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The role of *Phalaghrita Uttarbasti* in the management of Infertility w.s.r. Cervical Factor

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ABSTRACT

Vandhyatva (infertility) has been a long standing problem since ancient times. Many herbal and herbo-mineral formulations are mentioned as treatment of infertility in the ancient texts, but they are not categorized according to the responsible factor of infertility. It is need of the hour to evaluate the efficacy of formulations with respect to various factors. With the above aim a clinical study was conducted to evaluate the efficacy of *Phalaghrita Uttarbasti* on cervical factor i.e scanty cervical mucus. For clinical trial total 7 patients were selected for this study. Intracervical *Uttarbasti* of *Phalaghrita* (3 ml) was administered in every sitting for 6 days after end day of menses subsequently for two cycles. Sims-Huhner and Moghissi cervical mucus Test and post coital test were selected for the diagnosis and for evaluation of efficacy of therapy on cervical factor. Statistically highly significant result were found on spinnbarkeit ($p < 0.01$). and significant result were found in amount and viscosity ($p < 0.05$) and insignificant result were found in cellularity, and ferning ($p > 0.1$). Hence, in nutshell it was concluded that *Phalaghrita Uttarbasti* showed good results in all the properties of cervical mucus.

Key words: *Vandhyatva*, *Uttarbasti*, *Phalaghrita*, Cervical factor, Infertility, Pregnancy.

INTRODUCTION

In the present scenario of the rapid advancement in technology, infertility is still a problem that has continued since ages. Many factors are responsible for female infertility, which is Tubal factor - 40%, ovarian factor - 05%, cervical factor - 20% and uterine factor - 10%.

J.M Sims (1868) first identified cervical factor in infertility.^[1] The cervical mucus acts as filter allowing only functioning to penetrate cervical mucus. When

this is hostile and unfavorable it reduces the quality or quantity of sperm, affect sperm viability and ultimately infertility. *Acharya Sushruta* has described the essential factors for conception i.e. *Ritu* (season or ovulatory period), *Kshetra* (field i.e. reproductive organs) and *Ambu* (water i.e. nutritive material and hormones) which are responsible to maintain the pregnancy and defect in either of these factors may result in to infertility.^[2]

Less quantity and poor quality of cervical mucus may be due to inadequate estrogen level or less utilization of estrogen through receptor is the main factor of infertility caused by cervical factor. Proper secretion of cervical mucus is a result and of balanced *Tridosha* (three humors of body) *Prasada Rasa Dhatu* (essence of plasma or nutrients), *Raktadhatu* (blood), *Mamsadhatu* (muscles, tissues) and *Sthanika Agni* (local metabolism at cellular level). According to *Ayurveda*, functions of cervical mucus can be linked with the *Kledana Karma* (moisturizing action) of *Kapha*. *Vata* vitiated due to *Ruksha Guna* (dry property) and *Tikshna Guna* (penetrating or pungent property) is mainly responsible for reduction in cervical mucus. Treatment of *Vandhyatva* (infertility)

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is broadly classified into two groups i.e. *Taila* (oil) treated conditions or *Ghrita* treated conditions. The choice of *Taila* (oil) or *Ghrita* depends on the accompanying *Doshas* with *Vata*. If *Vata* is associated with *Kapha*, *Taila* has to be preferred, while in case of *Pitta* association, *Ghrita* has to be preferred.^[3] Considering this concept, *Phalaghrita* was selected for the present trial. *Uttarbasti* is one type of *Basti* which is best for the disease of female. It tones up reproductive organs and improves the quality of *Ambu* i.e. cervical mucus. Thus by applying proper drug through *Uttarbasti*, disorders of female reproductive tract can be cured. Hence, this study was planned to evaluate the efficacy of *Phalaghrita Uttarbasti* on cervical factor responsible for infertility.

MATERIALS AND METHODS

Selection of Patients

Patients (n=7) suffering from infertility due to cervical factor were registered from O.P.D of Prasuti and Streeroga (Gyneac) Department, IPGT & RA, Jamnagar, irrespective of cast, religion etc. Informed written consent was taken from all the patients. The study was approved by the Institutional ethics committee.

Criteria for diagnosis

Based on Moghissi mucus scale (Cervical mucus test) and Post Coital Test (PCT), for diagnosis of Cervical Factor.^[5]

Criteria for selection of patients

Primary and Secondary both types of infertile patients have been selected for study. Patients having poor cervical mucus, (functional abnormality of Cxmucus) and abnormal PCT were selected for present study.

Exclusion criteria

The patients who had the problems such as anovulatory, structural abnormalities of cervix and blockage of both tubes were excluded.

Investigations

Endometrial Biopsy and Hysterosalpingography investigations were carried out to rule out ovarian and tubal factor of infertility. Routine hematological and urine investigations were carried out to rule out underlying other pathologies.

Criteria for Assessment

The criteria for assessment of treatment are based on Sims - Huhner and Moghissi's score for cervical mucus and Post coital test.

The cervical mucus score is as follows:

Amount

< 0.1 ml	=	0
= 0.1 ml	=	1
= 0.2 ml	=	2
>0.3 ml	=	3

Viscosity

Thick, highly viscous	=	0
Intermediate type	=	1
Mildly viscous	=	2
Thin	=	3

Ferning

No crystallization	=	0
Atypical fern formation	=	1
Primary / Secondary	=	2
Tertiary	=	3

Spinnbarkeit

< 1 cm.	=	0
1 to 4 cm.	=	1
5 to 8 cm.	=	2
>9 cm.	=	3

Cellularity

>11 cells / hpf.	=	0
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6 to 10 cells /hpf.	=	1
1 to 5 cells /hpf.	=	2
0 cells /hpf.	=	3

Density of sperm

Dead / No sperm /hpf.	=	0
2 to 5 sperm / hpf.	=	1
5 to10 sperm / hpf.	=	2
>10 to 15 sperm /hpf.	=	3

Motility of sperm

Immotile	=	0
Insitu motile	=	1
Sluggishly	=	2
Rapid	=	3

Criteria for assessment of Overall Effect of Therapy

Table 1: Showing the total effect of therapy on the basis of percentage relief.

Cured	100% result ,increase in cervical mucus score >10 and conception
Markedly Improved	75% result, increase in cervical mucus score > 10.
Moderately Improved	50% result, increase in cervical mucus score < 5
Improved	25% result, increase in cervical mucus score > 5.
Unchanged	0 % result, No change in the cervicalmucus score after treatment.

Treatment Protocol

Selection of Drugs

Phalaghrita has been selected for drug trial. *Phalaghrita*^[4] was prepared in Department of *Rasa Shastra* and *Bhaishajya Kalpana*, I.P.G.T. & R.A., Jamnagar.

Drugs and Posology

After proper diagnosis, all patients were given *Uttarbasti* of 3ml *Phalaghrita* for 6 days after completion of menses in a month.

Duration of Treatment: 2 months

Follow Up Study

2 month follow up for pregnancy or any late complications carried out after the completion of treatment. Any new complaint appeared during follow up period related to study was also noted.

Observations

Total 7 patients were registered. 6 patients had completed full course and remaining 1 patient left the course incomplete. Maximum no. of patients i.e. 57.14% were of the age group between 24-26 yrs., The distribution of the patients according the duration of their chief complaint shows that a majority of patient i.e. 57.14% had the complaint since 4-6 years, 28.57% of patients had the complaint since 1-3 years and 14.29 % patients had the complaint since more than 9 years.

Distribution of patients according to their associated complaint show that maximum number of patients i.e 42.86% had painful menstruation, 28.57% of patients had scanty menstruation while 14.29% of patients had painful menstruation with scanty menstruation, 14.29% of patients had no complaints.

All the patients (100) had regular menstrual cycle. All the patients showed absence of white discharge and cervical erosion. The 42.86% of patients were *Pitta-Kapha* and also 42.86% of patients were *Vata-Kapha Prakriti*. 85.71% of patients had *Katu Rasa* dominance in their diet.

RESULTS

Based on observations, the data obtained were statistically analyzed in terms of mean, standard deviation, standard error and unpaired 't' test was considered at the level of $p < 0.001$ as highly significant, $p < 0.05$ or $p < 0.01$ as significant and $p > 0.1$ as insignificant to assess the result.

Effect on cervical mucus

The effect of therapy on cervical mucus was found in all the patients. Analysis of the data related to improvement in highly significant ($P < 0.01$) relief in Spinnbarkeit (56.25%), of mucus, Statically

significant result ($P < 0.05$) was obtained on amount (66.67%), viscosity (50%). Statically insignificant result on ($p > 0.1$) ferning, (23.08%) cellularity (-28.57%) i.e. shown in Table 3.

Table 3: Effect of Phalaghrita cervical Uttarbasti on cervical mucous.

Cervical properties	Mean score		Relief %	S.D	S.E	t	P
	B.T	A.T					
Amount	0.67	2.00	66.67	0.82	0.33	4.00	<0.05
Viscosity	1.33	2.67	50	0.82	0.33	4.00	<0.05
Ferning	1.67	2.17	23.08	0.84	0.34	1.46	>0.1
Spinbarkeit	1.17	2.67	56.25	0.84	0.34	4.39	<0.01
Cellularity	1.50	1.17	-28.57	2.66	1.09	-0.31	>0.1

The data pertaining to the effect on PCT revealed statistically insignificant result ($P > 0.1$) on density of sperm (100). On motility of sperm (100%), statistically insignificant result ($P < 0.1$) was observed due to small data of patients. i.e. shown in Table 4.

Table 4: Effect of Phalaghrita cervical Uttarbasti on Sperm Density and Motility

Factor of cervical mucus	Mean score		Relief (%)	S.D.	S.E.	t	'P'
	B.T	A.T					
Density of sperm	00	1.50	100	0.84	0.34	0.34	>0.1
Motility of sperm	00	1.33	100	1.37	0.56	2.39	<0.1

66.67% of patients were markedly improvement and 33.33% of patients were moderately improved,. None of the patients remained unchanged out of the 6 patients i.e. shown in Table 5.

Table 5: Total effect of therapy

Effect of therapy	No. of patients	Percentage
Completely cured	0	00
Markedly improved	4	66.67
Moderately improved	2	33.33
Improved	0	00
Unchanged	0	00

DISCUSSION

As already described that *Ghrita* has *Tridoshaghna Karma* due to its properties and milk is also *Vata Pitta Shamaka, Jivaniya* and *Rasayana*. So, *Phalaghrita* has the properties of *Ghrita*, milk and other ingredients it contains. *Phalaghrita* contains mainly *Tikta, Madhura* and *Katu Rasa, Laghu, Snigdha Guna*, both *Katu* and *Madhura Vipaka* and also *Ushna* and *Sheeta Virya*. It also has *Dipana, Pachana, Anulomana, Shothahara, Krimighna* and *Prajasthapana* properties.

Action of drug on cervical factor

Action of *Phalaghrita* on each characteristic of cervical mucus are as follows;

Amount

Anabolic action of drug increases more secretory units and proper estrogenic effect on cervical epithelium, due to proper function of receptor mechanism thus the cervical mucus increases in amount.

Viscosity and Spinnbarkeit

It decreases *Picchilata* of *Kapha* and increases thinness (fluidity) of mucus due to *Laghu Guna*, the viscosity decrease and hence spinnbarkeit increases.

Cellularity

Pus cells and leucocytes are decreased by anti-infectious properties of drug as well as the debris is

decreased by anabolic properties, thus the mucus becomes clear.

Fern

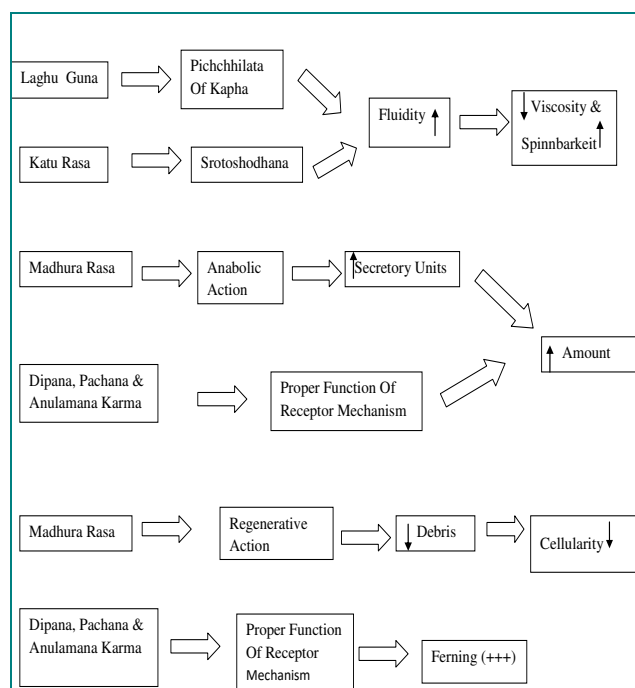
Dipana, Anulomana and *Pachanakarma* does the proper Oestrogenic effect on cervical mucus and results in proper ferning.

pH

Shita and *Snigha Gunas* inhibit the *Ushna* and *Tikshna Gunas* of *Pitta* and decrease acidic mucus.

As per the result, it can be said that increase in amount of cervical mucus and viscosity, ferning, spinbarkeit, Decrease in cellularity was observed due to anabolic effect of *Shatavari*. Increased amount of cervical mucus was observed due to its local regenerative effect on secretory unit of the cervix. The anabolic effect of *Phalaghrita* and *Prajasthapana Yoga* was observed on patients of infertility, which was reported with increment of cervical mucus along with enhanced *Agni*.

Table 1: Shown the diagram of drug action.



CONCLUSION

From the above discussion, it can be concluded that though the percentage of cervical factor (20%) in *Vandhyatva* (10) is less than other factors, but it is as important causative factor due to its adverse effect on sperm penetration. So, for healthy mucus patient

should be taken *Balya, Brumhana* and *Madhura Ahara* and avoid *Ushna, Tikshna Ahara*. They should be remained free from *Krodha, Chinta, Shoka* etc. which have great role to create, abnormalities in almost all causative factors of *Vandhyatva*. Local application of drug (intra cervical) may not be sufficient. There may be need to used oral route with local application The treatment for two months is not sufficient to eradicate the pathological factors. Local application of drug (intra cervical) may not be sufficient. There may be need to used oral route with local application. For healthy mucus patient should be taken *Balya, Brumhaniya* and *Madhura Rasa Pradhana Ahara* and avoid *Ushna Tikshna Ahara*. They should be remained free from *Krodha, Chinta, Bhaya, Shoka* etc. which have great role to create abnormalities in almost all causative factors of *Vandhyatva*. Both the drugs (oral and local) should be prescribed for a longer period or till conception instead of only for two month. So, further study on this subject should be carried out.

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