects had *Yoni Daha*. After treatment complete improvement was observed, with 35% (n = 7) of patients showing no *Yoni Daha*, and this result was sustained at follow-up 1.

Result of Wilcoxon signed rank test- Abnormal vaginal discharge on per speculum examination

Abnormal vaginal discharge	Mean		% of improvement	Negative rank	Positive rank	Ties	W	P value
	BT	AT						
Group A	1.6	0.3	81.3	19	0	1	**-3.963**	**<0.001**
Group B	1.9	0.3	84.2	19	0	1	**-3.987**	**<0.001**

Both groups demonstrated statistically significant improvement in abnormal vaginal discharge following treatment. Although Group B showed a slightly higher percentage improvement (84.2%) compared to Group A (81.3%), both interventions were highly effective in reducing abnormal vaginal discharge.

Result of Mann Whitney U test- Abnormal vaginal discharge

Abnormal vaginal discharge	Mean Rank		
	BT	AT	FU
Group A	17.5	20.5	20.5
Group B	23.5	20.5	20.5
Test Statistic	**140.0**	**200**	**200**
P value	**0.031**	**1**	**1**

A significant difference was observed between the groups at baseline, no significant differences were found after treatment or at follow-up. This suggests that both treatments were equally effective in reducing cervical discharge and maintaining the improvement over the follow-up period.

Result of Wilcoxon signed rank test- Vaginal pH

Vaginal pH	Mean		% of improvement	Negative rank	Positive rank	Ties	W	P value
	BT	AT						
Group A	1.0	0.0	100	8	0	0	**-2.828**	**0.005**
Group B	1.0	0.0	100	6	0	0	**-2.449**	**0.014**

Both groups demonstrated statistically significant improvement in vaginal pH following treatment. Since both groups achieved 100% improvement and complete normalization of vaginal pH scores after treatment, the interventions appeared equally effective in improving vaginal pH.

Result of Mann Whitney U test is as follows

Vaginal pH	Mean Rank		
	BT	AT	FU
Group A	7.5	7.5	7.5
Group B	7.5	7.5	7.5
Test Statistic	**24.0**	**24.0**	**24.0**
P value	**1.0**	**1.0**	**1.0**

No statistically significant differences were observed between Group A and Group B at baseline, after treatment, or at follow-up. This suggests that both treatments were equally effective in improving and maintaining normal vaginal pH levels throughout the study period.

Results of Chi-square test on vaginal swab gram staining

Groups	Grades	Vaginal Swab Gram Staining (Number and percentage of cases)						Within group Comparison McNemar–Bowker Test (BT-AT)
		BT		AT		F1		
		N	%	N	%	N	%	
Group A (n = 20)	No	0	0	17	85	17	85	χ2= 30.77 P= <0.001
	Presence of bacteria	10	50	3	15	3	15	
	Presence of fungal	10	50	0	0	0	0	
Group B (n = 20)	No	0	0	17	90	17	85	χ2= 31.27 P= <0.001
	Presence of bacteria	8	40	3	10	3	15	
	Presence of fungal	12	60	0	0	0	0	
Between group comparison Chi-square test	Test Statistic	0.404		0.000		0.000		
	P value	0.525		1.000		1.000		

For the between-group comparison, the Chi-square test showed no statistically significant difference between Group A and Group B at BT ($\chi^2 = 0.404$, p = 0.525). At AT and F1, the Chi-square value was 0.000 with a p-value of 1.000, indicating that the distribution of vaginal swab Gram staining findings was similar between the two groups.

This can be inferred that both Group A and Group B demonstrated significant improvement in vaginal swab Gram staining findings after treatment, while there was no significant difference between the two groups. This suggests that both treatments were similarly effective in improving vaginal swab Gram staining outcomes.

Results of Chi-square test on vaginal swab culture:

Groups	Grades	Vaginal Swab Culture (Number and percentage of cases)						Within group Comparison McNemar–Bowker Test (BT-AT)
		BT		AT		F1		
		N	%	N	%	N	%	
Group A (n = 20)	No	0	0	17	85	17	85	χ2= 32.05 P= <0.001
	Staphylococcus aureus	2	10	1	5	1	5	
	Gardnerella vaginosis	8	40	2	10	2	10	
	Candida albicans	10	50	0	0	0	0	
Group B (n = 20)	No	0	0	17	85	17	85	χ2= 32.42 P= <0.001
	Staphylococcus aureus	3	15	2	10	2	10	
	Gardnerella vaginosis	5	25	1	5	1	5	
	Candida albicans	12	60	0	0	0	0	
Between group comparison Chi-square test	Test Statistic	1.07		0.67		0.67		
	P value	0.585		0.717		0.717		

*Author for Correspondence: amrita.bharti@sharda.ac.in

For the between-group comparison, the Chi-square test showed no statistically significant difference between Group A and Group B at BT ($\chi^2 = 1.07$, $p = 0.585$). Similarly, at AT ($\chi^2 = 0.67$, $p = 0.717$) and F1 ($\chi^2 = 0.67$, $p = 0.717$), no statistically significant differences were observed between the two groups.

Thus, it can be inferred that both Group A and Group B showed significant improvement in vaginal swab culture findings following treatment. However, there was no significant difference between the groups at any assessment point, suggesting that both treatments were comparable and equally effective in improving vaginal swab culture outcomes.

Overall Effect:

Chi square test on overall Effect

Overall effect	Group A		Group B		Total	
	Frequency	%	Frequency	%	Frequency	%
Complete Remission	17	85	17	85	34	85
Marked improvement	3	15	3	15	6	15
Moderate Improvement	0	0	0	0	0	0
Mild Improvement	0	0	0	0	0	0
No Improvement	0	0	0	0	0	0
Total	**20**	**100**	**20**	**100**	**40**	**100**

Chi square test Statistic= 0.000, p value= 1.000

The comparison of overall therapeutic outcomes between the two groups using the Chi-square test showed a Chi-square value of 0.000 with a p-value of 1.000, indicating no statistically significant difference between Group A and Group B in terms of overall clinical improvement. This suggests that both trial interventions produced equally effective therapeutic outcomes, with the vast majority of patients in both groups achieving complete response and the remainder demonstrating marked improvement.

DISCUSSION:

Vulvovaginitis is a common gynecological condition encountered during pregnancy. Due to physiological changes and altered *Doshic* balance during pregnancy, women become more susceptible to various disorders. The classical symptoms described in *Upapluta Yonivyapad* resemble the clinical presentation of vulvovaginitis, particularly vulvovaginal candidiasis, Bacterial vaginosis which commonly affects pregnant women. *Upapluta Yonivyapad* is a condition where *Kapha* and *Vata Doshas* are vitiated resulting in abnormal vaginal discharge, vaginal itching, foul smell of vaginal discharge, pain or discomfort in vaginal region and burning sensation of vulva and vagina. Untreated vulvovaginitis during pregnancy may lead to adverse maternal and fetal outcomes, including ascending infection, premature rupture of membranes (PROM), and preterm labor. Therefore, early diagnosis and effective management are essential to prevent complications and improve maternal well-being.

The present study compared the efficacy of *Khadira* suppository with Clingen forte vaginal capsules in the management of vulvovaginitis. The findings shows that both interventions were effective in treating vulvovaginitis. However, *Khadira* suppository shows clinically more effective than clingen forte vaginal capsules. The selection of *Khadira* as a vaginal suppository was based on its well-known *Ayurvedic* properties, such as *Kashaya, Tikta Rasa, Laghu and Ruksha Guna, and Sheeta Veerya*[7], which are beneficial in vitiated *Kapha Dosha*.

The drug is traditionally indicated in *Pradara, Vrana, Kushta,* and other infectious and inflammatory conditions because of its *Kashaya Rasa* predominance and *Sthambhana* properties[8]. Major chemical components of the heartwood of *Acacia catechu* are catechin, epicatechin, epigallocatechin, epicatechin gallate, quercetin.[9] The medicinal value of *Acacia catechu* is attributed to its strong antioxidant activity and high tannin content. The tannins possess excellent astringent properties, which promote wound healing by reducing inflammation, enhancing tissue repair, and protecting the affected area[9].

The *Kashaya and Tikta Rasa of Khadira* possess *Sthambhana, Ropana, and Kledashoshaka* properties, which helps to control abnormal vaginal discharge. The tannins and polyphenols present in *Khadira* exhibit an astringent action on the vaginal mucosa, causing contraction of superficial tissues and reducing abnormal secretions and local exudation, thereby relieving *Yoni Srava*[10]. *Yoni Kandu* in *Upapluta Yoni Vyapad* is associated with excessive *Yoni Srava*. The *Ruksha Guna* reduces excess moisture in vagina. As the discharge decreases, the moist environment responsible for irritation and itching is also diminished. Quercetin present in *Khadira* decreases histamine release, which contributes to reduction of itching and irritation.[11]

Yoni Daha is primarily caused by inflammation and irritation of the vaginal mucosa. The *Sheeta Veerya* of *Khadira* helps to reduce the burning sensation and local irritation. Flavonoids and phenolic compounds exhibit potent anti-inflammatory activity. They inhibit

inflammatory mediators such as prostaglandins and cytokines, thereby reduces redness, swelling, and burning sensation.[12]

Yoni Dourgandhya in vulvovaginitis is mainly caused by the growth of pathogenic microorganisms and the decomposition of vaginal secretions which produce volatile amines and other odour-causing substances. The astringent action of tannins helps to reduce excessive moisture in vagina, and thereby eliminating the favourable condition for microbial proliferation. Consequently, the production of odour-causing metabolites decreases, thereby reducing *Yoni Dourgandhya.*

In addition, catechu-tannic acid supports tissue repair and healing of inflamed vaginal mucosa by promoting epithelial regeneration.[13] The astringent action Tannins also reduces excessive vaginal secretions, and may create an unfavourable environment for bacterial proliferation. Polyphenols and catechins in *Khadira* may exhibit antifungal activity by damaging fungal cell walls. This inhibits fungal growth and helps to eliminate fungal infections.

The anti-inflammatory and wound-healing properties of *Khadira* support restoration of the vaginal mucosa, while its antimicrobial activity helps to normalize the vaginal flora, thereby aiding in the maintenance of physiological vaginal pH. Collectively, these actions helps to break the pathogenesis of *Upapluta Yoni Vyapad*, resulting in symptomatic relief and restoration of vaginal health during pregnancy.

Several studies have demonstrated the antimicrobial activity of *Acacia catechu* heartwood extracts. Ethyl acetate, methanol, and ethanol extracts have shown inhibitory effects against a wide range of microorganisms, including Bacillus subtilis, Staphylococcus aureus, Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Salmonella typhi, Shigella spp., and Candida albicans (Joshi et al., 2011; Negi and Dave, 2010; Lakshmi et al., 2011). These findings support the broad-spectrum antimicrobial potential of A. catechu heartwood[14]. The methanolic extract of this plant was found to have antimicrobial activities against six species of pathogenic and non-pathogenic microorganisms: Bacillus subtilis, Staphylococcus aureus, Salmonella typhi, Escherichia coli, Pseudomonas aeruginosa and Candida albicans[15].

CONCLUSION:

The present study demonstrated that both the trial and control interventions were effective in the management of *Upapluta Yoni Vyapad* vis-à-vis vulvovaginitis during pregnancy, with significant improvement in clinical symptoms. However, the *Khadira* suppository group showed greater clinical efficacy in reducing vaginal discharge, itching, burning sensation, and associated discomfort compared to the control group. The formulation was found to be safe, well tolerated, and acceptable for use during pregnancy. These findings suggest that *Khadira* suppository is a promising Ayurvedic local therapeutic modality for the management of *Upapluta Yoni Vyapad* and may serve as an effective alternative treatment of vulvovaginitis during pregnancy. Further multicentric studies with larger sample sizes are recommended to validate these findings and strengthen the evidence for its clinical application.

REFERENCE

1. Charaka, Charaka Samhita ed.by Satyanarayan Shastri, reprint, Varanasi Chaukhamba Bharti Academy 2003 Cha.Sa.Chi.30/39,40,41
2. K R S Murthy 1995, Ashtanga Hridayam volume 3 Krishnadas academy, Varanasi page no. 314
3. Shastry PPV, editor. Sharangadhara Samhita. Reprint ed. Varanasi: Chaukhambha Orientalia; 2013. p. 127.
4. Konar H. DC Dutta's Textbook of Obstetrics. 9th ed. New Delhi: Jaypee Brothers Medical Publishers; 2018. p. 53.
5. F Gary Cunningham, K.J.L.S.L.B.,J.C.H.,D.J.R,C.Y.S, 2010 Williams Obstetrics 23ed. by Gary Cunningham.usa;2010 pg no.164
6. Vulvovaginitis in pregnant women - PMC https://share.google/GQKrvw81n0r5VVFZc
7. Sharma P V, Dravya Guna Vignyana part 2 Chaukhambha Bharati Academy Varanasi, pg. no. 159-160
8. Sharma PV. Dravyaguna Vijnana. Vol. 2. Varanasi: Chaukhambha Bharati Academy; 2013. p. 87-89.
9. Sharma P, Lingha R. A Recent Update on the Pharmacognostical as well as pharmacological Profiles of the Acacia Catechu Heartwood: A Mini Review. J Ayu Herb Med 2021; 7(3):188-192. DOI: 10.31254/jahm.2021.730
10. Kokate CK, Purohit AP, Gokhale SB. Pharmacognosy. 56th ed. Pune: Nirali Prakashan; 2021
11. Middleton E Jr, Kandaswami C, Theoharides TC. The effects of plant flavonoids on inflammatory cells. Pharmacol Rev. 2000;52(4)
12. Stohs SJ, Bagchi D. Antioxidant and anti-inflammatory properties of flavonoids. Free Radic Biol Med. 1995;18
13. Singh KN. Traditional uses and pharmacological properties of Acacia catechu. Anc Sci Life. 2004;23(4)
14. https://onlinelibrary.wiley.com/doi/10.1002/ptr.5335
15. https://link.springer.com/article/10.1007/s12088-011-0061-1