Original Article

Dhatakyadi Varti – An effective local treatment for *Upapluta Yonivyapad* (vulvovaginitis during pregnancy): A standard controlled randomized clinical trial

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Abstract

Background: Pregnant women are more prone to vulvovaginitis which is a great challenge for obstetricians today. In *Ayurveda, Upapluta Yonivyapad* described by *Acharya Charaka*, *Sharangadhara*, and both *Vagbhata* can be compared to vulvovaginitis during pregnancy. **Aims:** The present study aimed to evaluate efficacy of *Dhatakyadi Varti* in the management of *Upapluta Yonivyapad* (vulvovaginitis during pregnancy). **Materials and Methods:** A total of 80 female patients in the age group of 19–40 years were registered and divided into two groups. In Group A ($n = 46$), *Dhatakyadi Varti* was inserted intravaginally, and in Group B ($n = 34$), Clingen vaginal suppository was inserted intravaginally once at bed time for 14 days. The effect of therapy was assessed on the basis of relief in subjective and objective criteria, i.e., vaginal smear test. **Results:** In subjective parameters, such as *Yoni Srava, Yoni Kandu, Yoni Vedana, Yoni Daha* and *Yoni Daurgandhya,* better result was observed in trial Group A receiving *Dhatakyadi Varti*. Highly significant relief ($P < 0.001$) was observed in fungal infection, and significant relief ($P = 0.005$) was observed in Gram - negative bacterial infection and pus cells in Group A. In Group A, 34.88% patients had complete remission, marked improvement was found in 34.88% cases, and only 2.32% patients remained unchanged, while in Group B, 33.33% patients reported complete remission, marked improvement was found in 10% cases, and 20% patients remained unchanged. **Conclusion:** It was concluded from the clinical trial that *Dhatakyadi Varti* is highly effective in reducing subjective and objective variables of *Upapluta Yonivyapad* and can be introduced as a safe herbal therapy of vaginal discharge during pregnancy.

Keywords: Clingen vaginal suppository, *Dhatakyadi Varti*, Pregnancy, *Upapluta Yonivyapad*, vulvo-vaginitis

Introduction

Pregnancy is a beautiful phase in women's life and desire to have a healthy progeny is innate and very intense in every living being. Pregnancy is associated with specific anatomical, physiological, and immunological changes that can predispose to infection and also alter the response to the disease process. Some of the infections may be serious and life-threatening for the mother, while others may seriously jeopardize the fetus or neonate leaving the mother asymptomatic. Fetal infections may develop early in pregnancy to produce obvious stigmata at birth. Alternatively, organisms may colonize and infect the fetus during labor and delivery. Infection is the most clearly recognized and more widely studied and responsible for about 20%–40% of all cases of pre-term birth and other complications such as premature rupture of membranes, chorioamnionitis, and spontaneous abortion.[1] As per *Acharya Sushruta,* as fruits detach from tree untimely due to the effect of *Krimis* (parasites), *Vata* and *Abhigata*, similarly fetus also gets detached due to the influence of all these factors. *Upapluta Yonivyapad* has been described by *Acharya Charaka*,[2] both *Vagbhata*,[3,4] and *Sharangadhara*,[5] but only *Acharya Charaka* has clearly mentioned that it is a disease of a pregnant woman, and thus, it can be compared to vulvovaginitis during pregnancy. According to *Acharya Charaka*, when a pregnant woman consumes faulty diet or indulges in mode of life capable of vitiating *Kapha*

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and also suppresses desire of vomiting and inspiration, then vitiated *Vayu* withholding *Kapha* affects *Yoni* and produces abnormalities such as yellowish vaginal discharge associated with pricking pain and this condition is known as *Upapluta Yonivyapad*.[6] *Acharya Charaka* has mentioned *Dhatakyadi Taila*[7] for *Yoni Pichu,* for this disease, but in the present study, the same has been prepared in the *Varti* form considering that *Varti Kalpana* is convenient for patients as it can be administered by self without much precaution and supervision.

Hence, the clinical study was carried out with the aim to evaluate and compare the efficacy of *Dhatakyadi Varti* with Clingen vaginal suppository in the management of *Upapluta Yonivyapad* (vulvovaginitis).

Materials and Methods

Patients

In the present study, patients were selected from the outpatients Department of Stree Roga and Prasuti Tantra with positive *Trichomonas vaginalis*/fungal hyphae/pus cells in the vaginal smear or Gram-negative organisms in Gram staining were registered for the trial. A detailed history was taken according to the proforma specially prepared for this purpose.

Drugs

The raw drugs for *Dhatakyadi Varti* [Table 1] were obtained from Pharmacy of Gujarat Ayurved University and authenticated in the Pharmacognosy Laboratory of IPGT and RA. *Varti* was prepared in the Department of Rasashashtra and Bhaishajya Kalpana. Table 2 shows the ingredients of *Dhatakyadi Varti.*

Method of preparation

Dhatakyadi Yavakuta was taken in a big container, and then eight times distilled water was added and heated till it was reduced up to ¼. *Prakshepa Dravya* was added into *Kwatha* and the solution was stirred for 5 min. Then, gelatin powder was added into mixture. Whole solution was melted in water bath and propylparaben sodium salt was added. Heat was constantly supplied and the solution was continuously stirred until a homogeneous mixture was obtained; then, it was poured into suitable chilled molds. After the drug settled, it was kept in refrigerator for 15 min and then it was packed into sterile plastic packets.

Ethical clearance

The study had a due clearance from the Institutional Ethics Committee (Ref. PGT/7-A/Ethics/2013-14/1767, dated 10/09/2013) and CTRI registration was done (CTRI Number: CTRI/2015/05/005747). Before initiation of the study, informed written consent was taken from each patient. Patients were asked to withdraw their name from the study at any time without giving any reason if they wish.

Study design

For this clinical trial, an open-labeled randomized standard control interventional method was adopted.

Table 1: Ingredients of *Dhatakyadi Yavakuta*

Drug	Botanical name/chemical constitute	Part used	Ratio
Dhataki	*Woodfordia fruticosa* Kurz.	Dried flower	1 part
Amalaki	*Phyllanthus emblica* Linn.	Dried fruit	1 part
Srotanjana	Sb_2S_3	Powder	-
Madhuka	*Glycyrrhiza glabra* Linn.	Dried root	1 part
Utpala	*Nymphaea stellata* Willd.	Dried leaves	1 part
Jambu	*Syzygium cumini* Linn.	Dried seed	1 part
Amra	*Mangifera indica* Linn.	Dried seed	1 part
Kasisa	$FeSO_4.7H_2O$	Powder	-
Lodhra	*Symplocos racemosa* Roxb.	Stem bark	1 part
Kataphala	*Myrica esculenta* Buch.	Dried fruit	1 part
Tinduka	*Diospyros peregrina* Guerke.	Stem bark	1 part
Saurashtrika	$KAl(SO_4)_2\ 12H_2O$	Powder	-
Dadima	*Punica granatum* Linn.	Dried fruit bark	1 part
Udumbara	*Ficus glomerata* Roxb.	Dried fruit	1 part

Table 2: Ingredients for each *Dhatakyadi Varti* of 3 g

Ingredients	Quantity required
Dhatakyadi Yavakuta	0.60 g
Distilled water	4.80 ml (8 times)
Gelatin powder	0.3 g
Propylparaben sodium salt	0.02 g
Prakshepa Dravyas	0.02 g

Inclusion criteria

1. The pregnant women belonging to age group from 19 to 40 years having clinical features such as *Yoni Srava* (vaginal discharge), *Yoni Kandu* (itching vulva), *Yoni Daha* (burning sensation in vagina), *Yoni Vedana* (pain in vagina), and *Yoni Daurgandhya* (foul smell in vagina)
2. White discharge or inflammation present during Speculum examination
3. Presence of either of *Trichomonas vaginalis,* fungal hyphae, and pus cells in the vaginal smear or Gram-negative organisms in Gram staining.

Exclusion criteria

1. Nonpregnant women
2. Pregnant women having age below 19 years or above 40 years
3. Hypersensitivity to drug and inability to confine to the protocol
4. Women with severe physical illness, any systemic disease such as diabetes mellitus, any organic pathology or hepatic, cardiac, renal disease, or any acute infection
5. History of sexually transmitted diseases or/and of human immunodeficiency virus (HIV).

Investigations

1. Routine hematological examination such as complete blood count and urine routine and microscopic examination

were carried out before and after the course of treatment
2. Biochemical test, i.e., fasting blood sugar and serological test such as S. venereal disease research laboratory (VDRL) and S. HIV were carried out in all the patients before starting the course of treatment.
3. Specific investigations such as vaginal pH, vaginal smear, and Gram staining tests were carried out before and after the course of treatment.

Treatment protocol

In Group A, *Dhatakyadi Varti* (each of 3 g) was inserted intravaginally once at bed time for 14 days, and in Group B, Clingen vaginal suppository (clotrimazole 100 mg, clindamycin 100 mg) was inserted intravaginally once at bed time for 14 days.

Criteria for assessment

Subjective criteria

- The improvement in the patient was assessed on the basis of relief in the signs and symptoms of the diseases such as *Yoni Srava, Yoni Kandu, Yoni Vedana, Yoni Daha* and *Yoni Daurgandhya* and a special scoring pattern was adopted for this.

Objective criteria

Assessment of the therapy was carried out by comparing the before treatment and after treatment changes of vaginal pH, vaginal smear, and Gram staining test.

Follow up

After completion of course, patients were advised to report every 15 days for 1 month.

Assessment criteria for overall effect of therapy

If <25% changes were found in sign and symptoms of disease, then it was considered as no change in condition, like wise changes of 26%–50% were considered as mild improvement, changes of 51%–75% were considered as moderate improvement, changes of 76%–99% were considered as marked improvement, and 100% relief was considered as complete remission in disease condition.

Statistical analysis

Wilcoxon signed-rank test for nonparametric paired data, paired *t*-test for quantitative parametric paired data, and unpaired *t*-test for quantitative unpaired data were used. The results were interpreted at the level of $P > 0.05$ as insignificant, $P < 0.05$ as significant, $P < 0.001$ as highly significant, and $P < 0.0001$ as extremely highly significant.

Observations

A total of 80 patients of *Upapluta Yonivyapad* (Vulvovaginitis during pregnancy) were registered. Among them, 46 patients were registered in Group A and 34 patients were in Group B. A total of 73 patients completed the course of treatment while seven patients left the course of treatment (3 patients from Group A and 4 patients from Group B). In the present study, maximum numbers of patients, i.e., 68.75%, belonged from the age group of 25–30 years. Maximum numbers of patients i.e., 76.25% were Hindu, 87.5% were homemakers, 66.25% patients were from lower middle class, and 73.75% of patients were from the joint family. 82.5% of patients belonged to urban area. 62.5% patients had second-trimester pregnancy. 72.5% patients were vegetarian. In diet, 81.25% of patients were consuming *Madhura Rasa* while 70% were consuming *Katu Rasa. Mandagni* and *Vishamagni* were observed in 33.75% and 31.25% of patients, respectively. 47.5% patients were having habit of *Vishamashana* and 21.25% patients were having the habit of *Adhyashana*. 38.75% of patients were addicted to tea while 08.75% of patients were addicted to tobacco. *Divaswapa* (day sleep) was observed in 75% of patients, 56.25% of patients had the history of intercourse 1–2 times/week and *Chhardi Nigrahana* (suppression of vomiting) was found in 58.75% of patients. Among the chief complaints, maximum numbers of patients, i.e., 100% patients, had complaint of *Yoni Srava* (vaginal discharge). *Yoni Kandu* was found in 58.75% of the patients, *Yoni Vedana* and *Yoni Daha* were found in 37.5% and 13.75% of cases, respectively. *Pandu Pichchhila Yoni Srava* (white mucoid discharge) was present in 71.25% of cases, *Dadhivat Yoni Srava* (curd like discharge) was present in 25% of cases, and *Jaliya Yoni Srava* (watery discharge) was present in 3.75% of cases. Among the associated complaints, 51.25% patients had complaint of *Katishula* (backache), 40% patients had *Mutradaha* (burning micturition), and 26.25% patients had complaint of *Udarashula* (abdominal pain). On the basis of per speculum examination, vaginitis was observed in 60% of cases, while vulvitis and cervicitis were observed in 43.75% and 15% of cases, respectively. In vaginal pH test, most of the vaginal samples, i.e., 31.25%, indicated vaginal pH 6.0 (acidic) while 28.75% indicated vaginal pH 7.0 followed by 20%, 10%, 8.75%, and 1.25% of vaginal samples indicated 3.0, 4.0, 5.0, and 8.0 (alkaline) vaginal pH, respectively. In vaginal smear test and gram staining, pus cells were observed in 100% cases, fungal hyphae was found in 35% of cases, and Gram-negative bacteria organism was found in 92.5% of cases. During follow-up, 5 patients in Group A and 12 patients in Group B had complaint of recurrence of vaginitis within 1 month.

Results

In symptom of *Yoni Srava,* better percentage of relief, i.e., 87.5% was found in Group A compared to control group, i.e., 49.15%, and this value is statistically highly significant ($P < 0.001$). *Yoni Kandu* was better relieved, i.e., 91.07% in Group A than in Group B, i.e., 64%. These comparative data were statistically highly significant ($P < 0.001$). Better percentage of relief, i.e., 87.88%, was found in Group A in relieving *Yoni Vedana* compared with the Group B, i.e., 50%, which was statistically highly significant ($P < 0.001$). In relieving *Yoni Daha* and *Yoni Daurgandhya,* Group A showed better results, i.e., 84.61% and 90%, respectively, than that of Group B which is 57.14% and 70%, but these findings were not statistically significant ($P > 0.05$) [Table 3 and Graph 1].

Better percentage of relief was found in Group A in relieving *Katishula, Udarashula*, and *Mutradaha*, i.e., 50%, 47.37%, and

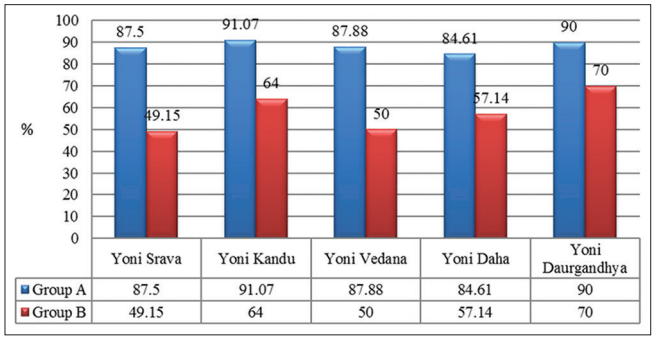
94.12%, respectively, when compared with the control group, i.e., 23.08%, 40%, and 72.22%. This value was statistically insignificant ($P > 0.05$).

One hundred percent relief was found in vulvitis in Group A and in control group, i.e., 62.5%. Vaginitis was better relieved in Group A, i.e., 96%, than in Group B, i.e., 87.5%, [Table 4 and Graph 2].

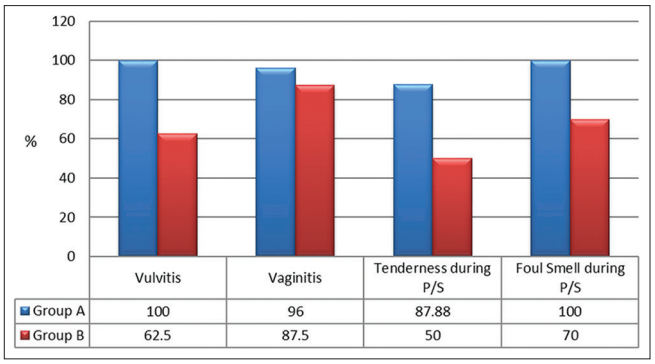
Fungal infection was better relieved in Group A, i.e., 78.12%, than in Group B, i.e., 50%, and the difference of effect between the groups was statistically insignificant ($P = 0.187$). Better percentage of relief was found in Group B in relieving bacterial infection, i.e., 50%, when compared with the Group A, i.e., 17.33%, and it was statistically insignificant ($P = 0.002$). Better percentage of relief was found in Group B in relieving pus cells 87.5% when compared with the Group A, i.e., 50%. This value was statistically insignificant ($P = 0.515$) [Table 5 and Graph 3].

Overall effect of therapy

In the trial group, 15 patients (34.88%) got complete remission and 15 patients (34.88%) had marked improvement.



Graph 1: Comparative effect of Group A ($n = 43$) and Group B ($n = 30$) on chief complaints of the patients of *Upapluta Yonivyapad*



Graph 2: Comparative effect of Group A ($n = 43$) and Group B ($n = 30$) on gynecological examination of the patients of *Upapluta Yonivyapad*

Table 3: Comparative effect of Group A ($n=43$) and Group B ($n=30$) on chief complaints of *Upapluta Yonivyapad*

Chief complaints	df	Percentage of relief		Mean difference	*t*	*P*	Significance
		Group A	Group B				
Yoni Srava (vaginal discharge)	71	87.5	49.15	0.824	4.859	<0.001	HS
Yoni Kandu (itching vulva)	44	91.07	64	0.933	5.939	<0.001	HS
Yoni Vedana (vaginal pain)	31	87.88	50	0.864	4.225	<0.001	HS
Yoni Daha (burning sensation in vagina)	9	84.61	57.14	0.571	1.144	0.282	IS
Yoni Daurgandhya (foul smell in vagina)	15	90	70	0.125	0.451	0.658	IS

df: Degree of freedom, HS: Highly significant, IS: In significant

Table 4: Comparative effect of Group A ($n=43$) and Group B ($n=30$) on gynecological examination of the patients of *Upapluta Yonivyapad*

Gynecological parameters	df	Percentage of relief		Mean difference	*t*	*P*	Significance
		Group A	Group B				
Vulvitis	26	100	62.5	0.425	3.082	0.005	S
Vaginitis	39	96	87.5	0.0850	0.764	0.449	IS
Tenderness (during P/S examination)	31	87.88	50	0.864	4.225	<0.001	HS
Foul smell (during P/S examination)	15	100	70	0.236	0.970	0.347	IS

df: Degree of freedom, S: Significant, IS: In significant, HS: Highly significant, P/S: Pelvic/speculum

Table 5: Comparative effect of Group A ($n=43$) and Group B ($n=30$) on vaginal smear test of the patients of *Upapluta Yonivyapad*

Vaginal smear test	df	Percentage of relief		Mean difference	*t*	*P*	Significance
		Group A	Group B				
Fungus	23	78.12	50	0.470	1.359	0.187	IS
Gram-negative bacteria	66	17.33	50	−0.625	−3.224	0.002	S
Pus cells	71	50	87.5	0.116	0.654	0.515	IS

IS: In significant, S: Significant, df: Degree of freedom

While 8 patients (18.60%) were found with moderate improvement, 4 patients (9.30%) with mild improvement, and 1 patient (2.32%) remained unchanged. In the Clingen vaginal suppository group, 10 patients (33.33%) had complete remission and 3 patients (10%) had marked improvement, while 3 patients (10%) had moderate improvement, 8 patients (26.66%) had mild improvement, and 6 patients (20%) remained unchanged [Graph 4].

Discussion

On the basis of all clinical features and principles of treatment, *Upapluta Yonivyapad* seems to be nearer to vulvovaginitis during pregnancy. *Acharya Charaka* has mentioned *Dhatakyadi Taila* for *Yoni Pichu,* but in this present study, the same drug has been used in the *Varti* form. *Varti Kalpana* is convenient for patients to administer by own, and there is no need of any precaution and supervision. As in modern science, vaginal suppositories are of fixed dose, to resemble that parameter vaginal suppositories were prepared.

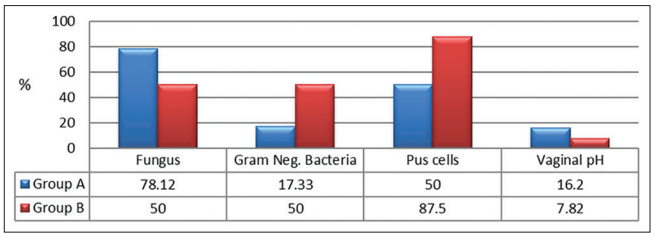
Most of the drugs of this *Yoga* have *Kashaya Rasa, Ruksha Guna* and *Kapha Dosha Shamaka* properties. They have been reported as *Stambhaka*[8-15] (styptic), *Garbhashayashothahara* (anti-inflammatory),[9,10,12,15-18] *Kandughna*[16,17,19] (antipruritic), *Twagdoshahara*[8,9,16] (dermatic), *Krimighna*[8,11,18-20] (anthelmintic), antibacterial,[9,11,18] antifungal,[8,9,11,17] and antimicrobial[9,16] [Chart 1].

In the present study, maximum numbers of patients were from the age group of 25–30 years. This indicates that this disease is a common problem of active reproductive life.[21] Most of patients were from lower middle class; these people cannot get proper diet and hygienic environment. Hence, the chances of infection are higher in lower strata. Most of patients were of second trimester; this suggests that during second trimester, decreased immunity causes decreased local defense mechanism which is also responsible for growth of microorganism. According to *Acharya Charaka,* 5th month onward *Garbhini* becomes emaciated, suffers from loss of strength, and feels excessively exhausted.[22] Most of patients had the history of intercourse 1–2 times/week. It is mentioned in Ayurvedic classics that *Atimaithuna* (excessive sexual intercourse) is one of the important causative factor for all *Yonivyapad* and during pregnancy is prohibited by *Acharyas*.[23,24]

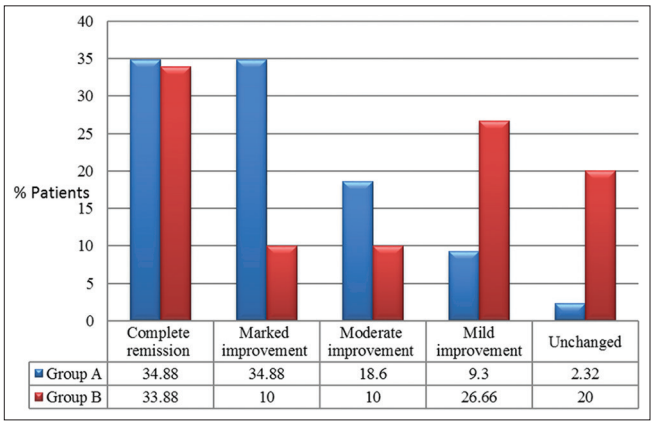
Results of clinical study suggest that *Dhatakyadi Varti* is much more effective to treat fungal infection compared to clingen vaginal suppositories. In bacterial infection, control group shows better relief compare to *Dhatakyadi Varti* trial group. Recurrence rate is also low in *Dhatakyadi Varti* trial group, and it can definitely become effective herbal formulation to treat vulvovaginitis during pregnancy.

Conclusion

Upapluta Yonivyapad is the disease of the pregnant women which produces untowards outcomes if left untreated.



Graph 3: Comparative effect of Group A (n = 43) and Group B (n = 30) on vaginal smear test of the patients of *Upapluta Yonivyapad*



Graph 4: Overall effect of therapies on 73 patients of *Upapluta Yonivyapad*

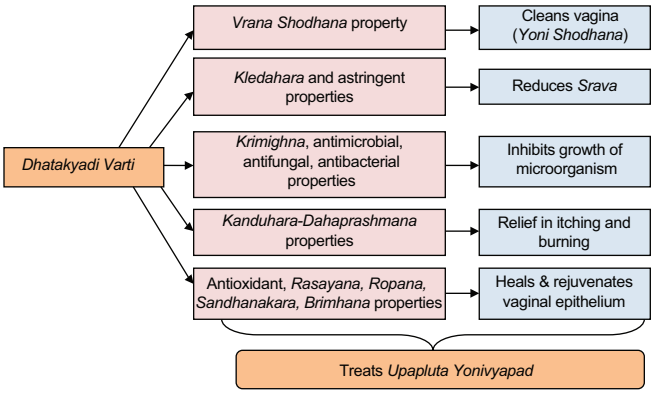


Chart 1: Probable mode of action of *Dhatakyadi Varti*

Dhatakyadi Varti not only treats the disease but also normalizes the vaginal flora. It can be concluded that *Dhatakyadi Varti* is highly effective in reducing subjective and objective variables of *Upapluta Yonivyapad* (vulvovaginitis during pregnancy).

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Nil.

Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

धातक्यादि वर्ति-उपप्लुता योनिव्यापद के लिए स्थानिक प्रभावी चिकित्सा- एक मानक नियंत्रित यादृच्छिक चिकित्सीय परीक्षण

निलोफर मोहम्मद शफ़ी शेख़, लक्ष्मीप्रिया देई, शिल्पा डोंगा

गर्भवती महिलाएँ वल्वोवैजिनाइटिस से अधिक ग्रस्त होती है जो कि आज के प्रसूति निष्णातों के लिए एक बड़ी चुनौती है। आयुर्वेद में वर्णित उपप्लुता योनिव्यापद की गर्भावस्थाजन्य वल्वोवैजिनाइटिस के साथ तुलना की जा सकती है। प्रस्तुत शोध में उपप्लुता योनिव्यापद (गर्भावस्थाजन्य वल्वोवैजिनाइटिस) का चिकित्सीय अध्ययन धातक्यादि वर्ति से किया गया है। इस हेतु १९ - ४० वर्ष के आयु समूह में कुल ८० रोगियों को पंजीकृत किया गया। उनको सामान्य विवरण प्रणाली से दो वर्गो में विभाजित किया गया। वर्ग 'ए' में ४६ रोगियों को धातक्यादि वर्ति ३ ग्राम की मात्रा में प्रतिदिन एक बार चौदह दिनों तक योनि में स्थानिक प्रयोग के लिए दी गई। तथा वर्ग 'बी' में ३३ रोगियों को क्लिंजेन वैजाइनल सपोजिटरी (क्लोट्रायमेज़ोल१०० मि. ग्रा. तथा क्लिंडामायसिन १०० मि. ग्रा.) प्रतिदिन एक बार चौदह दिनों तक योनि में स्थानिक प्रयोग के लिए दी गई। जिसमें वर्ग 'ए' में ४३ रोगियों तथा वर्ग 'बी' में ३० रोगियों द्वारा नियमित रूप से चिकित्सा अवधि पूर्ण की गई। वर्ग 'ए' में ३ रोगियों तथा वर्ग 'बी' में ४ रोगियों ने बीच में ही चिकित्सा छोड़ दी। चिकित्सीय परिणामों का आंकलन सब्जेक्टिव पैरामीटर तथा ओब्जेक्टिव पैरामीटर जैसे वैजायनल स्मीयर टेस्ट से प्राप्त परिणाम के आधार पर किया गया। वर्ग ए में फंगल इन्फेक्शन में सांख्यिकीय रूप से ($p<०.००१$) सार्थकपरिणाम, ग्राम ऋणात्मक जीवाणु और मवाद कोशिकाओं में भी ($p=०.००५$) उत्तम परिणाम पाये गए। वर्ग ए में ३४.८८% रोगियों को पूर्ण लाभ, ३४.८८% को मध्यम लाभ एवं २.३२ % को न्यूनतम लाभ प्राप्त हुआ जबकि वर्ग बी में ३३.३३ % रोगियों को पूर्ण लाभ, १० % को मध्यम लाभ एवं २० % को न्यूनतम लाभ प्राप्त हुआ। परिणामतःचिकित्सीय अध्ययन से यह निष्कर्ष निकलता है कि धातक्यादि वर्ति उपप्लुता योनिव्यापद के लक्षणों को कम करने में प्रभावकारी है और साथ ही गर्भावस्था के दौरान विकृत योनिस्राव में निरापद आयुर्वेद चिकित्सा के रूप में प्रयोग की जा सकती है।