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'CLINICAL STUDIES ON UDUMBARA TAILA PICHU DHARANA IN KAPHAJA YONIVYAPADA (VAGINAL CANDIDIASIS).'

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Abstract: Background: Now a days vulvo vaginal candidiasis is also very common in women's, vulvo vaginal candidiasis is yeast infection on the vulva or and vagina caused by candida albicans being the major culprit. about 90% of this infection is caused by candida albicans and 10% by other Species of candida, about 75% of females experience at least one episode of vaginal candiasis during their life time. Prevalence rate of vaginal candidiasis in reproductive age group women is 35%[(2)]. **Objective:** To study the Efficacy of *Udumbara tail yonipichu Dharana* in *kaphaja yonivyapada.* **Methodology:** The research was carried out at the *Prasuti* and *Streeroga vibhag* of Govn Ayurved college of Osmanabad. In the clinical controlled randomised study on *Udumbara taila Yoni pichu Dharan* in *Kaphaja Yonivyapada,*we have selected total 60 patients divided into 2 groups A and B,in group A 30 patients were selected and *udumbara taila yonipichu* were given for 7 days for 3 consecutive cycle and in group B 30 patients were selected randomly and given clotrimazole v3 tablet vaginally for 3 days at bed time for 3 consecutive cycles. **Result:** *Udumbara taila yonipichu* is to be statistically equally effective but sightly more percentage of relief in *katishul* in comparison with Candid V3 VT. **Percentage % of relief :** Group A- 83.76 %,Group B- 83.42%. **Statistical Analysis:** After the present study and statistical analysis, it is found that the signs and symptoms are improved with mentioned dose and duration of *udumbar taila* .**Conclusion:** In both groups it shows nearly equal effect on symptoms like *strava, kandu, gandha* but slightly more percentage of relief in *katishula* of Trial group than control group hence overall Group A shows sightly more percentage of relief than group B without having any side effects.

KEYWORDS: *Kaphaja Yonivyapada, Udumbara taila, Yonipichu.*

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INTRODUCTION:

White discharge is very common among the females due to this changing life style, about 41% of women in reproductive age group suffer from white discharge. Itching at vagina, mild pain in vagina and *katishul* is also very common, these may be due to poverty as she can't get proper diet which leads to malnutrition. Improper hygiene and local uncleanliness is also responsible for above symptoms. This all symptoms come under *Kaphaja yonivyapada*. *Kaphaja yonivyapad* is described by many *Aacharya Bruhatrayi*, *Laghutariyas*, *Nighantus* and in other *grantha* as a condition in which *pichil sheetal strava* from vagina with *kandu* and *manda ruja* along with *pandu* and *arthva dusti*. These features can be correlated to vaginal candidiasis which shows pruritis, abnormal vaginal discharge, vaginal irritation and soreness of vagina. For the treatment of vaginal candidiasis broad spectrum antifungal agents along with the topical application of azole drugs are used. Symptoms of *kaphaja yonivyapada* are major source of discomfort due to uncontrolled vaginal pruritis or vaginal discharge so that it can generate stress and sexual anxiety, nearly 40% of women suffer from white discharge, sometimes patient prefer to undergo hysterectomy before 40 yrs because of extreme white discharge. Now a days vulvo vaginal candidiasis is also very common in women, which shows the symptoms of curdy white discharge and vaginal itching. Vulvo vaginal candidiasis is fungus or yeast infection on the vulva or/and vagina caused by candida albicans being the major culprit. About 90% of this infection is caused by candida albicans and 10% by other Species of candida, about 75% of females experience at least one episode of vaginal candiasis during their life time, prevalence rate of vaginal candidiasis in reproductive age group women is 30-35%. Considering above facts and to give new easily available, affordable treatment options, the topic for dissertation *'Kaphaja yonivyapada'* was selected. For that in *samhita's* many useful *ayurvedic* drugs is mentioned, one of them in *Udumbar tail pichu*, it is *ayurvedic* preparation and has properties to reduce *kaphaja yonivyapada. Aacharya Charaka* in *Chikitsa sthan* 30 *shlok no.*77 has mentioned that *Udumbara taila* yonipichu should be used for *kaphaja yonivyapada.*

Udumbara taila-

Considering properties *(rasa, guna, virya, vipaka, doshaghanata and rogaghanata, karma)* of *udumbara taila* contents i,e *udumabara phala and tila taila* which is used to prepare *udumbara taila,* due to action of

drug in *kaphaja yonivyapada* this study was selected.

AIM AND OBJECTIVES

Aim :

To study the efficacy Of *Udumbara Taila Pichu Dharana* in the management of *kaphaja yonivyapada*.

Objective

- To evaluate efficacy of *udumbar taila*.
- To review the literature of *kaphaja yonivyapada.*

MATERIAL AND METHOD

Materials

Literary review:

1. Review of literature was done from classical text, *samhitas, granthas*, modern literature and web sites.
2. References of *kaphaja yonivyapada* were collected from *Ayurvedic samhitas* and about leucorrhea, vaginal candidiasis, differential diagnosis of white discharge was collected from modern text.

Clinical study:-

Ethical Clearance :

Clearance from the Institutional Ethical Committee was obtained.

a. Study design:

A randomized open controlled study in patients diagnosed as *Kaphaja yonivyapada* was done.

b. Sample Size :

60 patients (30 patient in each group)

c. Selection of patients : For clinical study, 60 patients with complaints of white discharge were randomly selected irrespective of religion, occupation,socio economic conditions equally divided in two groups namely- Trial group/Case group (Group A) and Control group (Group B) with 30 cases in each group.

d. Study population: Married women suffering from white discharge between age group 20-45 yrs

e. Place of work: The study was conducted in IPD and OPD of *Prasuti avum streeroga* department of govn ayurvedic college and hospital Osmanabad. Total 60 patients were selected randomly.

f. Consent : A consent explaining about the clinical study and a written consent was taken from the patients in the language best understood by them, before their participation in the trial.

Criteria for selection of patients

I. Inclusion criteria-

1. Age between 20-45 years
2. Shweta strava
3. Itching
4. Katishula
5. Mild pain at vuval region

II. Exclusive criteria-

1. Unmarried Women
2. Pregnancy
3. Patient with major illness (HT, DN, STD, AIDS etc.)
4. Known case of any malignancy
5. Anaemia

III. Withdrawal Criteria:

1. The patient is not willing to continue the treatment or to follow the assessment schedule.

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2. If patients will be migrated to any other place

Per abdomen

Investigations:

CBC, BSL-R, HbsAg, ICTC

Urine - Routine examination

USG if required, Papsmear if required

Gynaecological Examination:

Per speculum examination

Pervaginal examination

TABLE NO.1 : Subjective criteria:

Observation	Criteria	Grades
1.*Strava pramana*	Heavy white discharge(pad requiered)	3
	Cloths get wet	2
	Slight discharge	1
	No discharge	0
2.*Strava gandha*	Present	1
	Absent	0
3.Sthanik kandu	Extreme itching(can't resist itching) (severe)	3
	Hamper daily activity(moderate)	2
	Doesn't hamper daily activity (mild)	1
	No itching(absent)	0
4.*katishula*	Severe	3
	Moderate	2

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	Mild	1
	No pain	0

TABLE NO.2 : Observational table:

Assessment Final: Percentage of relief in symptoms with respect to the patient as follows

Percentage of relief	Result	Grade
Above 75 upto 100%	Marked Improment	1
Above 50% to Below 75%	Moderate Improvement	2
Above 25% to Below 50%	Mild Improvement	3
Below 25%	No improvement/unchanged	4

For assessment of clinical results, we prepared symptom flow chart by giving gradations to symptoms. The symptoms like gandha could not be graded so we gave these symptoms a subjective type of gradation in present absent manners.

2. OBJECTIVE CRITERIA-

1. Curdy white discharge or watery discharge

2. Red and Swollen vulva with evidence of pruritis like scratch marks.

DRUGS:

1. *Udumbar taila* - Trial drug

2. V3 tablets - Control drug

1. Trial drug-

Authenticate raw product of Udumbar and tila was taken to prepare Udumbar taila and standardization was done of final product and used pichudharan for 7 days after 7th day of menses for 3 consecutive cycles.

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2. Control drug-

Standard Candid V3 VT (Glenmark) available in the market which was given to the patient for 3 days after 7th day of menses for 3 consecutive months.

Standardization of Drug:

Authentication done of raw material from Sheetal analytical laboratory Pune and prepared according to the standard method given in the *charaka samhita* and standardization done at the Sheetal analytical laboratory Pune of final Drug.

Methods:

Preparation of drugs:

Udumbar taila - *Udumbar taila* prepared in college pharmacy according to reference in *charaka Samhita Chikitsa sthan 30 adhya*.

TABLE NO.3 : Method of preparation:

According to Charaka

Content	**Parts**
Udumbara kalka	*1 bhaga*
Tila taila	*4 bhaga*
Udumbara Kwatha	*8 bhaga*

Udumbara tail was prepared as given in *Charak Samhita* and Standardization was done of final product.

Site-

1. *Dwitiyavarta* (External and internal Os) - Circular Pichu

2. *Prathamavarta* (Vagina) - Elongated pichu

***PICHUDHARAN* PROCEDURE:**

Instruments-

1. Stainless steel bowl
2. Piece of cotton wrapped in gauze piece
3. Cotton, gauze piece

Udumbara taila Pichudharan vidhi:

- Under all aseptic precautions *Pichu* soaked in *Udumbar taila* inserted in vagina by index finger and the long thread kept outside vagina for easy removal of Pichu after 3-6 hours (upto retention of urine)

TABLE NO.4 . Drug Administration

No. of Patients	30
Drug	*Udumbara taila*
Treatment	*Pichudharana*
Route of administration	Per vaginal (dwitiyaavarta)
Quantity of *Udumbara taila*	10 ml BD
Dharana kaal	3-6 hours(upto retention of urine)
Duration	7 days
Follow up	Every month for 7 days of 3 consecutive cycle of menses
Size of *Pichu*	Length-2cm Breadth-2cm
Weight of *Pichu*	2-3 gm approximately

- *Pathya - Apathya* explained to patients.
- Written consent taken by all patients.
- Proforma prepared and daily observations noted.
- Patients were told to report for any side effect.

OBSERVATIONS AND RESULTS:

General Observations

Distribution of patients

There are 60 patients divided into 2 groups 30 patients from group A trial group and 30 patients were from group B control group

Effect of therapy:

According to % Relief in Symptoms

Table No.5: % Relief in Symptoms of Group A & Group B

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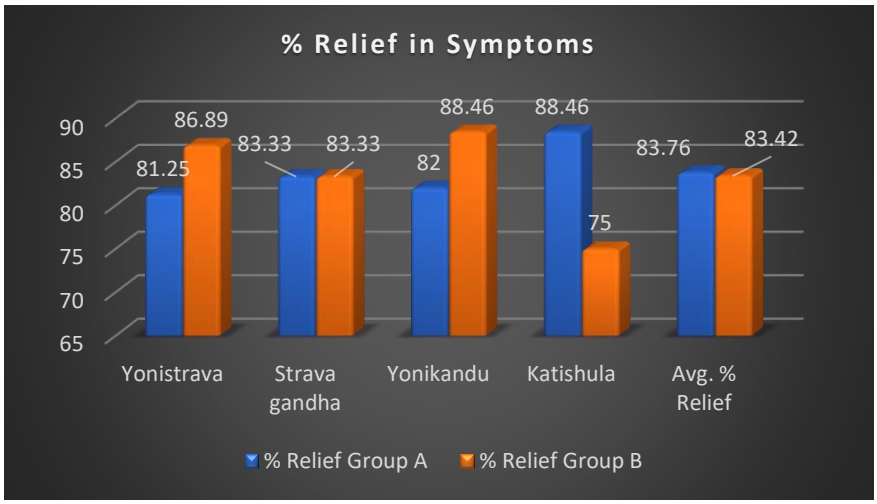
Sr. No.	Symptoms	% Relief	
		Group A	Group B
1	Yonistrava	81.25	86.89
2	Strava gandha	83.33	83.33
3	Yonikandu	82.00	88.46
4	Katishula	88.46	75.00
5	Avg. % Relief	**83.76**	**83.42**

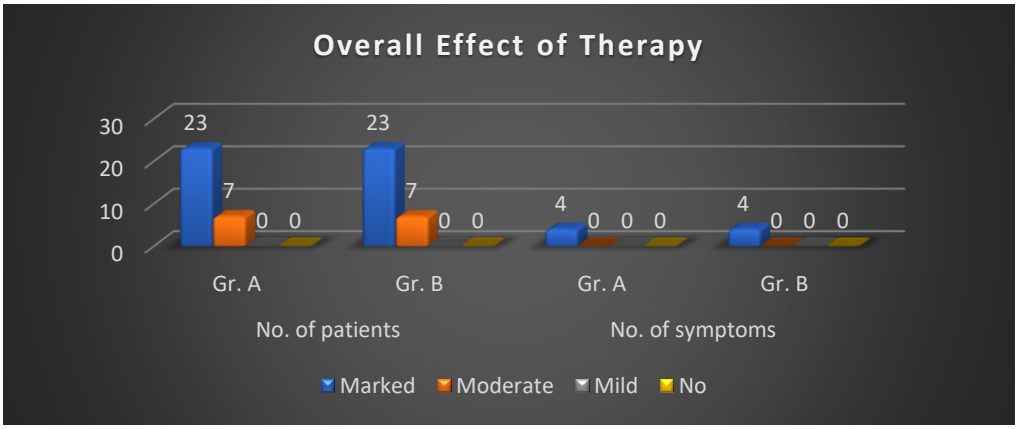
Graph 1 : % Relief in Symptoms of Group A & Group B



According % Relief

Overall Effect of Therapy

Graph 2: Overall Effect of Therapy according % Relief



According to statistical analysis Subjective Parameters

Table No.6 : Overall Effect of Therapy Statistical analysis (Subjective)

Sr. No.	Subjective Parameters	Within Groups (Wilcoxon test)		Comparison (Mann-Whitney's test)
		Group A	Group B	
1	**Yonistrava**	Significant	Significant	Insignificant (A ≈ B)
2	**Stravagandha**	Significant	Significant	Insignificant (A ≈ B)
3	**Yonikandu**	Significant	Significant	Insignificant (A ≈ B)
4	**Katishula**	Significant	Significant	Insignificant (A ≈ B)

(≈ - means statistically equal, not exact equal)

Objective Parameters

Table No.7: Overall Effect of Therapy Statistical analysis (Objective)

Sr. No.	Objective Parameter	Within Groups (McNemar's test)		Comparison (Chi square test)
		Group A	Group B	
1	**Discharge**	Significant	Significant	Insignificant (A ≈ B)
2	**Swollen vulva**	Significant	Significant	Insignificant (A ≈ B)

(≈ - means statistically equal, not exact equal)

DISCUSSION:

In present study, discussion on observations and result is done to make conclusion. Discussion on "Controlled randomized clinical studies on *udumbara taila pichu dharana* in *kaphaja yonivyapada*" is done according to literary review drug, plan of work, observations.

1. Discussion on literary review-

Description about *khaphaja yonivyapada* is mentioned in Samhitas like *Charaka, Sushruta, Bhela, Kashyapa, Sharangdhara,*

Ashtang Sangraha, Ashtang Hridaya, Yogratnakara and *madhavnidana etc.*

Acharya Charaka have mentioned:

In present study, *Udumbara taila yoni pichudharana* has been selected according to following reference where *charaka* has described *stravahara* role of *udumbara taila pichurana*.

2. Drug discussion-

As drug action depends on *rasa, veerya, vipak, guna* for its efficacy hence drug having properties which can break *Samprapti* is used.

Drug used- *Udumbar phala, tila taila*

Action of *Udumbara taila*:

Udumbar taila contains *udumbar phala* and *tila taila*. Drug action mainly takes by *rasa, guna, veerya, vipaka, karma* and *prabhava*. In the same way *Udumbara taila* acts as *kaphagna, kandughna*, *varnya, shothhara, shulhara* for *kaphaja yonivyapada*. *Yonipichu* acts on *prathamavarta* and *dwitiyavarta* and due to *snighdha* and *ushna guna* of *tila taila* it reduces *katishula*. When *Udumbara taila pichudharana* is given, *taila* gets absorbed as it comes in contact with *prathamavarta* and *dwitiyavarta* and action takes place. *Kasaya rasa* of *Udumbara phala* causes *sthanika sira sankoch* which reduces *strava* in vagina thereby reducing *kandu.* Due to *snehana* and its *ushna virya guna tila taila* which is used to prepare *udumbara taila* is *vedananasthapak, tila taila* itself is *vatasamaka* due to its properties hence *Udumbara taila* also reduces *katishula. Ushna virya* of *tila taila* causes *kleda pachana* which is responsible for *strava* and *kandu. Ushna virya* cause *shamana* of *sheeta guna* of *kapha*. *Ruksha guna, katu vipaka* causes *kapha shaman* and *lekhana* of vitiated *kapha*. Finally, we can say that contents present in *Udumbara taila* are *yonigata shweta pichhila stravahara, kandughna, shophahara, vedanahara*, this action was seen in *kaphaja yonivyapada*.

3. Discussion on plan of work

The patients coming to the hospital were with varied

TABLE NO.7 : a. inclusion, exclusion and withdrawal criteria

Inclusion criteria	Exclusion criteria
1. Age between 20-45 Years 2. *Shweta strav* 3. Itching 4. *Katishula* 5. Mild pain at vulvo vaginal region	1. Unmarried Women 2. Pregnancy 3. Patient with major illness (HT, DN, STD, AIDS etc.) 4. Known case of any malignancy 5. Anaemia

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Withdrawal Criteria:

1. The patient is not willing to continue the treatment or to follow the assessment schedule.
2. If patients will be migrated to any other place.

b. Drug quantity:

Group A - Drug quantity to each patient was decided according to pilot study.

Patients were treated with 10 ml of *Udumbara taila yonipichu* BD for seven days for 3 consecutive cycles of menses.

Group B - Patients were treated with Candid V3 VT for 3 days at bed time for 3 consecutive cycles after 7 day or stoppage of menses.

c. Route of drug administration:

Udumbara taila pichudharan and v3 tablets was administered per vaginally in *Stree-roga* and *Prasutitantra* OPD, IPD of college or self by patient at home with taking all aseptic precautions.

d. Formulations:

The contents in *Udumbara taila* helps in *sampraptibhanga* thereby reducing *yonigata shweta picchil strava, yonikandu, yonishotha, vrana* and *katishula.* Also content in v3 tablets helps reducing symptoms

e. Follow up examination:

Group A- Follow up taken every month for 7 days after stoppage of menses for 3 consecutive cycle which helped in assessment of reduction of symptoms according to gradations.

Group B- taken every month for 3 days after stoppage of menses for 3 consecutive months.

Discussion on observation:

For purpose of clinical trial and control, patients were enrolled according to assessment criteria and detail clinical examination along with per vaginal and per speculum examination, inform consent, lab investigations was done and 60 patients were selected out of them 30 patients were treated with 10 ml BD of *Udumbara taila pichudharan* per vaginally for seven days and 30 patients were treated with v3 tablet for 3 days at bed time after stoppage of menses for 3 consecutive months.

Subjective criteria

1. *Strava pramana:*

Patients were selected having *yonigata shweta picchila strava* in according to severe, moderate, mild, absent in both groups.

After the treatment

1. *Yonigata shweta picchil strava-*

In group A - *Shwetastrava* was absent in 19, *alpa* in 10, *madhyam* in 1
In group B - *Shwetastrava* was absent in 22, *alpa* in 8 and *madhyam* in 0.

Due to pharmacological action in both drugs *strava praman* was reduced. As value of p is greater than 0.05, insignificant difference was observed between the mean of difference of group A and group B, hence drug of both group A and B are almost equally effective to reducing *strava pramana*.

2. *Yonikandu* - After treatment *kandu* in group A it was absent in 21, *Alpa* in 9 patients and *madhyam* in 0 patients.

In group B it was absent in 24 patients, mild in 6 patients and moderate in 0 patients.

As value of p is greater than 0.05, insignificant difference was observed between the mean of difference of group A and group B, hence both drugs are almost equally effective to reducing *kandu*.

3. Strava gandha - Strava gandha is found in very few patients among the both group A and B, out of 6 patient of group A it was absent in respectively in control group.

Strava gandha was found in very few patients hence interpretation cannot be made.

4. Katishula

In group A - After treatment *katishula* was absent in 24 patients, mild in 6 patients and moderate in 0 patients.
In group B - After the treatment *katishula* was absent in 18, mild in 12 and moderate in 0 patients.
P value is greater than 0.05, insignificant difference was observed between the mean of difference of group A and group B, hence both groups are almost equaly effective to reducing *katishula*.

Objective criteria - This is based Subjective criteria, it is a nominal data Curdy white discharge or watery discharge - After treatment in group A it is absent in 11 patients and absent in 19 patients.In group B it is present in 8 patients and absent in 22 patients.

As value of p is greater than 0.05,

insignificant difference was observed between the mean of difference of group A and group B hence both groups drug has equally affected on reducing curdy whote or watery discharge. Red and swollen vulva with evidence of pruritis like stretch marks - In group A it is present in 9 patients and absent in 21 patients. In group B it is present in 6 patients and absent in 24 patients. As value of p is greater than 0.05, insignificant difference was observed between the mean of difference of group A and group B, both drugs have equal to improve swollen vulva due to pruritis.

CONCLUSION:

After completion of the study, it is found that an *Ayurvedic* Regimen-*Udumbara taila yonipichu* is effective on reducing symptoms of *kaphaja yonivyapada* as per Subjective/Objective parameters. Statistical analysis after study showed *udumbara taila yonipichu* is to be statistically equally effective with control group Candid V3 VT but not exactly equal. Total % of relief : Group A-83.76 %, Group B-83.42%. Hence it is concluded that Group A is not exactly equally effective with group B but it is to be statistically equally effective with Group B but overall Group A shows slightly more percentage of relief without having any side effects.

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