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A COMPARATIVE STUDY ON UTTARABASTI OF *YAVAKSHARA TAILA* AND *KUMARI TAILA* IN THE MANAGEMENT OF *VANDHYATVA* w.s.r. TUBAL BLOCKAGE

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ABSTRACT
Background: Tubal blockage is one of the most important factors for female infertility. *Uttarabasti* is a unique procedure mentioned in *Ayurvedic* classics especially for the treatment of *Vandhyatva* and other gynecological disorders. **Objectives:** To evaluate the efficacy of *Yavakshara Taila* and *Kumari Taila Uttarabasti* and to compare their effect in tubal blockage. **Materials and Methods: A** Total of 38 Patients of child bearing age with active marital life of one year or more having complaint of failure to conceive with at least one fallopian tube blocked diagnosed by H.S.G.(Hysterosalpingography) were randomly selected and divided in two groups. In Group A, *Yavakshara Taila Uttarabasti* 5 ml each day for 6 days with three days interval after completion of menses for two consecutive cycles and in Group B *Kumari Taila Uttarabasti* was given as mentioned in Group A. The effect of therapy in both the groups on tubal blockage was compared and analyzed statistically with Chi-square ($\chi 2$) test. **Results:** Total 38 patients were registered, out of them 19 patients in each group for the study, with 47.37% unilateral and 52.63% bilateral tubal blockage. Among them 34 patients completed the course of treatment, 16 patients in group A and 18 patients in group B. The tubal blockage was removed in 68.75% of patients in group A and 66.67% of patients in group B. **Conclusions:** The results suggest that *Uttarabasti* is a highly effective procedure for the management of tubal blockage with no apparent evidence of complications. *Yavakshara Taila* and *Kumari Taila*, both are equally effective to achieve the patency of fallopian tubes. With some further researches, *Uttarabasti* can be established as a reliable *Ayurvedic* tool against tubal blockage.

KEYWORDS: HSG (Hysterosalpingography), *Kumari Taila*, Tubal blockage, *Uttarabasti*, *Yavakshara Taila*.

INTRODUCTION
Tubal blockage is the second most common factor responsible for female infertility with a prevalence of 25-35%.[1] It is very difficult to manage, because the treatment choices for it are only tubal reconstructive surgery and In vitro fertilization (IVF).

Both of these, being run in very few infertility clinics in developing countries are not easily accessible. Chances of ectopic pregnancy and other complications are also there. On the other hand, there is not established any reliable *Ayurvedic* treatment for the tubal blockage. The present study was carried out to find out a reliable and data-based *Ayurvedic* management of tubal infertility.

Purpose of the study
To evaluate the efficacy of *Yavakshara Taila* and *Kumari Taila Uttarabasti* and to compare their effect in tubal blockage.

Rationale for the comparison of two groups
Group A: *Yavakshara Taila* as *Anubhuta Yoga* is selected for the study. *Kshara-Taila* is mentioned for *Stree Roga Adhikara* in Bhaishajya Ratnavali.[2] *Kshara Taila* (*Karna Rogadhikar*) is being practiced for Intra Uterine Tubal Blockage in some parts of India for its *Ushna-Tikshna* Property. *Yavakshara* is considered as *Garbhaprada* (fertility creating) and effective in *Artavanasha* (amenorrhoea) in *Ayurvedic* treatises and is indicated for internal administration.[3] Group B: *Kumari taila* is Mentioned for *Vata Kaphaja Shiroroga (*Bhava Prakasha, Madhyama Khanda, Shirorogadhikara*)*.[4] It includes various drugs effective in gynaecological disorders.

MATERIALS AND METHODS
Participants
Patients attending the outpatient department of *Stree Roga* and *Prasuti Tantra*, I. P. G. T. and R. A.,

Jamnagar, fulfilling the criteria for selection were incorporated into the study irrespective of caste, religion etc. A detailed history regarding infertility, family history, obstetric history, menstrual history, past illness and clinical finding pertaining to *Dosha, Dushya, Dushti, Agni, Srotasa* etc. were filled up in specially prepared proforma on *Ayurvedic* guidelines. All the patients were examined per vaginally to assess any sign of infection or disorder related to tubal blockage or infertility. The patient was admitted one day after cessation of menstruation.

Sample size: The present study was carried out in total 38 patients of tubal infertility,19 in each groups.

Selection criteria

Inclusion criteria

Patients of child bearing age with failure to conceive with at least one year of regular and unprotected coitus and patients having primary or secondary infertility with reports of at least one sided tubal blockage in hysterosalpingography (HSG) findings were included for the study.

Exclusion criteria

Patients with any possibility of active urogenital infections and patients with history of excessive menstruation, suffering from any chronic disease, Hepatitis B, STDs, contagious disease etc. were excluded.

Study design: Randomized clinical trial.

Comparator groups: Group A- *Yavakshara Taila* and Group B- *Kumari Taila.*

Details of interventions drugs

Sources: Both drugs were prepared in the pharmacy of Gujarat Ayurved University, Jamnagar.

Dose: 5 ml of each drug for single intrauterine *Uttarabasti.*

Duration: Intra uterine *Uttarabasti* was given for 6 days with the interval of 3 days in between in each cycle. The course of the treatment was for two consecutive cycles.

Statistical analysis: The effect of therapy in both the groups on tubal blockage was compared and analyzed statistically with Chi-square($\chi 2$) test.

Ethical aspects: Study started only after obtaining Ethical clearance from the Institutional Ethics Committee. Ref. PGT/7-A/Ethics/2011-12/2087 (dated 5/9/11)

CTRI Registration number – CTRI/2013/03/003500

Measurement of outcome

Patients were selected on the basis of Hysterosalpingography (HSG) for the least chances of false reports before treatment. HSG was repeated for the analysis of results after the cessation of menstruation in third cycle.

Other investigations

Biochemical screening tests for HIV (Human Immunodeficiency Virus), HBsAg (Australia antigen for hepatitis B) and VDRL (Venereal Disease Research Laboratory) were carried out in all the patients before starting the course of treatment. Trans vaginal sonography was carried out before treatment to rule out any pelvic pathology. Routine haematological investigations, urine were done before and after treatment.

Follow-up study

Follow-up study for pregnancy or any late complication was carried out for two months after the completion of treatment. Any new complaint emerged during follow up period related to study was also noted.

Method of *Uttarabasti*[5]

Purvakarma – *Snehana* of *Bala Taila*[6] on lower abdomen, back and lower limbs and then *Nadi Sveda* with the help of water steam for 15 minutes on lower abdomen and back was done in patients before each *Uttarabasti*. *Yoni Prakshalana* with *Panchavalakala Kvatha*[7] was done as aseptic care of the private part.

***Pradhana Karma* –** The procedure is carried out in the operation theatre. The oil and instruments are autoclaved. Patient is taken on operation table in dorsal lithotomic position. The private part (already shaved) is cleaned with antiseptic solution. Vagina and cervix is visualized with the help of Sim's speculum[8] and anterior vaginal wall retractor[9]. The anterior lip of cervix is caught with the help of Allis' forceps.[10] Uterine sounding is done and then *Uttarabasti* cannula, already attached with 5 ml. syringe filled with medicated oil is passed in uterine cavity after making head low position. The drug is pushed above the level of internal os with constant force, but fast to make the drug reached up to the tubes.

Pashchat Karma – The patient is sent to bed and the bed is kept with head low for 2 hours. The lower abdomen is fomented with hot water bag.

Precautions

The patients were asked to avoid very spicy food during treatment. Coitus was prohibited during the course of *Uttarabasti*. Proper care was taken for not allowing patients to suffer from constipations.

Assessment of complications

As the *Taila* prepared with *Ushna-Tikshna Dravyas* was administered inside the uterus. Possibility of complications cannot be neglected totally. Per vaginal bleeding and lower abdominal pain were the most probable complaints during and after procedure. It was considered as complications, only if the is was very much troublesome for the patient. Features of any type of

urogenital infection during and after procedure was taken as complication.

Endpoints of the treatment

Some points were decided to stop the treatment, if develop during treatment:

- If the patient conceives in between the course of study.
- If signs of any type of urogenital infections are observed.
- If heavy per vaginal bleeding starts.
- If there occurs severe abdominal pain, which troubles the patient much.

DISCUSSION AND RESULTS

The data regarding the status of registered patients brings out that 89.47% patients completed the course of treatment. This data shows that the patients suffering from infertility are generally compliant and until and unless some unavoidable causes are involved, they are tolerant enough to undertake long course of treatment. This reflects that the desire to have a pregnancy is so intense that patients do not mind taking pain and inconvenience in the process of being treated[Table 1]. The description regarding the prevalence of unilateral and bilateral tubal blockage is not available. The main reason behind it can be that the tubal block is thought to be very serious problem, only if is bilateral. It is assumed that if one tube is patent and functioning, it will perform as the channel between peritoneal ovum and sperm. Unilateral blockage is not given importance by modern gynaecologist, and that is why literature regarding its incidence is not available in modern books. Yet unilateral blockage is also important to give due consideration, because, it reduces the possibility of conception. And the condition becomes worse, if another patent tube is not normal physiologically[Graph 1]. It shows the prevalence of both the conditions high in the society. The most prevalent site of blockage was cornual block [Graph 2, 3]. This data supports the already established fact that proximal (cornual) tubal block is the commonest. Proximal tubal occlusion is mostly due to an inflammatory phenomenon, secondary to an ascending sexually transmitted disease, puerperal infection or septic abortion. It may also be associated to salpingitis isthmica nodusa, endometriosis, polyposis, or other rare causes of endosalpingitis.[11] The other tubal anomalies were also observed in the present study [Graph 4]. Analyzing the clinical manifestations during procedure, very few patients complained lower abdominal pain[Table 2]. The pain was within tolerating capacity and no patient complained pain beyond their tolerating limit. The abdominal pain within the tolerating capacity was not considered as complication, because it shows the contractile response of uterus to remove the blockage from the site of obstruction. It was assumed that with the obstruction from the blockage site will be removed with the *Lekhana* (~scraping) property of *Ushna-Tikshna* drugs and also by the contractile response of uterus. The contractile response was confirmed by the lower abdominal pain, which was a common complaint after procedure. No patient had excessive or fresh bleeding. It proves the removal of the inner uterine as well as tubal lining by the *Ushna-Tikshna* and *Lekhana* drugs. The total effect of therapy was very encouraging and highly significant on tubal blockage[Graph 5]. The statistical analysis showed the probability >0.05 and hence, the comparative effect of therapy in both the groups was found insignificant[Table 3]. Thus, it was concluded that *Yavakshara Taila* and *Kumari Taila Uttarabasti*, both are equally effective to remove the blockage in fallopian tubes. Conception rate is also very encouraging in both groups[Table 4]. It shows the potency of the drugs used and also the efficacy of *Uttarabasti*. The conception rate however was found relatively less in the studies but since conception is a multifactorial problem, its comparison as the effect of a particular treatment, seems illogical and unscientific because most of the patients had some other factors responsible for infertility[Table 5 & Graph 6]. For this purpose, a comparative study is needed in the patients with no factor other than tubal blockage, and it is really difficult, as very few patients can be found with only tubal factor. No complication was noted during and after procedure in any patient. The most probable complications of *Uttarabasti*, for which it is misunderstood, are genito-urinary infections and oil embolism. Good surveillance was carried out to diagnose any of such complications as early as possible. But the most encouraging point is that, no feature of such type of infection or oil embolism was observed during or after procedure and even in follow up period. Proper antiseptic care, before and after procedure does not allow any infection to grow. And *Uttarabasti* carried out gently with steady pace and confident skill prevents any complication like oil embolism. No modern antibiotics or any other *Ayurvedic* drugs were given. Still patients did not show any sign of infection. It is because of the potent anti- inflammatory and anti-infective effect of various herbal drugs, *Kshara* and *Tila Taila*. These results are encouraging and prove that, there should not be any unnecessary fear towards *Ayurvedic* procedures because of modern influence.

Interpretation of mode of action of intra uterine Uttarabasti on tubal blockage

While analyzing the effect of *Uttarabasti* on tubal blockage, the highly significant results show the potency of the drugs used and also the efficacy of *Uttarabasti*. It is clear that its action on various disorders is in two ways, local as well as systemic. In case of tubal blockage, this effect seems to be more local than systemic. The *Tila Taila*[12],[13],[14],[15] is *Vranashodhaka* and *Vranapachaka*. It is *Krimighna* too. In addition, its specific role on uterus and reproductive tract is also mentioned as *Garbhashayashodhana* and *Yonishulaprashamana*. These all the properties indicate towards its antiseptic as well as anti-inflammatory actions. Its *Vyavayi* and *Vikasi Guna* show its potency to enter in minute channels and to get spread easily. Thus, it should be the best medium for any drug to reach in tubal

cavity and remove the blockage. In both the groups, the selected drugs were also having the same *Doshaghnata*. *Yava-Kshara*[16] is very good *Vata-Kapha Shamaka* and *Aampachaka* drug. It also has *Gulmanashana* and *Kaphanissaraka Karma*. Any of the *Kshara* is said to be the best for not allowing recurrence. Hence, the *Yava-Kshara* works with its *Tikshna* and *Vata-Kapha Shamaka* properties in removal of blockage. It helps in scraping of obstructing substance and also removes the endometrial lining of tubes and uterus. It removes the fibrosed and damaged endometrium and promotes its rejuvenation. Thus, this management not only removes the blockage, but also creates an environment conducive for inside the intra uterine implantation. The same mode of action can be hypothesized for the *Kumari Taila Uttarabasti*. *Kumari* (Aloe vera) [17],[18],[19] is now well established for its anti-inflammatory, ulcer-healing & antibacterial properties. It is *Tikshna* and *Vata-Kaphavardhaka* in *Karma*. Thus, it removes the fibrosis of endometrium and helps in its rejuvenation. Its Anti-inflammatory action decreases the inflammation and ulcer-healing property heals the inner lining of tubes and uterus. The another important content of *Kumari Taila*, *Bhringaraja* (Eclipta alba)[20] is a very potent *Vata-Kapha Shamaka* drug, which contains antiviral, antibacterial, antioxidant and antihaemorrhagic qualities. All these properties make the medicine more potent in removing the chronic inflammation and fibrosis. Its *Shothahara* and *Vishahara Karma* reduce swelling and oedema of the tube and render it in a healthier atmosphere. Another major content of *Kumari Taila*, *Dhatura* (Datura metel)[21],[22],[23] is *Krimighna*, *Vranahara* and *Vishaghna*. It is known for its anti-inflammatory property and hence, it accelerates the healing and rejuvenation of the inner lining of tubes. All this description expresses the fact that Intra Uterine *Uttarabasti* of *Tila Taila* with *Vata-Kaphaghna* and *Lekhana* properties scrap the inner lining of endometrium. Thus, the inner fibrosed layer is removed. It is rejuvenated later, as endometrium has capacity to regenerate and antioxidant and healing properties of various contents also help it for the same. It is not only the patency of tubal lumen, what is needed for the treatment of tubal infertility.

Normalization of the actions of fallopian tube is also another very important objective of the study. It can be achieved by pacifying the vitiation of *Vata*. *Snigdha Guna* of *Taila* is definitely helpful to relieve the abnormality generated by the *Ruksha*, *Daruna* and *Khara Guna* of *Vata*. It restores the tonic phasic contractions of tube and movement of cilia. It is supported by the results of *Uttarabasti* in study, because no ectopic pregnancy was reported. Another supporting fact is that all these patients conceived within the two months follow up period, most of them in the very next cycle after treatment. Hence, Intrauterine *Uttarabasti* with *Vatashamaka* drugs not only helps to get the patency of tubes, but also restores its normal physiological functions.

OBSERVATIONS

Table 1: Status of Patients

Groups	Group A	Group B	Total
Total Registered	19	19	38
Completed	16	18	34

Table 2: Observations of complications during and after procedure(n=38)

Findings		%
Abdominal pain		23.68%
Severity	Tolerable	23.68%
	Intolerable	-
Duration	< 1 hour	23.68%
	>1 hour	-
Per vaginal bleeding		
Amount	Spotting	7.89%
	More	-
Quality	Fresh blood	-
	Dark blood	2.63%

Table 3: Comparative effect of therapy in both the groups (χ2 test)

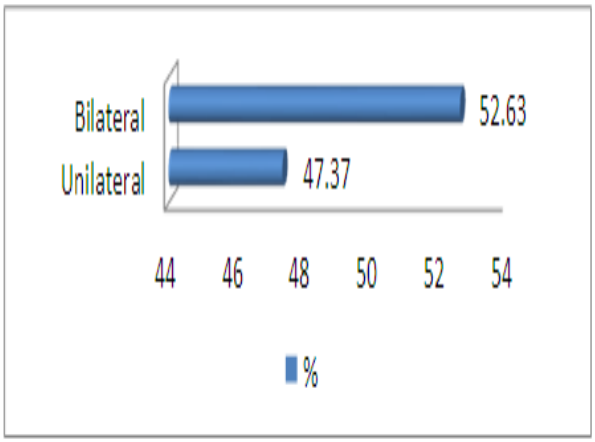
Group	Positive	Negative	χ2	P
A	11	05	0.017	0.45(> 0.05)
B	12	06		

Table 4: Effect of therapy on conception (n=34)

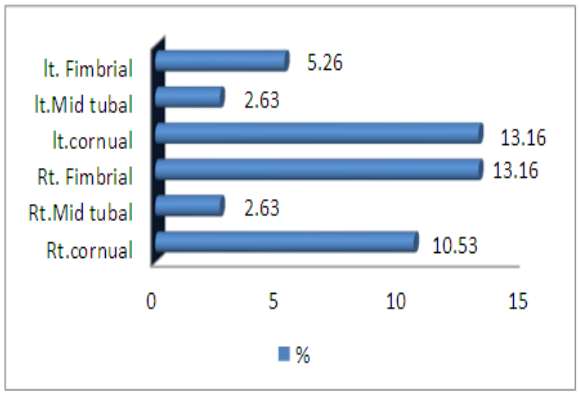
Groups	Group A	Group B
Conceived patients	06.25%	11.11%

Table 5: Patients, who could not conceive within follow up period after block removal

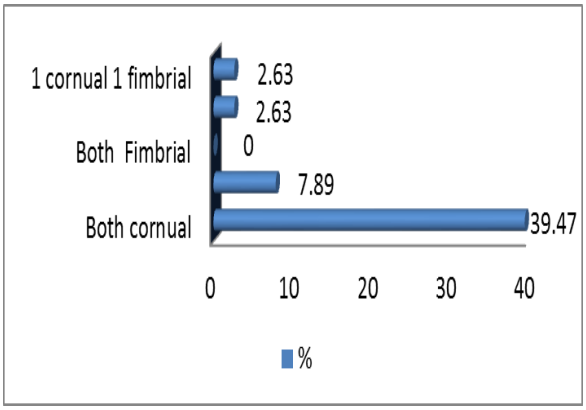
Group	No. of patients in which block was opened but no conception occurred	Patients, in which no other factor could be detected	Patients, in which other factors were involved
Group A	11	04	07
Group B	12	02	10



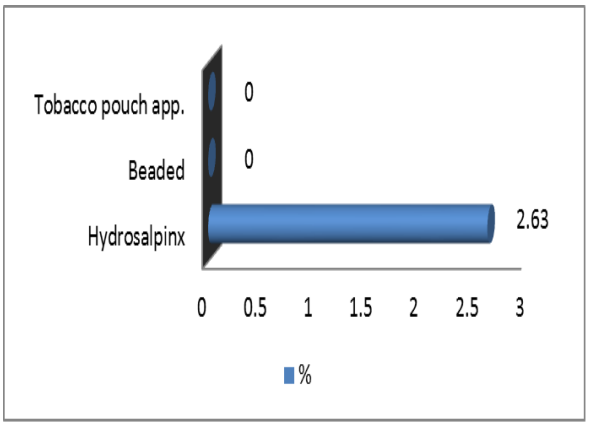
Graph 1: Types of tubal blockage (n=38)



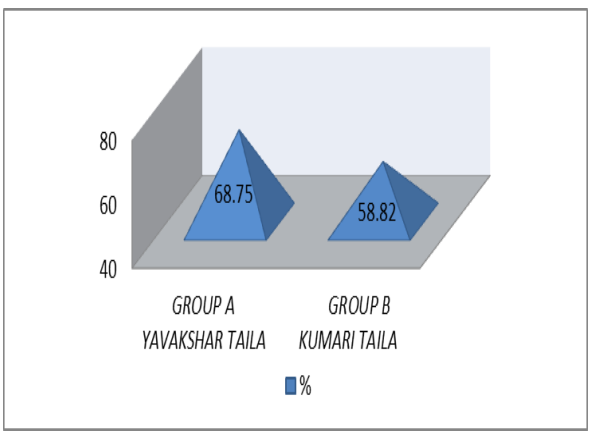
Graph 2: Sites of unilateral blockage (n=38)



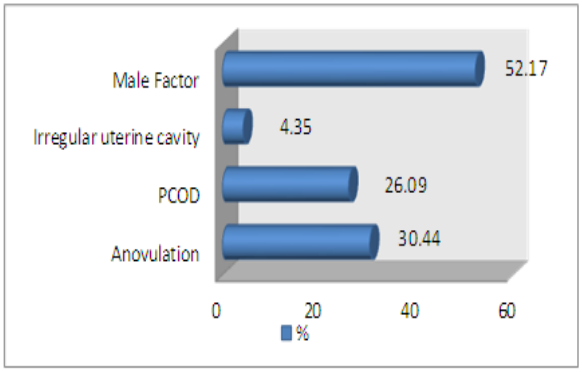
Graph 3: Sites of bilateral blockage (n=38)



Graph 4: Other tubal anomalies in 38 patients



Graph 5: Tube patency after *Uttarabasti* (n=34)



Graph 6- Other factors responsible for infertility (n=23)

CONCLUSION

Uttarabasti is a highly effective procedure for treating tubal blockage with no apparent evidence of complication. *Yavakshara Taila* and *Kumari Taila*, both are equally effective to achieve the patency of fallopian tubes with a highly encouraging rate of conception with *Kumari Taila*. With some further researches, it can be established that *Uttarabasti* is an *Ayurvedic* procedure which has the potential to replace microsurgeries for management of Tubal infertility in near future.

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