

International Journal of Research in Indian Medicine

Clinical Evaluation of Uttarbasti in PCOS (Poly cystic ovary syndrome) with special reference to Śatāvḥādi Tail

Shubhangi Katkar*¹, Santosh Chavan²

1. Associate professor

2. Prof. and HOD,

Department of Panchakarma, Bharati Vidyapeeth University College of Ayurveda,
Katraj-Dhanakawadi Pune 411043 (Maharashtra)

*Corresponding author :- Email-drsantoshchavan5@gmail.com

Abstract- PCOS means polycystic ovarian Syndrome PCOS affects 5% to 10% of women of reproductive age In Ayurvedic classics, Ācārya Kāśyapa mentioned PCOS in terms of ‘Puṣpaghni Revatī. He narrated that woman who observes her fruitless menstruation in appropriate time, has corpulent and hairy cheeks, she is also (seized with) called as Puṣpaghni Revatī.

The present clinical trial by trans cervical route by Śatāvḥādi Tail based on the classical reference in Ashtang Samgraha The ingredients of Śatāvḥādi Tail are viz, śatāvḥā, Saṛśapa, Ajavāyan, Śigru, Hingu, Kustha, Mandanaphala, processed in Mustard oil. It has been given by Uttarbasti module. All the ingredients are mainly Katu Ras Usna Virya and Uṣṇa Tikshna Guna.

The 30 married female recruited this clinical trial who received Śatāvḥādi Tail 5-7 ml transcervical route at Bharati Vidyapeeth(D.U) College of Ayurved and Hospital, Katraj Dhanakawadi, Pune 43. The results assessed in terms of USG (Ovarian volume and no of follicles), LH:FSH Ratio and S.Testosterone and subjective parameter Sthula Lomash Ganda (Corupurulent hair on cheek) and

Arthavkshaya. It showed effect on hormonal level {LH, FSH} but slight effect on serum testosterone.

Key word:- PCOS, Puṣpaghni Revatī, Śatāvḥādi Tail

Introduction: -

PCOS means polycystic ovarian Syndrome It accounts for 1/3 of the female health population. PCOS affects 5% to 10% of women of reproductive age. Common in Indian women, especially in south India¹¹. Asian women with PCOS are much less likely to be obese as defined by current WHO criteria; however, there are increasing data that cardiovascular risk may be evident at lower BMI among Asians compared with other white/European populations. PCOS affects 80% women who experience 6 or fewer period per year but many of them don't know

In Ayurvedic classics, Ācārya Kāśyapa mentioned PCOS in terms of ‘Puṣpaghni Revatī. He narrated that woman who observes her fruitless menstruation in appropriate time, has corpulent and hairy cheeks, she is also (seized with) called as Puṣpaghni Revatī. ¹⁰

The present clinical trial by trans cervical route by Śatāvḥādi Tail based on the classical reference in Ashtang Samgraha²

The ingredients of Śatāvḥādi Tail are viz, śatāvḥā, Saṣṣapa, Ajavāyan, Śigru, Hingu, Kustha, Mandanaphala,^{5,6} processed in Mustard oil. It has been given by Uttarbasti module. All the ingredients are mainly Katu Ras Usna Virya and Uṣṇa Tikshna Guna. So it ruptured poly cyst on the Ovary. Which in turn helped in normalizing the ovarian volume

Concept of Uttarbasti

Commentator Cakrapāni Says Uttarbasti is given in upper (Uttar) passage¹

Ācārya Vāgbhata narrated Uttarbasti should be given in Ārtava Vikāra²

Uttarbasti is indicated in yoni & Gaṛbhāśaya Vikar.² It usually has given after Niruha Basti. It means the Basti, which is given after Niruha Basti and can be given two to three times and can be given through urogenital organs is could Uttarbasti. Uttarbasti can be given 3 or 4 times.

Uttarbasti Kala, Matra and Duration

Ācārya Caraka has advised to administer Uttarbasti during Ṛtukala⁹ because during this period uterus and vagina are free from coverings and their orifices (Orifices of fine Srotasas) are open, thus, receive unction easily. Ācārya Caraka and Vāgbhata – also advised two or three Asthapana Basti before Uttarbasti administered. Ācārya Caraka has mentioned the Mātra of Uttarbasti is 1/2 Pala³. According to Ācārya Caraka and Vāgbhata, the Uttarbasti should be given consecutively for 3 days.

Importance of Uttarbasti- Basti is one of the important therapy of Sansodhan Cikitsā. Śuddha Ārtava is necessary for

conceiving. Ācārya Suśruta has narrated in his Śukṛaśonita Śuddhiśārira Adhyāya that Uttarbasti is necessary for Ārtava Śuddhi.⁴

Aim & Objective:-

- **Aim:** To study the effect of Uttarbasti in PCOS with special reference to Satāvḥādi Tail.^{7,8}

Objective:

- Clinical evaluation of Uttarbasti on PCOS on various scientific parameter.
- Standardization Satāvḥādi of tail with reference to Uttarbasti in terms of dose, time duration.
- To assess the cardinal symptoms of PCOS viz. Corpulent and hairy cheeks.
- To assess the decrease ovarian volume and follicular size.
- To assess the hormonal changes viz. LH:FSH, S. Testosterone

Material & methods

Following materials & methods adopted for clinical trials by trans cervical route. The raw material purchased from Pune market

Drug Authentication has been done at Department of Botany, University of Pune and Śatāvḥādi tail^{7,8} prepared by Tailpaka vidhi at Rasaśāstra & Bhaiṣyaja Kalpanā BVDU College of Ayurveda Katraj Dhankwadi

Ethical committee clearance taken from institutional ethical committee-IEC-3/PK/2013

Materials Required:-

Cusco's speculum, Rubin's canula, Infant feeding tube no. 10. Anterior vaginal wall retractor, Rubber catheter, Uterine sound, 20ml disposable syringe, cotton swab. Pichu ball, Hole Towel, Kidney Tray Antiseptic solution: -

(Savlon, Betadine Solution) Taila: - Śatāvḥādi Tail (Sterilized) All instruments should be sterilized.

The procedure done at Minor OT. After menstruation, Daśmūla Niruha Basti has been given for 3 days i.e. 5th, 6th, 7th then Uttarbasti consecutively has been given on 8th, 9th, 10th (3 days) in every month successively for 3 month.

SOP (Standard Operative Procedure)

Purvakarma- External local oleation has been done on lower abdomen, pelvic and thighs and local sudation by Dashmool Kashaya on that particular area before administering above mentioned Niruha Basti. The patient's fitness taken from Dept. of Gynecology.

Preparation of patient

It has been done in proliferate phase from 8th day of menstruation. It has been done for 3 consecutive days in every month successively for 3 months.

Shaving has been done from Umbilicus to Knee joint and Painting should be done on that particular area by betadine. Lastly draping should be done Hole Towel.

Pradhan Karma-

Uttarbasti has been done at around 11am. The patient is made to lie in dorsal position. Cleaned the labia using antiseptic cotton swabs. Then separated labia with thumb and index finger and wipe with antiseptic cotton swab of savlon Introduced Cusco's speculum into the vaginal cavity to visualize the cervix. The cervix is also cleaned with antiseptic cotton swab. Applied anterior vaginal wall retractor. Introduced the uterine sound to note the direction of uterus.

Rubin's canula or infant feeding tube used for doing Uttarbasti. Before Basti, the canula is rinsed in tail once to make sure that there is no air bubble.

Then take 5-7 ml of Śatāvḥādi Tail in disposable syringe and connected it to the canula or infant feeding tube. Then introduced the canula or infant feeding tube carefully and make sure that it has passed the internal os. Then slowly inserted the Bastidrava into the uterine cavity and withdraw the canula or infant feeding tube.

Then raise the buttocks of patient using a pillow and maintain as such for 10 minutes. Then slowly remove Cusco's speculum and simultaneously a pichu ball, which is soaked in taila, is kept in order to retain the Bastidrava inside the vaginal cavity. Then remove the pillow and ask patient to lie down for 10 min. in supine position until the next mutravega occurs.

Paścāta Karma –

Anuvāsana Basti module i.e. light diet rest. Consumption of luke warm water Uttarbasti given & Aṣṭa Mahadoṣkar varjya Viṣay followed.

Administration of Drug:-

	Experimental Group
No. of patients	30
Place of Study	Bharati Vidyapeeth(D.U) College of Ayurved and Hospital, Katraj Dhanakawadi , Pune 43
Pre Operative	Dashmool Niruha Basti 5 th , 6 th ,7 th Days After Menstrual Cycle
Medicine	Śatāvḥādi Tail
Route	Tran uterine route
Dose	5-7 ml
Time	11 am just having breakfast

Duration	90 days i.e. After menstruation Niruha Basti 3 days has been given on 5 th 6 th 7 th and Uttara Basti on 8 th , 9 th , 10 th (3 days) in every month successively for 3 month.
Assessment Day	5 th Day (Initial Assessment) and 10 th day in every month successively for 3 month.
Follow up	1 month after completion of clinical trial.
Pathyapathya	has been advised according to vyadhi.

Statistical Analysis

It has been done by paired 't' test and willcoxon sign test for visual analogue scale

Clinical Study

30 diagnosed cases of PCOS (Polycystic Ovary Syndromes) visiting to the OPD dept of BVMF'S Ayurveda Hospital has been selected for clinical trial. The

Inclusion Criteria

- Only Married Female
- Diagnosed case of PCOS selected by USG diagnosis (Pelvis)
- Patient between 20 yrs to 45 yrs

Exclusion Criteria

- Unmarried female has not been selected.
- Patients below 20 yrs and above 45 yrs has not been selected.
- Female who were suffering from pelvic inflammatory diseases, premenopausal and menopausal syndrome, and

menorrhagia has not been selected

Assessment Criteria

- BMI – Weight /h² (in meter) assessed before & after the treatment
- USG (Pelvis) for size & no. of follicle) assessed before & after the treatment.

Grade	Follicular Size	Grade	Ovarian Volume
1	8-10mm	1	16-18 CC
2	10-16mm	2	18-20 CC
3	Above 16mm	3	Above 20 CC
0	No cysts	0	No cysts

Hematological improvement It assessed before & after the treatment on following parameter

LH:FSH ratio

Testosterone Levels

Subjective Improvement It assessed before & after the treatment on following parameter

Hirsutism- it comes under Sthūla Lomaśa Ganda

Acne Acanthosis Nigricans- no patients with this patients were found.

Grade	Acne Seveity
1	Comodomes only
2	Comodomes and Papules
3	Papule and pastules
0	No Acne

Subjective Improvement (Accoring to Ayurvedic Classic is Kāśyapsamhitā Revati Kalpa adhyāy) assessed before & after the treatment on following parameter

- Sthūla ganda, Lomaśa ganda (hairy & corpulent cheeks.)

2. Ārtavakṣaya (oligomenorrhea)

Grade	Sthūla Lomaśa ganda	Grade	Ārtavakṣaya
1	Mild hair on cheek with no obesity	1	3 pads used with three day scanty menses
2	Mild hair on cheek with signs of obesity	2	2 pads used with two days scanty menses
3	Moderate hair on cheek with signs of obesity	3	1 pad used with single day scanty menses
0	Absence of symptoms	0	4 or more pads used with menses lasting more than 4 days

Observations and Results

General observation and Results

The present study undertaken with 30 subjects. All married female above 20yrs were registered. The female in reproductive age group dominated also the present series dominant with hindu religion. We observed the menstrual pattern of all female are delayed.

Incidence of Age

The incidence of age in this disease worked out in different age group. The highest incidence is the present trial is between (20-25 age group) which (93%). The present series dominated with 20-25 age group.

Incidence of Educational status

The education status categorized into H.S.C, S.S.C and graduate group. The percentage wise incidence of each group is 7(23.3%), 12(40%), 11(36.7%). The present series dominated with S.S.C passed female.

Occupational Incidence

In the present series of subjects the largest numbers of cases registered were from house wife 17(56.7%), service 7(23.3%), teacher 6(20%). house wives had more disease incidence

Pattern of food habits

As is clear from data that the subjects registered for present trial mostly mix 12(40%) and same incidence of vegetarian & Non- vegetarian 30-30% respectively.

Incidence of prakriti

Out of 30 subjects registered for the clinical trial. Out of which 7(23.3%) subjects had kapha- vataj and 11 subjects (36.7%) Pitta- kaphaj, 5(16.7%) subjects have vata-kaphaj and 7 subjects (23.3%) have vata Pittaj Prakriti. In this current series of patients, Pitta- kaphaj Prakriti female Patients mainly showed disease incidence of PCOS.

Incidence of Sarata

While assessing the status of Sarata, it was observed that out of 30 subjects registered for the series Asthi (3.3%), Majja (7.0%), Mamsa(6.7%), Meda(33.3%), Rakta(33.3%), Rasa(6.7%), shukra (6.7%). Medasara and Rakta sara women equally mainly showed the disease incidence of PCOS

Incidence of Agni

While assessing the status of Agni, it was observed that out of 30 subjects registered for the series, 12(40%) Subjects had Mandagni, 13 (43%) Subjects had vishamagni, Teeleshagni 5 (17%). The female having

Mandagni showed more incidence of PCOS.

Incidence of Koshtha

While assessing the status of Koshtha, it was observed that out of 30 subjects registered for the series, 12(40%) Subjects had Mridu, 13 (43%) Subjects had Krura, Mahyama 5 (17%). The female having Krura Koshtha showed more incidence of PCOS.

Clinical trial

As mentioned earlier, Uttarbasti with shalavahadi tail trans cervical route assessed in 30 subjects on various Scientific parameters. The observations made on the effects of the trial drug in trans cervical route in these are summarized below-

Haematological Improvement –

The mean score rate of initial reading of Hb (11.82) was improved statistically after the Uttarbasti with shalavahadi tail (12.34). So there is significant Improvement.

As is clear from the data, mean score rate of ESR of final follow up (15.67) study. Showed significant reduction in ESR in comparison to initial mean score (16.23). So there was improvement in ESR.

Biochemical Changes -

The Biochemical Changes were studied in the form of lipid profiles. It is clear from the data that mean rate score of final follow up study of HDL.

While assessing LDL it was observed significant difference between mean score rate observed significant difference. While assessing VLDL, we observed significant difference between mean score rate of initial (42-23) and after final follow up study (18-23), it was significant improvement.

So it was observed that there is significant improvement in lipid profile.

While assessing the another component of lipid profile, there significant improvement between mean score rate of before treatment (135-33) and after treatment (87-53).

It was observed that the subjects treated with Uttarbasti Śatāvadhī jail shaved significant reduction in BMI (BODY MASS INDEX). The formula calculated by- $\text{Weight} / \text{Height}^2$ (in meters).

It was observed that mean score rate before treatment (26.38) and after treatment (25.76). It was observed that significant difference after final follow-up study.

Pattern of improvement in (H: FSH Ratio) Hormonal Changes-

Harmonal Changes assessed in terms of LH: FSH Ratio. As it is clear from the data there is no significant difference between mean score of LH: FSH Ratio between initial assessment (0.71) follow up study (0.87). So it was observed that there is no significant difference in Hormonal level.

Pattern of Improvement in serum Testosterone

Serum Testosterone- While assessing hormonal changes in term of serum Testosterone. As it is clear from the data, there is significant difference between the mean score rate before treatment (0.69) and after treatment (0.72). There is significant improvement in serum Testosterone level.

Pattern of improvement in Radiological changes

Follicular size :- By using Wilcoxon sign rank test p-value < 0.05 therefore there is significant difference between before treatment and after treatment with respect to follicular size.

Ovarian volume - By using Wilcoxon sign rank test p-value < 0.05 therefore there is significant difference between before treatment and after treatment with respect to ovarian volume

Subjective Improvement-The Subjective Improvement assessed interns of Lomaśa Ganda (Corpulent and hairy cheeks), Ārtakṣaya and Acne

1. Gradation were made like 0, +1,+2,+3
- 0 – Normal or No Improvement
- 1 – Mild (decrease of increase symptoms)
- 2 – Moderate 3- Severe

I used wilcoxon sign for statically analysis of Grading or visual analogue scale. Since we can't calculate the mean in grading pattern (Visual Analogue Scale). So used wilcoxon sign. So there is significant different in hairy & corpulent cheeks.

Pattern of improvement in Artava kshaya

While assessing the improvement in Artava kshaya (oligomenorrhoea) It was observed in this subjective improvement.

By wilcoxon sign tert these is marked improvement in Artakshaya. So it was observed that observed that menstrual. How after final follow up study improved.

Pattern of improvement in Acne

By using Wilcoxon sign rank test p-value < 0.05 therefore there is significant difference between before treatment and after treatment with respect to severity of acne

Pattern of improvement in Acne

By using wilcoxon sign test it was observed that there is significant improvement in Acne after final follow-up study.

Discussion -

The present clinical trial I with trans cervical route by Śatāvḥādi tail aims to undertake clinical study on PCOS (Poly Cystic Ovarian Syndrame) to evaluate its bio- chemical, serological, Hormonal, radiological as well as subjective Improvement as mentioned in Classics.

In Ayurvedic Classics, Uttarbasti is described as Yoni- Gaṛbhāśaya Vikarhar, It should be given after Niruha Basti in each cycle. Niruha Basti with Dashmool Kaṣāya with Niruha Basti vidhi Vidan. In the three cycles of menstruation. This Clinical trial by Trans – cervical route conducted. i.e After 4 days of menstruate on 5th, 6th, 7th day for Niruha Basti followed by 8th, 9th, 10th day uttarbasti with Śatāvḥādi Tail given.

For this clinical trial by trans cervical rate 30 women were registered.

About Patients -

The while considering the incidence of age. The dominance of age group between (20-25 age group) of married female. The probability of primary infertility after marriage in this age group observed. Since in this group of active reproductive, married female seeks treatment. So incidence is more in this age group.

The married female till matriculation dominant in this educational incidence. May be due to low education suggest poor socio-economic status leading to negligence towards health as compared to well-educated women.

The largest numbers of married females were housewives in this clinical trial may be housewives neglect their health due to her daily activities

which in turn lead to Gynecological problem like PCOS.

While considering food habits, mixed food habits females dominated the series as compared vegetarian & non-vegetarian diets.

But generally observation were mainly diet, containing kapha varadhaka āhār and Vāta vridhakar āhārs manifested this diseases in this current series of patients.

Bodily constitution is more important. While assessing the aetiological factors of PCOS (Poly Cystic Ovarian Syndrome) the female married females having obesity dominated the current series. The incidence of kapha-pitta prakriti female were more in this current series. It confirms that kaphapradhan prakriti patient were more prone to develop PCOS. As it is clear from the samprapti of PCOS (Poly Cystic Ovarian Syndrome), Kapha Doṣa is predominantly responsible for the genesis of this disease.

Medasāra married female along with Rakta sārata dominated the series. As it is clear from Ayurvedic classics, Rasasāra female had low incidence since stanya and Ārtava it properly constituted then there no chance of PCOS. Due to medasara female the chance of depletion of further Dhatupoṣaka Bhāva successively towards next, Dhātus Like Shukra-created Shukrakshinata. Which in turn leads to alteration in reproductive System.

Mandāgni female patents dominated the series Mandāgni also affects the Dhatwāgni leads to Bahu and Abaddha Dhātus especially meda which further responsible for the genesis of the disease.

Clinical Trial-

The present clinical trial with trans-cervical route by Śatāvadhādi Tails aims to undertake clinical study on PCOS (Poly Cystic Ovarian Syndrome) on various Scientific Parameters like, Haematological Improvement including Bio- chemical, Serological and Harmonal Assessment, BMI (Body Mass Index), USG (Abdomen and Pelvis) to assess Ovarian Volume and no of follicles and Subjective Improvement like Lomash Ganda (Conpulent hariry cheeks), Artakshya (Oligomenonhe) and Acne.

While assessing its clinical effect, the observations reveal that there significant improvement in Haemoglobin % shatvahadi Tail having uṣṇa, Tikṣṇa, guna breaks the avarodhātmaka Samprapti of this vyādhi which in turns helps to conduct dhātu Poṣaka Bhāva in successive Dhātus.

It was also observed the decrease in ESR values confirming better prognosis of this disease.

While further assessing Haematological Improvement Bio-chemical changes reveal the significant improvement in blood. There is significant reduction in lipid profile. There is reduction in the value of HDL, LDL and VLDL implies that Śatāvadhādi Tail also works like Anuvāsana Basti module. Being Katu Rasa, Uṣṇa Virya and Tikṣṇa guna it corrects Dhatwāgnimandya of Meda Dhātus. Which in turn affects the normal physiological function of Meda Dhātus ad also acts locally to correct obstructions in the channels of Meda Dhātus. It also corrects the triglycerides levels which in turn collectively reducing the weight of patients during 3 months trial. Patients

also suggested dietary restrictions during clinical trial that also affected the values of Lipid profile.

As state earlier Śatāvhādi Tail by trans cervical route mainly has got pharmacodynamic action affinity towards Meda Dhātus.

The observations reveal that there significant reduction in the body weight which affected the values of Body Mass Index. It generally observed obese female in this clinical trial. There was no abrupt and sudden decline of body weight is the range of 1+_ kg only.

While assessing the Hormonal changes, we observed there is no significant difference in LH:FSH Ratio after the clinical trial with Śatāvhādi Tail by trans cervical route. It confirmed that there is no role of Śatāvhād Tail in hormonal Imbalance.

Further assessing the testosterone, we observed minor changes in Serum Testosterone may be due to negative feedback signals to pituitary system due to local effects of Śatāvhādi Tail on cyst rupture and there by decreasing ovarian volume Improvement

While assessing the radiological changes. It was observed that there is statically significant improvement in both the parameters of USG (Ovarian Volume & effect follicular Size). It suggest highly significant local effect of Śatāvhādi Tail due its Uṣṇa Tikṣṇa Guna & It ruptures the Cysts and thereby decreasing ovarian volume Thus showing only local effects on cysts.

In Subjective improvement were observed on some scientific parameters in all the subjects. It was observed that there significant reduction in the hair pattern on cheek in these married female, which suggest the cosmetic

effects of Śatāvhādi Tail. It may be due to decreased level of Serum Testosterone. But not reflected in investigations.

Improvement in another subjective parameter like Ārtavkṣya (oligomenorrhea) was observed in the present series of patients. There is significant improvement in the menstrual flow of the patients alleviating this symptoms Ārtavkṣya. As it is clear from the pharmacodynamic action of Śatāvhādi Tail, it breaks the margāvarodhajanya samprapti of PCOS thereby normalizing the flow of menstruation .

While assessing the last symptoms of Acne, it showed improvement apart the collective effects of reduction in Meda dhatu and Aarodhātmaka samprate. Śatāvhādi Tail also possesses the property of Tikta Rasa which help in Rakta prasādan. Ayurvedic classics, Uttarbasti has some effect like Anuvāsan Basti . Anuvasan Basti has got systemic effect on whole body thereby corrective the samprapti of this disease.

About the Karma:

No services adverse drug reaction where observed during this clinical trial with Śatāvhādi Tail by Trans cervical route since all aseptic precautions were taken during this clinical trial in minor operation theatre

About the Drug:

In Ayurvedic classics, the dose of Uttarbasti, mentioned by Ācārya Caraka is ½ pala which equivalent to 20 ml. But practically it has been used only 5 -7ml, it means only 5ml went in Uterus considering the losses in the infant feeding tube.

But as it was observed that even this minimal dose by Trans cervical route

creates irritation in peritoneum, in case it has not been sterilized properly may create mild symptoms of peritonitis leading to abdominal pain. Since such quantity oozes out from fimbriated end of ovary to the peritoneum.

Conclusion

1. Śatāvḥādi taila Uttar basti as per classics, proven to be effective in PCOS. {Polycystic Ovarian Syndrome.}
2. Śatāvḥādi taila has got no significant effect on hormonal level {LH, FSH} but slight effect on serum testosterone. It may be due to negative feedback to Pituitary System.
3. Thus Śatāvḥādi Taila Uttar basti is effective only on local effect of cysts of ovaries, and also helps in reducing ovarian volume. Uttarbasti with Shavhadi taila has got no serious adverse reactions during the therapy.
4. The standardized quantity of Śatāvḥādi taila Uttarbasti for intra uterine sufflation (Uttar marga) is 5-7 ml.

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Cite this article:

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Ayurline: International Journal of Research In Indian Medicine 2020; 4 (2) :01-11