

PROGESTOGENIC ACTIVITY OF LAGHU MALINI VASANT (AYURVEDIC FORMULATION) IN FIRST TRIMESTER OF PREGNANCY

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ABSTRACT

Background

Researches articulate that solitary role of progesterone in implantation is doubtful but nutrients & enzymes are responsible for implantation and nidation. In this study Laghu Malini Vasant (LMV), containing zinc, cytokines, chemokines, fatty acids, L-arginine is used.

Aim: To study the progestogenic activity of LMV in first trimester of pregnancy.

Methodology: Dose 250 mg, twice a day, with butter 5gm & sugar 500 mg, duration- from 5th to 7th week till 12th weeks, selection criteria- history of two or more first trimester abortions, Objective criteria - Serum progesterone before & after treatment. Supplementary progesterone or HCG was drop out. Follow up kept till labour. Study duration 2017-2019.

Results: Evaluated 52 patients, 18 recruited, 10 patients completed the treatment, 8 dropped out, side effects not observed. Serum progesterone levels were normal, all patients completed 38- 40 weeks with average birth weight 2.79 kg.

Conclusions: It could be concluded that not only progesterone but other factors also play important role in implantation. So LMV proved to be effective prevention of abortion.

Key words: LMV, abortion

INTRODUCTION

Progestogenic activity means activity like progesterone. Previously it was assumed that progesterone plays crucial role in sustaining pregnancy especially in first trimester. But present researches differ in this opinion. They say that other micronutrients, enzymes along with estrogen are also responsible for this activity. So the term is coined as progestogenic activity.

Garbha sthapan, i.e. implantation is very important for continuation of pregnancy. Jarayu (endometrium) which is the innermost layer of the uterus (*Ka. Sh. 3/6*), where Prasad Rup Raja (*Ch. Sh. 4/7*)¹ accumulates for implantation. As per Ayurved Rasa dhatu is responsible for the proper nourishment and providing the essential nutrients to the embryo after fertilization through *upasnehan* (attract moisture) (*Ka. Su. 18/6,7*)² After fertilization garbha (embryo) gets covered by Rakta³. Thus Rasa & Rakta play important role in Garbha sthapan.

All the above factors should be in the state of normal functioning for pregnancy to be continued, if not so, it will lead to miscarriage.

According to modern science also for healthy pregnancy implantation is a major step. Implantation is a very intricate process, which is controlled by a number of complex molecules like cytokines, hormones, and growth factor and their cross talk. The ovarian steroids, progesterone and estrogen have a major regulatory role, in which progesterone is essential for implantation and pregnancy maintenance, if the egg is fertilized, progesterone stimulates the growth of blood vessels that supply the lining of the endometrium and stimulates glands in the endometrium to secrete nutrients that nourish the early embryo.

Lower progesterone is a major cause of recurrent implantation failure and abortion, so progesterone supplementation is one of the remedy for implantation failure in ART, women with first trimester abortion and premature labour. Ample of researches have been done on benefits and side effects of use of progesterone during pregnancy.⁴ Hormonal supplementation prepares an intrauterine atmosphere hormonally challenged for foetus and abnormal hormonal changes during rest of life. So it is essential to find out some alternative medicine in Ayurveda for this condition. One of the solutions can be ante-natal programming with non-hormonal support. Thus, ayurvedic way of designing the foetus can result into healthy pregnancy.

While studying the treatment given by various Ayurvedic vaidyas for recurrent/habitual abortions it was found that *vasant kalpas* are used by them to treat the condition. *Vasant kalpas* are the *Kharaliya Rasayana kalpanas*, explained in Ayurveda. They promote growth of endometrium so that it gets prepared for implantation of embryo if fertilization occurs.

LMV with its attributes acts as rasaphoshak, yogavahi, deepan, pachak on rasavaha and raktavaha srotas. It helps in proper nourishment of foetus during pregnancy. LMV which is rich in Zinc, is used in ante-natal complaints. Present researches concluded, Zinc is an essential component for implantation & stimulating healthy cytokines for nidation⁵. It also acts on uterus and regulates hormonal imbalance which plays important role in endometrial proliferation. *Parthivansh* of LMV provides “*sthiratwa* to the garbha” so miscarriage can be avoided and the will help in foetal growth, implantation and prevent abortion.

Hence, in current scenario, there is necessity to formulate an alternative medical support. If the treatment protocol is planned well by scientific method then can achieve this goal to a certain limit. So, there is a wide scope of research in Ayurveda to find a medicine, which is safe and potent remedy to reduce the chances of abortion in first trimester of pregnancy.

AIM: To study the progestogenic activity of LMV in first trimester of pregnancy.

OBJECTIVES:

- 1) To study the progestogenic activity of drug.
- 2) To study LMV.
- 3) To study the effect of LMV in first trimester of pregnancy.
- 4) To study the effect of LMV on Serum Progesterone Level.
- 5) To study any untoward side effects if any.

MATERIALS AND METHODS

CONTENTS OF LAGHU MALINI VASANT

1. Rasakbhasma i.e. Zinc Carbonate.
2. Maricha i.e. Piper Nigrum.
3. Navneeti.e. Butter.
4. Nimbu Swaras i.e. Citrus limon.

PHARMACOKINETICS OF LAGHU MALINI VASANT

Contens	Latin name and Family	Guna	Rasa	Vipaka	Veerya	Doshagnata	Rogagnata	Karma
Rasak Bhasma	Zinc Carbonate	LekhanBh edan	KashyaK atu	Katu	Sheet	Kapha-Pitta shamak	Pradar, balya, Vajikaran.	Avarodh-nashak.

Shweta Maricha	Piper Nigrum. (Piperaceae)	Laghu, tikshna.	Katu	Katu	Ushna	Kapha-vatashamak	Garbhashaysa nkokhaka, udarshula	Yogavahi, Rasayana.
Navneet	Butter	Snigdha, phichil.	Madhur	Madhur	Sheeta	Kaphavardhakvat ashamak	Grahani, Arsha, Aruchi, Arditha.	Agni- vardhak, Hrudya, Mala-sangrahi.
Nimbu	Citrus Limon. (Rutaceae)	Guru, Tikshna.	Amla	Amla	Ushna	Kaphavata shamak	Amla-pitta, Jwara, Ajirna.	Agnideepak, Amapachak.

PHARMACODYNAMICS OF LAGHU MALINI VASANT⁶

- Implantation failure or abnormality is due to *kapha kshaya*. *Kapha* plays an important role in nourishment as it has the property of *dharana* i.e. to hold.
- *Kapha kshaya, vata vrudhhi*. Decreased attributes of *kapha dosha* i.e. decrease in *sthirata, snigdhatata* etc., increases the attributes of *vata dosha* i.e. *chalata, rukshata* etc., hence, it leads to expulsion of fertilized embryo outside uterus.
- Hence, *kapha vatashamak* and *pitta vardhak*, medicine will help to reduce their vitiation and will help in implantation.
- LMV is *katu rasapradhan*. *Katu rasa* is *agni mahabhuta Pradhan*, hence *sthanik* and *sarvadehik* agni will be increased also *pitta dosha* will be at *samyavastha* by *dhatvagni pachan*. This will lead to balance of *kapha* and *vata dosha*, which will help in implantation process.
- LMV has *sheeta veerya*, which will help to increase *sthanik kaphadosha*, leading to increase in endometrial nourishment. This will to increase endometrial receptivity and correct implantation process.
- *Rasak* one of the content of LMV. According to *Ayurveda*, *rasak* is *shukral, balya, vrushya* i.e. increases the capacity of ovum for fertilization.
- *Navneet* -it helps for the absorption of *rasak bhasma*. Also, it contains lacto bacillus necessary for absorption.

METHODOLOGY:-

- 1) This is an open clinical labeled study.
- 2) Sample size: 10 patients.
- 3) Place: Bharati Ayurveda Hospital, OPD and IPD.
- 4) Consent: written consent as per guidelines in local language was taken from each patient.

TREATMENT DETAILS:

A)	Dose	250 mg twice a day.
B)	Form	Vati (Tablet)
C)	Time	Rasayanakala (Morning 6-7 am and Evening 6-7 pm on empty stomach)
D)	Anupan	Butter(Navneet) 5 gm , 500mg Sugar
E)	Follow up	After every 7-15 days. Subchorionic bleeding – every 7 days Without subchorionic bleed- every 15 days
F)	Route of Administration	Orally
G)	Duration	From 5 th or 7 th week of pregnancy to 12 th week of pregnancy

SELECTION CRITERIA

- **Inclusion criteria:**
 1. Patients from age group 18 years to 45 years.
 2. Patients come up to 7th weeks intrauterine pregnancy with the history of two abortion.
 3. All parity.
- **Exclusion criteria:**
 1. Patient with abnormal structural deformity of reproductive organs.
 2. Patient with abnormal growth in reproductive system.
- **Discontinue criteria:**
 1. Noncompliance of the patient.
 2. If patient has developed untowards side effect then treatment will be discontinued.

ASSESSMENT CRITERIA:

- **Subjective criteria:**

Agni parikshan	Mrudu	Madhyam	Tikshna	
Shabda	Mrudu	Madhyam	Uttam	
Akruti	Sthoola	Madhyam	Krush	
Prakruti	Vatta	Pitta	Kapha	
Mala	Days interval		Consistency	
	Daily	Alternate	Hard	Soft
Mutra	Frequency in day		Frequency in night	
Jeevah	Sam		Niram	
Sparsha	Ruksha		Snigdha	

- **Objective criteria:**

USG

WEEKS	USG
4 th / 5 th / 6 th / 7 th	Yes
8 th	If necessary
9 th	If necessary
10 th	If necessary
11 th	If necessary
12 th	Yes

LAB INVESTIGATIONS:

No.	INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
1	Haemogram	Yes	If necessary
2	BSL(Random)	Yes	If necessary
3	Blood group	Yes	No
4	Serum TSH	Yes	If necessary
5	Serum. Progesterone	Yes	Yes
6	Urine (routine & microscopic)	Yes	If necessary
7	TORCH	Yes	No
8	HIV, HbsAg, VDRL	Yes	No
9	APLA	Yes	No

OBSERVATIONS AND DISCUSSION

In this study the sample size was of 10 patients for final analysis. However the total screened patients were 52, out of which 18 patients were enrolled in the study after they fulfilled all the inclusion criteria for the study. Out of these 18 enrolled patients 8 patients were dropped out of the study due to non-compliance and not willing to continue treatment. Based on the detailed analysis of 10 patients, the observation and discussion is done as follow:

Maximum number of patients in this study was the age group of 20-30yrs i.e 8. This is because most females in our society are married around the age of 20 years and they get pregnant within one or two years (According to National Population survey 2010-2011). Hence most patients enrolled were from the age group of 20-30 years.

In this study group 50% patient recruited were having 6 weeks of pregnancy. Due to the history of previous 2 or more than 2 abortions, the patients and their relatives were more careful & concerned about the wellbeing of the foetus, so patients were come as early as possible for recruitment.

Maximum number of patients 40% had *Vata-Pittaj* prakruti. As pitta has *ushna* and *tikshna* properties, dominance of pitta may act as a contributing factor for recurrent pregnancy loss. The patient's constitution may affect implantation by altering the balance of factors needed for implantation and continuation of pregnancy. First trimester of pregnancy is Kapha dominance state, if Pitta increases or becomes dominant due to reasons like prakruti, ahaar & vihar it can interfere in implantation and growth of early pregnancy. Pitta has *ushna*, *drava*, *tikshna* properties so it can prevent stability of fetus. When the beeja enters in to garbhashaya it is immediately surrounded by rakta (Rakten pariveshtate). If this rakta is vitiated by pitta then it will certainly cause problems with stability.

Anti-phospholipid antibody (APLA) was found to be positive (weakly) in 30% of patients. APLA is associated with recurrent loss of pregnancy.

APLA are categorized as Lupus anticoagulant and anticardiolipin antibody. Their presence indicates some form of auto immune reaction. As pregnancy is allograft (50% genetic material is foreign), sometimes body tries to reject the pregnancy by creating changes like spiral artery thrombosis, placental vascular atherosclerosis, intervillous thrombosis and decidual vasculopathy with necrosis. All these changes can cause either abortion or failure of implantation.

In present study 10% patients were CMV and Rubella Ig G antibody positive, 40% patients were Rubella Ig G positive and 50% patients were found to be TORCH negative.

TORCH category of micro-organisms namely, Toxoplasma gonadii (parasite), Rubella, cytomegalo and herpes (viruses) are sometimes responsible for recurrent pregnancy loss. These organisms cross the placenta and harm the foetus causing recurrent abortions. This means 50% patients had past exposure to embryotoxic viruses in the past. They may have had active infection in previous pregnancies which were resulted in to loss of pregnancy.

In this study before treatment 6 patients had sever nausea, 2 had moderate nausea and 2 had mild nausea & after treatment 7 patients were having mild nausea and 3 had no nausea. As described in drug review LMV has kapha shamak properties, thus effective against the dosha which is responsible for nausea. Thus it can be said that LMV was effective on relief in NAUSEA in first trimester pregnancy

In this study before treatment 6 patients had severe vomiting, 3 had mild vomiting and 1 had moderate vomiting & after treatment 6 patients were having no vomiting and 4 had mild vomiting. As described in drug review LMV has kapha-pitta -shamak properties, i.e effective against the doshas which are responsible for vomiting. So it can be said that LMV was effective in relief on VOMITING in first trimester pregnancy.

In this study before treatment 6 patients had moderate weakness, 4 had mild weakness & after treatment 3 patients were having no weakness and 7 had mild weakness. Being a “Rasayan kalpa”, “Agni-varadhan” and kapha-pitta shamak properties LMV helps in reigniting the digestive fire (agni), thereby reducing nausea and vomiting and inducing good appetite (Agni-deepan). Hence the patients are able to eat better, get better nutrition and thus weakness is reduced. It can be said that LMV was effective on WEAKNESS reduction in first trimester pregnancy.

In this study before treatment 6 patients had mild giddiness, 4 had moderate giddiness & after treatment 9 patients were having no giddiness and 1 had mild giddiness. So it can be said that LMV was effective on GIDDINESS in first trimester pregnancy. This effect can be attributed to the significant improvement in general nutrition and tissue nutrition (dhatvangni deepan, poshan) by LMV.

The mean grade of Serum PROGESTERONE levels before treatment was 20.52 which increased to 24 after treatment. It was found that LMV has caused significant improvement in progesterone levels thus helping in maintenance of early pregnancy and thereby reducing the chances of early pregnancy loss. LMV doesn't contain progesterone but by its rasayan guna it stimulates corpus luteum to secrete adequate progesterone for maintenance of pregnancy.

CONCLUSION

As discussed previously LMV showed significant progestogenic action in this study. LMV is devoid of progesterone, but *Rasak bhasma* i.e. primordial zinc essential mineral for implantation. Lemon juice which is rich source of natural vitamin C, significantly increases progesterone level by increasing cholesterol synthesis, Cow butter contains saturated fatty acids & natural L-Arginine. *Marich (Black paper)* which have vitamin E, having antibacterial and antiviral improved intrauterine atmosphere for nidation. The constituents of LMV regulated cytokines and chemokines by their antioxidant property. Thus LMV proved to be significantly effective in preventing recurrent pregnancy loss.

Attributes like agnivardhak, sukshma pachan of LMV balanced dosha, dhatu & mala leading to garbha stheeratva. LMV improved quality & the functioning of rasa dhatu, thus nourished remaining dhatus which resulted into garbha poshan. Sarata of Rasa & Rakta dhatu improved quality of their upadhatu, raja i.e. endometrium where garbha is getting implanted. LMV is proved to be effective in increasing the thickness and receptivity of endometrium by its content, hence implantation failure can be corrected by its use.

LMV along with its contents, increases micro-circulation which on contrary increase endometrial thickness and serum progesterone levels, hence it can be concluded that, LMV is effective in nidation and sustains first trimester pregnancy.

Apart from its significant progestogenic action in maintenance of pregnancy and prevention of RPL, LMV showed some other beneficial actions too. It helped in reducing nausea, vomiting, giddiness and generalized weakness during first trimester.

There were no untoward side effects of the formulation. Patient did not reported any signs or symptoms of zinc toxicity.

This study was performed on a small sample size of patients. It should be conducted on large scale, to confirm the above mentioned benefits of LMV.

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