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ROLE OF UTTARABASTI OF KUMARI TAILA IN THE MANAGEMENT OF FALLOPIAN TUBAL BLOCKAGE

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ABSTRACT :

Tubal blockage is one of the most essential causative factors for female infertility (*Vandhyatva*). It accounts for about 25-35% of female infertility. It is the need of the era that a secure, more expenditure effectual and absolute therapy of this sensitive problem should be developed. The current study is an attempt to evaluate the efficacy of *Kumari Taila Uttarabasti* in tubal blockage. 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 Hysterosalpingography (HSG) were selected. Total 19 patients were registered from the OPD of *Stree Roga* and *Prasooti Tantra* Department, IPGT & RA, Jamnagar. Among registered patients, 18 patients completed the course of treatment, with 52.63% unilateral and 47.37% bilateral tubal blockage. *Kumari Taila* (5 ml) Intrauterine *Uttarabasti* was given for 6 days (with interval of three days in between), after completion of menses for two consecutive cycles. The tubal patency was found in 66.67% of patients and conception was achieved in 11.11% of patients without any complication. *Uttarabasti* is an imperative and an exclusive *Ayurvedic* procedure stated in classics particularly for the management of *Vandhyatva* and other gynecological disorders. *Kumari Taila Uttarabasti* is a highly effective procedure for treating tubal blockage with no apparent evidence of complication.

Key words: Hysterosalpingography (HSG), Intrauterine *Uttarabasti*, *Kumari Taila*, Tubal blockage, *Vandhyatva*.

INTRODUCTION : Infertility is the failure to conceive (regardless of cause) after one year of unprotected intercourse. It affects approximately 10-15% of reproductive-aged couples. Among the responsible factors of female infertility, tubal blockage is the second highest i.e. 25-35% and one of the most notorious factors and very difficult to treat.[1] The management alternatives for it are only tubal reconstructive surgeries and In vitro fertilization (IVF) and available in a very few infertility clinics in developing countries which are not easily accessible. Probability of ectopic pregnancy and other complications are also there. Previously two works which were carried out on the same topic in the department gave very encouraging results, but in both the studies sample size was small. Hence, it was planned to continue the same study with the aim to further evaluate the efficacy of *Kumari Taila* in tubal blockage in a large sample so that a significant data based treatment regimen for tubal blockage can be established through *Ayurveda*.

MATERIALS AND METHODS: The Patients attending from Out-Patient

Department of *Stree Roga* and *Prasooti Tantra*, IPGT&RA, Jamnagar fulfilling the criteria for selection were included into the study irrespective of caste, religion etc. A special research proforma was prepared.

AIMS AND OBJECTIVES: To evaluate the efficacy of *Kumari Taila* in tubal blockage.

Ethical clearance:

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

Criteria for selection of cases:

Written informed consent of the patients will be taken before including in the study.

INCLUSION CRITERIA:

Patients of child bearing age having complaints of failure to conceive due to tubal blockage were selected for the study, on the diagnostic basis of Hysterosalpingography (HSG) for minimizing the chances of false positive reports were registered for the study.

EXCLUSION CRITERIA: Following patients were excluded from the trial.

- Patients with any possibility of active urogenital infections
- History of excessive menstruation
- Suffering from any chronic disease, Hepatitis B, sexually transmitted diseases, human immunodeficiency virus (HIV), contagious diseases etc.

INVESTIGATIONS:

- Serological 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.
- Transvaginal sonography was done before treatment to rule out any pelvic pathology.
- Routine haematological and urine investigations were done before and after treatment.

Selection of drug: Tubal blockage has been considered as the *Vata* predominant *Tridoshaja* condition, with *Kapha* as being the next *Dosha*, as *Vata* was responsible for *Sankocha*,[2] *Kapha* for *Shopha* and *Puya* while *Pitta* for *Paka*[3]. Thus, all the three *Dosha* are collectively responsible for the stenosis or the hampering type of pathology of the fallopian tubes. The drug assumed as effective to open the fallopian tube was considered to have *Tridoshaghna* properties mainly *Vatakaphashamaka*. Local administration of any drug which containing *Sukshma, Laghu, Sara, Vyavayi, Vikasi, Pramathi Guna, Katu Vipaka* and *Ushna Virya* can be assumed to have some effective role in removing tubal blockage and to restore the tubal functions by reaching up to the minute channels. *Kumari Taila* is mentioned for *Vata Kaphaja Shiroroga*[4]. It includes various drugs effective in gynaecological disorders. Several contents of *Kumari Taila* are highly efficacious and established for their role in menstrual disorders and hormonal imbalance. The drug was prepared in the Pharmacy of Gujarat Ayurved University, Jamnagar and then analyzed pharmaceutically.

Treatment protocol: *Uttarabasti* of *Kumari Taila* (Autoclaved) was given 5ml in each dose for six days with an interval of three days in between[5], in one cycle (after cessation of menses), for two consecutive cycles, with the consent of the patient. *Snehana* (oleation) of *Bala Taila*[6] on the lower abdomen, back and lower limbs followed by *Nadi Sveda*

(fomentation) with water steam was done on the lower abdomen, back and lower limbs to the patients, before each *Uttarabasti*. For sterilization of peri vaginal part *Yoni Prakshalana* (vaginal douche) with *Panchavalkala Kvatha*(decoction)[7] was performed. The procedure was carried out in the operation theater with all antiseptic and aseptic precautions. Patient was made to lie in lithotomy position. External genital region was cleaned with antiseptic solution. Vagina and cervix were visualized with the help of Sim's speculum and anterior vaginal wall retractor. The anterior lip of cervix was held with the help of Allis' forceps. Uterine sounding was done. The *Uttarabasti* cannula, already attached with 5 ml syringe filled with *Kumari taila* was passed in uterine cavity after making head low position. The drug was pushed above the level of internal os with constant and gentle force and then the patient was kept in head low for two hours. The lower abdomen was 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: The chances of complications cannot be ignored totally, because the *Taila* prepared with *Ushna-Tikshna Dravya* was administered inside the uterus. Lower abdominal pain and per vaginal bleeding were the most apparent complaints during and after procedure. It was considered as complication, only if it is was very much irritating for the patient. Any type of features of urogenital infection during and after procedure was considered as complication. Hence, close study was kept to detect complications as early as possible.

Criteria for Assessment: Patients were selected on the basis of Hysterosalpingography (HSG) with the report of unilateral or bilateral tubal blockage. After completion of treatment HSG was repeated for the analysis of results to see the patency of unilateral or bilateral block after the cessation of menstruation in third cycle.

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 appeared during follow up period related to study was also noted.

OBSERVATIONS AND RESULTS:

Total Registered	19
Completed	18
Drop out	01

Table 1: Status of Patients of fallopian tube blockage

Unilateral Tubal Block		No. of Patients	%
Right Tubal		07	36.84
	Cornual	02	10.53
	Mid tubal	01	5.26
	Fimbrial	04	21.05
Left Tubal		03	15.79

	Cornual	02	10.53
	Mid tubal	00	00
	Fimbrial	01	05.26

Table 2: Sites of unilateral blockage (N=19)

Bilateral Tubal Block	No. of Patients	%
Both Cornual	05	26.32
Both mid tubal	02	10.53
Both Fimbrial	00	00
One cornual, other mid tubal	01	5.26
One cornual, other fimbrial	01	5.26

Table 3: Sites of bilateral blockage (N=19)

Sexual History	No. of Patients	%
Satisfactory	17	89.47
Unsatisfactory	02	10.53
Associated problems Dyspareunia	08	42.11

Table 4: Sexual history of patients (N=19)

Observation		No. of Patients	%
Abdominal Pain			
Severity	Tolerable	6	33.33
	Intolerable	0	0
Duration	<1 hour	6	33.33
	>1 hour	0	0
Amount of per vaginal bleeding	Spotting	1	05.56
	More	0	0

Table 5: Observations during and after procedure (N=18)

Case	Type of Block	History of other disease	Chronicity
1st case	Bilateral mid tubal	-	>7 years
2nd case	Bilateral Cornual	History of PID	>7 years
3rd case	Right Fimbrial, Left Cornual	History of PID	>5 years
4th case	Left Fimbrial, Right mid tubal	-	>5 years
5th case	Bilateral mid tubal	History of PID	>5 years
6th case	Bilateral mid tubal	-	>6 years

Table 6: Patients in which block could not be opened

No. of patients	Anovulation	PCOD	Male factor
12	02	03	07

Table 7: Evaluation of other factors of infertility in patients in whom, block was opened but no conception occurred within follow up period of 2 months

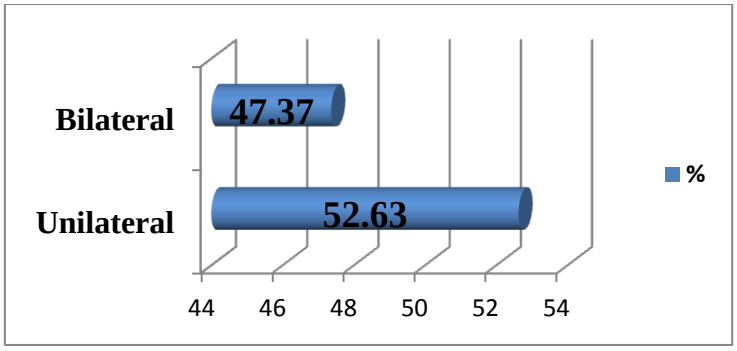

Chart 1: Types of tubal blockage (N=19)

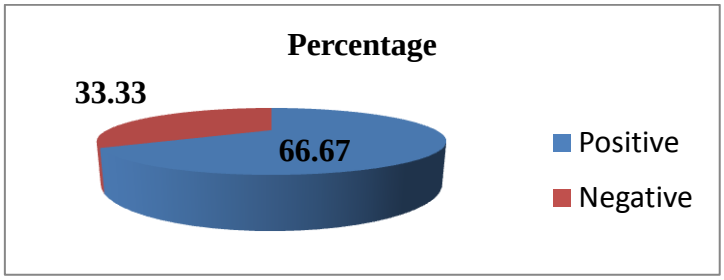

Chart 2: Tube patency after *Uttarabasti* (N=16)

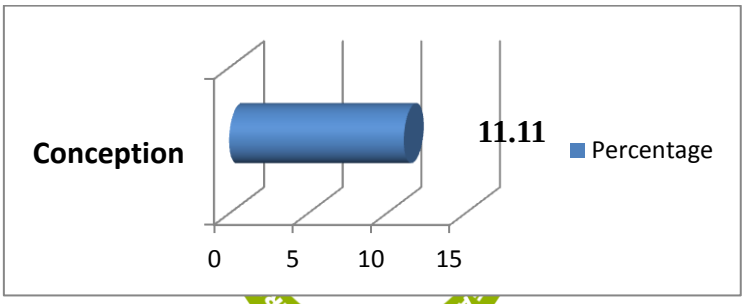

Chart 3: Effect of therapy on conception (N=18)

DISCUSSION: The data regarding the status of registered patients brings out that 94.74% 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]. It has been established that in 47.36% of the cases of tubal blockage, a previous history of pelvic inflammatory disease (PID) has been found, and in 52.63% of the patients, it has not been possible to elicit the history of PID, although it is the most important etiological factor of tubal blockage.[8] There was not much significant difference observed in unilateral and bilateral tubal blockage. The incidence of unilateral and bilateral tubal blockage in the present study shows the prevalence of both the conditions high in the society [Chart 1]. 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. Much authentic data are not available on the incidence of unilateral and bilateral tubal blockage. Hence, it is difficult to co-relate. The most prevalent site of blockage was cornual [Table 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, tubal polyposis, or other rare causes of endosalpingitis.[9] The maximum patients had the history of satisfactory sexual life [Table 4]. Most of the persons, who visit the infertility clinics are intensely longing for a child. Desire for child is mainly the outcome of a normal marital life, which includes a normal and satisfactory sexual life. The complaint of dyspareunia of patients is generally very significant for the patients of infertility and especially tubal blockage. Dyspareunia on penile introduction can be due to vaginal infection or vaginisimus. The cases with any types of reproductive tract infection were already excluded from the study. So, the cases found with the history of superficial dyspareunia might be due to vaginisimus, which is psychological [Table 4]. Analyzing the clinical manifestations during procedure, very few patients complained lower abdominal pain within tolerating capacity, and no patient complained pain beyond their tolerating limit [Table 5]. 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* properties of drug. Symptoms of genitourinary infection and oil embolism were not reported during and after procedure and even in the follow up period in any patient, which is the most probable complication of *Uttarabasti*. It was because of the potent anti-inflammatory and anti-infective effect of *Tila Taila*. It proves the intra uterine *Uttarabasti* as a safe therapeutic measure against tubal blockage. This total effect of therapy was very encouraging and highly significant on tubal blockage. It shows the potency of the drugs used and also the efficacy of *Uttarabasti* [Chart 2-3]. All the patients who could not achieve tubal patency during the study period had chronicity of the disease more than five to seven years. Among them more than 50% of the patients were found to have history of PID [Table 6]. On evaluation of the cases in which the conception did not occur even after the block was removed, it was found that most of the patients had some other potent factor accounting for infertility. The analysis of conception rate is not possible with the data obtained in the present study, because most of the patients who could not conceive were suffering from some other factors [Table 7]. For this purpose, the analysis 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.

Probable mode of action of intra uterine *Uttarabasti* on tubal blockage:

All three *Dosha*s are involved in the pathogenesis of tubal block with predominance of *Vata Dosha*. *Kapha* is also one of the responsible factors for vitiation of *Vata* due to its *Avarodhatmaka Guna*. *Vata* vitiated on its own as well as

by *Kapha* which is able to vitiated *Vata* by its property to cause *Avarodha*. For administration of the drug in tubal blockage, a medium is always required. The medium adapted must not be having any adverse effect in *Samprapti Vighatana* and it would be more appreciable, if it will contain some adjuvant role to open tubal blockage. So, *Tila Taila* was selected for this purpose, as it has most of the qualities, which were required for the present study. Several contents of *Kumari Taila* are highly efficacious and established for their role in menstrual disorders and hormonal imbalance. In case of tubal blockage, effect seems to be more local than systemic. The *Tila Taila*[10],[11],[12],[13] 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. *Kumari* (Aloe vera)[14],[15],[16] is now well established for its anti-inflammatory, ulcer-healing and 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)[17] 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 make it in a healthier atmosphere. Another major content of *Kumari Taila*, *Dhatura* (Datura metel)[18],[19],[20] is *Krimighna*, *Vranahara* and *Vishaghna*. It is known for its anti-inflammatory property and hence, it hastens the healing and rejuvenation of the inner lining of tubes.

CONCLUSION: The results suggest that *Uttarabasti* is a safe and efficacious measure in management of infertility due to tubal blockage. *Kumari Taila* in the form of *Uttarabasti* is a highly effective to achieve the patency of fallopian tubes. Chances of complications are negligible, if proper antiseptic and aseptic care is taken before, during and after the procedure. Conception within follow up period shows high chances of pregnancy, if other factors are normal. Hence, it can be said that *Uttarabasti* may replace microsurgeries for management of Tubal infertility in near future.

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