

Efficacy Of Laghu Malini Vasant In Luteal Phase Defect

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Abstract:

Background: Luteal phase is the period of menstrual cycle which occurs after 16th day of menses. According to Ayurved, it is the rutavyateethakala which starts after 16th day of menses. Hence, as the time period is same, it can be considered that, rutavyateethakala is the luteal phase of menstrual cycle. Any defect in luteal phase can be considered as the defect of rutavyateethakala. The inner most part of garbhashaya (uterus), is called garbhashayya (endometrium). It is filled with minute hair like capillaries which nourishes it and the embryo after fertilization (Vishvamitra). Any defect in it will lead to implantation failure. Georgeanna Jones, first described luteal phase defect (LPD) as the inadequate secretory transformation of endometrium, resulting in deficient progesterone production by corpus luteum causing recurrent habitual abortions and infertility. Till date there is no specific pathology, pathogenesis, definite diagnostic criteria and treatment mentioned by anyone hence, by studying the outcome and the various treatment protocol followed by Modern and Ayurvedic Vaidyas, Laghu Malini Vasant (LMV) was selected for the treatment of LPD and was studied in detail, for its definite action on endometrium and accordingly study was planned.

Methodology: 40 patients were observed, out of which 10 patients selected according to the inclusion criteria. They were given tab. Laghumalini Vasant 250 mg, twice daily at 7 am and 7 pm with honey for three months.

Results: After studying for three months data was collected. It was seen that, there was considerable increase in the endometrial thickness, serum progesterone levels and ovulation occurred. In 50 % patients pregnancy occurred which continued above three months.

Conclusions: According to modern science researches, for implantation Vitamin C, Vitamin K, Vitamin E, Zinc, L-Arginine are needed. LMV contains all these contents necessary for implantation. In this study it was observed that there was improvement in endometrial thickness, serum progesterone and ovulation occurred in most of the patients. Large data is needed to prove this action in detail.

Keywords: Luteal Phase Defect, Laghu Malini Vasant.

I. INTRODUCTION

Ayurveda has given utmost priority to the health of women as she is considered the root cause of progeny i.e. ARYA, hence maximum care should be given to protect her from the disease or condition that affects her motherhood.

The word *Stree*, is derived from *Stru* i.e. *Stravati* means, one who discharges. Woman is called *Stravati* because of monthly *rajastrava* (menstrual discharge). *Rajastrava* is a phase of *Rutu chakra* i.e. menstrual cycle which is the base of female physiology. Normal functioning of the menstrual cycle results in fertilization. The menstrual cycle is divided into

three phases, they are *rutukaala*, *rutavyateethakaala* and *rajah kaala*. They are under the influence of specific doshas. *Rutukaala* (proliferative phase) is under the control of *kaphadosha* which leads to increase in the thickness of endometrium, *Rutavyateethakaala* (secretory phase) is under the control of *pittadosha* which leads to secretory changes in endometrium. *Rajahkaala* (menstrual phase) is under the influence of *vataadosha*, which leads to regressive changes in the endometrium. The essential factors for fertilization are, *Rutu* (proper period for fertilization), *Kshetra* (healthy, nourished endometrium), *Ambu* (proper functioning of hormones) and *Beeja* (healthy sperm and ovum). These are

called *asgarbhasambhav samgri*. They should contribute with each other in most accurate and calculated fashion for fertilization to occur. Any defect in the above said factors can lead to infertility.

Rutukaala, has been given prime importance as per the sequence quoted by *Acharyas*. *Jarayu* is the innermost layer of uterus, is the endometrium as per modern science. (Vd. NirmalaRajwade's interpretation). In this layer, *PrasadRoopa Raja* gets accumulates for implantation. *Jarayu*, i.e. endometrium plays an important role in nidation, implantation and embedment of the fertilized embryo. *Raja* is the *upadhatu* of *Rasadhatu* and *Arthava* is the *upadhatu* of *Rakta dhatu*. *Rasa* and *Raktadhatu* are responsible for the proper nourishment of the embryo after fertilization and provides the essential nutrients to the body and also to the *rasavaha* and *Arthavastrotas*.

Conception is the result of successful fertilization of the sperm and ovum along with normal hormonal supplementation, proper environment for embedment of the fertilized ovum etc. For pregnancy to be achieved all the above factors should be in the state of normal functioning. Abnormalities in these factors results in infertility.

Infertility may be the result of disturbed ovulatory phase of menstrual cycle even in females with regular menses and with no anatomical abnormality. In these females, even if pregnancy occurs there may be impaired ovarian function, inadequate progesterone secretion leading to incompatible intrauterine environment with the cycle phase resulting in increased wastage of pregnancy during the first trimester¹³. Number of social, environmental, medical factors profoundly affects the human reproduction. Among many treatment modules for infertility, Assisted Reproductive Technique (ART), is being more popular now a days. The failure chances of this technique is prominently high and the procedure is also too costly. The cause of failure in ART and in natural conception may be the defect in the correlation between the cellular events occurring in the ovaries and the failure of optimal growth of uterine endometrium during the menstrual cycle. Such a mismatch leads to a non-receptive endometrium which is not conducive for implantation of an embryo. The defect is attributed to the most common endocrine disorder associated with infertility and spontaneous abortion i.e. Luteal Phase Defect.

Rock and Bartlett (1937) were first to suggest that inadequate endometrial response might be associated with infertility, which is due to inadequate progesterone secretion from corpus luteum. Thus, it is quite obvious that abnormal function of the corpus luteum will result in impairment of reproductive performance, deficient output of serum progesterone affecting the endometrial decidual reaction, contractility of uterine muscle and tubal motility. Theoretically, ovum transport, localization of implantation and site of nidation will be affected. Infertility, wastage of pregnancy, either as "silent" or "occult" abortion, when the fertilized egg is shed with the menstrual flow or first trimester abortion results from disturbed correlation between the three aforementioned effects of insufficiency of progesterone.

Vasantkalpas are in use by various *Ayurvedic* practitioners as a *rasayanas* from ancient period in such conditions. *Vasantkalpas* are the *Kharaliya*

Rasayanakalpanas, explained in *Ayurveda*. *Vasant*, symbolizes greenery and reproduction similarly, these *kalpas* works on cellular rejuvenation and acts as *Rasayana* and immune booster. In preparation of these *Rasayanas*, various methods are used which not only alters the potency of the drugs, but are also capable to bring changes in characteristics of drug viz. regulation, addition of new or deletion of undesirable characteristics and make it easier for absorption in body. *Laghumalinivasant* is one of the *vasantkalpas* explained in *Ayurveda*.

Laghumalinivasant with its attributes acts as *rasaphoshak*, *yogavahi*, *deepan*, *pachaaketc.* on *rasavaha* and *raktavaha srotas*. These, are responsible *dhatu* for nourishment of the after *dhatu*s as *perupasnehannyaya*.

Hence, in current scenario, there is necessity to modulate an alternative medical support. If the treatment protocol is planned well by a scientific research we can achieve this goal to a certain limit. So, there is a wide scope of research in *Ayurved* to find a medicine, which is safe and potent remedy to reduce the condition effecting the luteal phase or correcting the *rutavyeetethkaala* and there by correcting the luteal phase defect and resulting in implantation of fertilized Ovum or blastocyte.

AIM: To study the efficacy of *LAGHU MALINI VASANT* in LUTEAL PHASE DEFECT.

OBJECTIVES

- ✓ Conceptualization of Luteal Phase Defect and *Ayurvedic* concept.
- ✓ To study the effect of *LaghuMaliniVasant* on Endometrial Thickness.
- ✓ To study the effect of *LaghuMaliniVasant* on Corpus Luteal Blood Circulation.
- ✓ study the effect of *LaghuMaliniVasant* on Serum Progesterone Level.
- ✓ To study any untowards effect if any.

II. METHODS AND MATERIALS

CONTENTS OF LAGHU MALINI VASANT

- ✓ *Rasakbhasma* - Zinc Carbonate.
- ✓ *Maricha* -Pippernigrumlinn
- ✓ *Navneet* - Butter.
- ✓ *NimbuSwaras* - Citrus limon.

No	Drug name	Latin name and family	Gun a	Rasa	Vipa ka	Veer ya	Dosh agna ta	Rogag nata	Kar ma
1.	<i>Rasa kbhasma</i>	Zinc Carbonate	<i>Lekha, Bhedan</i>	<i>Kashya, Katu</i>	<i>Katu</i>	<i>Sheet</i>	<i>Kapha-Pitta shamak</i>	<i>Pradar, balya, Vajikaran.</i>	<i>Avarodh-nashak.</i>
2.	<i>Maricha</i>	Piper Nigrum. Piperaceae.	<i>Laghu, tikshna.</i>	<i>Katu</i>	<i>Katu</i>	<i>Ushna</i>	<i>Kapha-vatas hamak</i>	<i>Garbh ashaya-sankoc haka, udarshula</i>	<i>Yogavahi, Rasayana</i>

3.	Navneet	Butter	Snigdha, phic hil.	Madhur	Madhur	Sheeta	Kaphavar dhak, vatas ham ak	Grahani, Arsha, Aruch, Arditha.	Agni - vardhak, Hrudya, Mala - sang rahi.
4.	Nimbu	Citrus Limon. Rutaceae.	Guru, Tikshna.	Amla	Amla	Ushna	Kaphavata sha mak	Amlapitta, Jwara, Ajirna.	Agni deepak, Amapachak.

Table 1: Harmacodynamics Of Laghu Malini Vasant

THERMODYNAMIC OF LAGHU MALINI VASANT

- Rasa* : *Katu*.
Veerya : *Katu*.
Vipak : *Sheeta*.
Doshagnata : *Kapha-vatashamak, Pitta vardhak*.
Karma : *Sarva-roghara, Garbhaphoshak*.
Rogagnata : *Jwara, Pradar, Raktaatisaar, Netraroga*
Anupan : *butter and sugar or madhu (honey)*

PHARMACOKINETICS OF LAGHU MALINI VASANT

Laghumalinivasant is having *katu rasa, katuveerya* and *sheetavipaka*.

- ✓ *Katurasa*: It is having *vayu* and *agnimahabhuta* and *laghu, ushna, ruksha, tikshanagunas*. It aggravates *vata-pitta* and alleviates *kaphadosha*. It does *mansalekhana* by its *ushna, teekshna* and *laghugunas*.
- ✓ *Sheetavipaka*: It leads to increase in *kaphadosha*.
- ✓ *Katuveerya*: It has *vayu* and *agnimahabhuta* and *laghu, ushna, ruksha, tikshanagunas*. It aggravates *vata-pitta* and alleviates *kaphadosha*. It does *mansalekhana* by its *ushna, teekshna* and *laghugunas*.

SELECTION OF DRUG/ PROBABLE ACTION OF DRUG

- ✓ Implantation failure or abnormality is due to *kapha vitiation*. *Kapha* plays an important role in nourishment also it has the property of *dharana* i.e. to hold. Hence, vitiation in *kapha* leads to disturbance in this property i.e. holding property is reduced.
- ✓ Vitiated *kaphadosha*, vitiates *vatadosha*.
- ✓ Decreased attributes of *kaphadosha* i.e. decrease in *sthirata, snigdhatata* etc., increases the attributes of *vatadosha* i.e. *chalata, rukshata* etc., hence, it leads to expulsion of fertilized embryo outside uterus.
- ✓ Hence, *kaphavatashamak* and *pitta vardhak*, medicine will help to reduce this vitiation and will help in implantation.
- ✓ *Laghumalinivasant* is *katurasapradhan*. *Katu rasa* is *Agni mahabhutapradhan*, hence *sthanik* and *sarvadehikagni* will be increased also *pitta dosha* will be increased. This will lead to balance of *kapha* and *vatadosha*, which will help in implantation process.
- ✓ *Laghumalinivasant* has *sheetavipak*, which will help to increase *sthanikkaphadosha*, leading to increase in

endometrial nourishment. This will lead to increase endometrial receptivity and correct implantation process.

- ✓ *Rasak* (Zinc) is one of the content of *laghumalinivasant*. According to *Ayurveda*, *rasak* is *shukral, balya, vrushya* i.e. it increases the capacity of ovum for fertilization.
- ✓ *Navneet* (Butter) – it helps for the absorption of *rasakbhasma*. Also, it contains lacto bacillus necessary for absorption of micro nutrients.
- ✓ LMV contains Vitamin C, Zinc, Vitamin A, Thamine, Riboflavin, Niacin and also bio-flavonoids, Vitamin E, Vitamin K, Niacin and Beta-carotene, L-arginine, these are all antioxidants and are necessary for regulation of menstrual cycle and ovarian function.
- ✓ These are also responsible for proper functioning of cytokines and chemokines which are responsible for proper implantation of embryo.
- ✓ Vitamin C significantly increases progesterone level by increasing cholesterol synthesis and thus, improving pregnancy rate.
- ✓ Vitamin E, is found to improve fertility, so it is also called as anti-sterility vitamin. Also, it increases the availability of oxygen to the embryo.
- ✓ Vitamin E and L-Arginine is responsible to increase luteal blood flow.

III. METHODOLOGY

Out of forty subjects, ten subjects selected on fulfilling the criteria for study and their primary data was collected. Detailed history, general examination, obstetric history was taken, USG and laboratory investigations were done prior to the study. The study drug *LaghuMalini Vasant* was given in the dose of 250 mg twice a day with 5ml Honey. Honey was used as *anupana* (vehicle). Follow-up taken on every 15 days i.e. 2nd and 17th day of menses. LMV given from 5th day to 1st day of following menstrual cycle for 3 consecutive cycles and data was recorded.

SELECTION CRITERIA

DIAGNOSTIC CRITERIA

- Luteal Phase Defect was diagnosed on fulfilling minimum two of the following criteria,
- ✓ Thickness of Endometrial – Less than 4-6 mm on 22nd day of menstrual cycle.
 - ✓ Level of Sr. Progesterone less than 11 mcg on 22nd day.
 - ✓ Blood supply to Corpus Luteum after ovulation on 22nd day by Trans Vaginal Sonography.

INCLUSION CRITERIA

- ✓ Age group 18 years to 45 years.
- ✓ History of 2 abortions.
- ✓ Short menstrual cycle i.e. less than 25 days.
- ✓ Married and taking treatment for infertility.
- ✓ Normal follicle study.
- ✓ Unexplained infertility.
- ✓ Normal semen analysis.

- ✓ Normal hysteroscopy with diagnostic laparoscopy showing normal anatomical structure.

EXCLUSION CRITERIA

- ✓ Abnormal structural deformity of reproductive organs.
- ✓ Congenital uterine abnormality, ovarian tumor, tubercular endometriosis, growth or fibroid in genital tract.
- ✓ Any inflammatory pathology of reproductive system.

DISCONTINUE CRITERIA

- ✓ Noncompliance.
- ✓ Voluntary withdrawal.
- ✓ Irregular follow up.

ASSESSMENT CRITERIA

Subjective

- ✓ Menstrual Flow.
- ✓ Rupture of follicles.
- ✓ Blood Flow to Corpus Luteum.

Objective

- ✓ Level of Serum Luteinizing Hormone, FSH, Prolactin, TSH, Progesterone, Testosterone.

A)	Dose	250 mg twice a day.
B)	Form	Vati(Tablet)
C)	Time	Rasayanakala (Morning 6 am and Evening 6 pm on empty stomach)
D)	Anupan	Madhu(Honey) 5 ml
E)	Pathya	Dugdha(Milk 40 ml in 24 hours) and Navneet (Butter 20 grams in 24 hours)
E)	Follow up	After every 15 days i.e. 2 nd day and 17 th day of menses.
F)	Route of Administration	Orally
G)	Duration	From 5 th day of menstrual cycle to 1 st day of following menstrual cycle for 3 consecutive cycles.

Table 2: Treatment Details

IV. OBSERVATIONS

In this study, According to age 60% were 20-25 years, 20% were 26-30 years and 20% were 31-35 years of age group. According to body weight 30% were 40-50 kg, 30% were 51-60 kg, 20 were 61-70 kg and 20 were 71-80 kg. 80% had history of 2 abortions and 20% had 3 abortions. 70% subjects were with *madhyamagni*, 30% with *uttamagni* before treatment. After treatment 20% subjects had *madhyamagni*, 80% subjects had *uttamagni*. 20% were of *vatta-pitta*, 20% of *vatta-kapha*, 10% of *pitta-vatta*, 30% of *pitta-kapha*, 10% of *kapha-vatta* and 10% of *kapha-pitta prakruti* were present.

80% subjects had duration of 21-30 days in between menses and 10% had 41-50 days and 10% had 51-60 days duration. 60% had menstrual flow for 1-4 days and 40% had 5-9 days but with less quantity. 40% subjects had *granthiyukta* (clots) menstrual flow and 60% had *agranthiyukta* menstrual flow. 40% subjects had no pain during menstrual flow and 60% had pain 1+ (feels discomfort). 50% subjects became pregnant and 50% were not pregnant. 80% subjects had regular menses and 20% had irregular menses before treatment. After treatment 90% had regular menses and 10% had irregular menses. 70% subjects had unovulatory cycle, 30% had ovulatory cycles and 0% had cyst, before treatment. After treatment 10% had unovulatory cycle, 70% had ovulatory cycle and 20% had cyst formation. Since the observations were on binary scale observed before and after treatment. McNemar's test was used to test the significance and the P-Value was less than 0.05, hence it was concluded that the effect observed was significant. In all the subjects, serum progesterone values were less than 10 ng/dl before treatment. After treatment, there was increase in serum progesterone in 50% subjects. 60% subjects had endometrial thickness less than 6 mm and 40% had more than 6 mm before treatment. After treatment, the endometrial thickness was increased in most of them.

V. DISCUSSION

20-25 years age group is considered as the most fertile age group. According to *Ayurved*, it is called as *Samatvagataviryakaala* and the pregnancy rate is considered high in this group. But may be due to changing environmental, psychological, social-economic conditions that maximum subjects were from this group. Also, they were from middle class socio-economic status who is mostly under various stress factors like family stress, economical stress, emotional stress etc. Hence, it is the cause of LPD in this group. All the subjects were married and had h/o of previous two abortions. No any hormonal treatment was given to any of them and those subjects who conceived during the study were kept under observation till twelve weeks of gestation and LMV was continued till twelve weeks of gestation. *Ayurveda* quotes, that *Agni* plays an important role in maintenance of health and *mandha-agni* (low digestive power) is causative factor of all diseases. As, *agni* (digestive power) is improved by LMV, *sukshmapachan* (micro-absorption) is also improved and resulted in increase in endometrial thickness. As LMV is *kaphavata shamak* and *pitta vardhaka*, *pitta-kapha*, *pitta-vatta* and *kapha-vatta*, *prakruti* patients conceived by correcting the *doshaavastha* in the endometrium and increasing serum progesterone levels. Scanty menses observed in LPD was corrected as, LMV is effective in nourishing the endometrium hence there, was increase in the thickness of endometrium leading to normal menstrual blood flow, normal interval and regularity of menstrual cycle. Due to *samyavastha* (normalizing) of *vata* and *kaphadosha*, pain and *granthilata* (clots) were absent after treatment. There was qualitatively increase in the quantity in *kapha*, which brought *amyavastha* of *vata* leading to *pitta prakopa* in the ovulatory phase of the menstrual cycle leading to ovulation and normal functioning of corpus luteum by producing serum progesterone. Also,

LMV contains Vitamin C, Vitamin E, L-Arginine, Zinc responsible for normal ovarian functioning and increasing the levels of serum progesterone leading to increase in the thickness of endometrium. As, ovarian functioning, serum progesterone levels and endometrial thickness was corrected, pregnancy was achieved in fifty percent subjects and was continued till twelve weeks of gestation. LMV was continued till twelve weeks of gestation in these subjects.

VI. CONCLUSION

For LPD there is no specific treatment explained till date in Modern science. The essential factors necessary for ovarian function, menstrual regulation and correction of LPD are Vitamin C, Vitamin E, L-Arginine, Zinc, Thamine. Beta carotene. Also, these are important for improving the function of cytokines and chemokines responsible for creating healthy atmosphere in uterus for implantation of embryo. LMV is being used since ancient time by Ayurvedic Vaidyas hence, its chemical composition was studied and was concluded that it contains all these essential factors. Hence, in this study it is proved that LMV is the choice of drug in LPD and implantation failure.

However, more sample size is needed for detail study of LMV to prove its action on LPD.

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Luteal phase deficiency affects women of all races. Sex. Luteal phase deficiency affects only women.Â Boutzios G, Karalaki M, Zapanti E. Common pathophysiological mechanisms involved in luteal phase deficiency and polycystic ovary syndrome. Impact on fertility. Endocrine.Â Luteal phase defects. Reproductive Endocrinology. 4th ed. Laghu Malini Vasant ras is an Ayurvedic medicine in tablet or powder form. It is used in the treatment of chronic fever, menorrhagia, eye disorders etc. This medicine should only be taken under strict medical supervision. Table of Contents.Â Laghu Malini Vasant ras ingredients, how to make: Rasaka Bhasma â€“ Bhasma (Calx) of Zinc Sulphide â€“ 20 g Vallija Nistusha â€“ Maricha â€“ Black pepper â€“ Piper nigrum â€“ 10 g Butter and lemon juice â€“ quantity sufficient. To be ground with butter and Lemon juice till the stickiness is removed from the medicine. Laghu Malini Vasanta Rasa is very effective Ayurvedic formulation for pitta diseases. This is an effective natural remedy for body heat and indicated in health issues where pitta and rakta vitiation is there. This Ayurvedic medicine is useful remedy to manage the chronic fever as well as good to use in intermittent fever as in case of malaria. It is also helpful in dealing with female health related problems. It is able to manage menorrhagia, controls the bleeding and supports the proper flow during mensuration. It also provides relief from the problems in leucorrhea, reduces the excessive vag Luteal phase defect or luteal insufficiency is the deficient release of progesterone all through the luteal phase. The insufficiency of progesterone will not thicken the uterus lining, which can result in improper embryo plantation. Hence, it reduces the chances of a pregnancy continuing. However, it is not yet confirmed if a luteal phase defect is a reason for infertility. A luteal phase defect can lead to the following problems: Improper working of corpus luteum, which results in lesser production of estradiol and progesterone. Incapability of the uterus lining to react to normal levels of e A luteal phase defect is defined as having low or inadequate levels of progesterone during the luteal phase. It is a theoretical cause of infertility and early miscarriage, but thereâ€™s a lot of debate and controversy surrounding the diagnosis. The American Society for Reproductive Medicine's position on luteal phase defects is that the condition does not exist as a standalone cause of infertility. The reasons for the controversy include: Diagnosis difficulties. Research has not found a definitive way to test or confirm a luteal phase defect. Unclear outcomes. A short luteal phase or low p