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Research Article

CLINICAL STUDY OF CONTRACEPTIVE ACTIVITY OF *TALISPATRA* AND *GAIRIKA*

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ABSTRACT

The world population is increasing much faster. Many socio-economic conditions of people have also been adversely affected. Various side effects have been observed with modern contraceptive methods. In Ayurveda many contraceptive drugs are explained, According to Yoga-Ratnakar "*Talispatra* with *Gairika*" is considered as a potent contraceptive, hence to assess its clinical efficacy, Ovulatory effects, side effects of the formulation and to provide cost effective, safe and effective method of contraception and contribute to national health programme like family planning this study was under taken.

Clinical study was conducted on 30 women, 15 in each group. In group I mixture of *Talispatra* (*Taxus baccate*) & *Gairika* (Red oxide) (10gm) a single dose was administered on 4th day of menstrual cycle with cold water. In group II tab Mala –D daily one administered from 5th day of M. C for 21 days, follicular study was done on 11th day of M. C. in each patient observed for 3 cycles.

In clinical study test drug in group I had shown In Ist, IInd, IIIrd month Dominant Follicle observed in one woman (6. 66%), eight women (53. 33%), twelve woman (80%) respectively and endometrial thickness observed less than 7mm in ten women (66. 6%), 4 women (26. 66%) 3 women (80%) respectively the study drug shown, significant contraceptive activity in I month than II, III month and group II. But side effects were noted only in group II.

Mixture of *Talispatra* & *Gairika* had shown significant contraceptive activity. It is effective, safe, acceptable, less expensive enough to obviate frequent administration & without medical supervision.

KEYWORDS: *Talispatra, Gairika,* Mala-D, Follicullar study, Contraceptive activity.

INTRODUCTION

Today there is pressing need for limiting the family size at a personal level and for the control of population at a national level with the increase in population it is obvious that serious problems loom ahead unless the number of our progeny is controlled[3]. The world population is increasing at much faster rate. Fertility control is very essential for maintaining satisfactory standards of living and for raising the existing standards in developing countries. A method or a system which allows intercourse and yet prevents conception is called a contraceptive method. Contraceptive measures may be used to avoid pregnancy entirely, to space pregnancies or to temporarily postpone pregnancy. [4]Presently available Oral contraceptives like Mala-D, Mala-N, Ovral-L, Novelan may induce weight gain, nausea, headache, CA of Cx, CA of breast, certain neurologic and neuro-opthalmologic syndrome, candida vaginitis, trichomans vaginitis. [5]

Because of all these above side effects the basic expectations of woman are with contraception which is safe, effective, acceptable, less expensive, simple to administer, independent of coitus, long lasting enough to obviate frequent administration and requiring little or no medical supervision. Ayurvedic scholars have used safe, reliable contraceptives since many centuries. As a witness to this Yoga-Ratnakar (17th A. D) has mentioned the combination of *Talispatra* (*Taxus Baccata*) and *Gairika* (Red Oxide) taken in equal quantity and administered in a dose of 1 *Karsha* (10 grams) on 4th day of *Rajakala* (Menustrual cycle) with cold water as *Anupan* (Vehicle). [6]

The clinical study was conducted to assess the contraceptive effects of mixture of *Talispatra* and *Gairika* and to provide a non-toxic, safe oral contraceptive to the main stream of national health programme like family planning. This clinical study was carried out to assess the contraceptive effect of mixture of *Talispatra* and *Gairika* and to provide non toxic, safe oral contraceptive to the main stream of national health programme like family planning.

MATERIALS AND METHODS

Thirty Women from both O. P. D. and I. P. D. of Banale nursing home, Gulbarga were included for the study. Mixture of *Shodhita* (Purified) *Gairika* & *Talispatra churna*, Mala-D, cold water and women (having child and regular menstrual cycle) formed the materials for clinical study. *Shodhan* (Purification) of *Gairika* & *Talispatra churna* were prepared in the practical pharmacy and used for this study.

Sample Size: 30 Women were selected considering the inclusive and exclusive criteria& distributed 15 in each group.

Inclusive Criteria

1. Healthy women having the age between 22 years to 40 years were selected.
2. Women of child bearing age and possessing at least two children and 1-1$^1/_2$ years after second child.
3. The women those who were having regular menstrual cycle.

4. Women not desirous of having further child.
5. Women having a child & voluntarily willing to take the drug, after taking proper consent.

Exclusive Criteria

1. Unhealthy women and age below 22 years & above 40 years.
2. Women suffering from anaemia, T. B., diabetes mellitus, ovarian cyst, fibroid etc.
3. Unmarried, newly married women.
4. Women having secondary amenorrhoea and other gynaecological disorders.
5. Women those having irregular menstrual cycle.

Methods: Clinical study was conducted in 2 groups, each containing 15 Women.

1]. Group I (study group) Administration of mixture of S. *Gairika* (5 grams) + *Talispatra churna* (5 grams) with cold water on the 4th day of menstrual cycle, single dose, for only one cycle. (as per text Ref.)

2]. Group II (standard group) Administration of Mala-D 1 tablet daily from 5th day of menstrual cycle for a period of 3 cycle. (as per drug schedule).

Both groups were observed for 3 consecutive menstrual cycles. A detailed history was noted. Women were asked to come in between 11th to 13th day of menstrual cycle for follicular study for 4 consecutive cycles. Follicular study by Transvaginal Scan was done for 4 consecutive cycles.

Parameters

Follicular study Before T/T After T/T

- 11th to 13th day of menstrual cycle for 3 cycles.

OBSERVATION AND RESULT

Table no. 1 Following table shows change in appearance of the Dominant Follicle after treatment in group I (n=15)

Sl. No.	Month	No. of women in which Dominant Follicle appeared after T/T (%)	No. of women in which Dominant Follicle did not appear after T/T (%)	Statistical test applied	P value
1	First	1 (6. 66%)	14 (93. 32%)	χ2= 16. 607	HS P=0. 000
2	Second	8 (53. 33%)	7 (46. 66%)		
3	Third	12 (80%)	3 (20%)		

Table no. 2 shows change in the Endometrial thickness after treatment in group I (n=15)

Sl. No.	Month	No. of women in which endometrium is less than 7 mm (%)	No. of women in which endometrium is more than 7 mm (%)	Statistical test applied	P value
1	First	10 (66. 66%)	5 (33. 33%)	χ2= 8. 130	HS P=0. 017
2	Second	4 (26. 66%)	11 (73. 33%)		
3	Third	3 (20. 00%)	12 (80. 00%)		

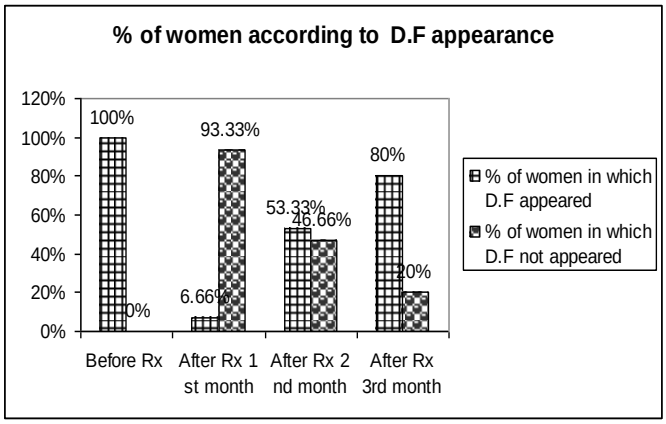
Table no. 3 shows change in the appearance of Dominant Follicle before and after treatment in group II.

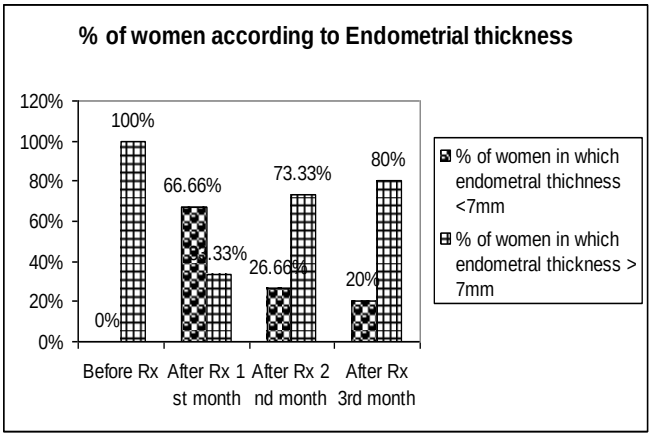
Sl. No.	Appearance of dominant follicle	Before treatment	After treatment		
			1st month	2nd month	3rd month
1	No. of women in which Dominant Follicle appeared	15 (100%)	0 (0%)	0 (0%)	0 (0%)
2	No. of women in which Dominant Follicle not appeared	0 (0%)	15 (100%)	15 (100%)	15 (100%)

Table no. 4 shows change in the Endometrial thickness before and after treatment in group II. (n=15)

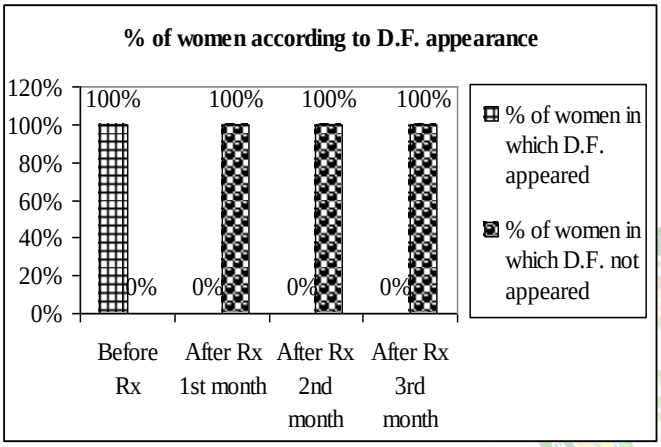
Sl. No.	Endometrial thickness	Before treatment	After treatment		
			1st month	2nd month	3rd month
1	No. of women in which endometrial thickness is less than 7mm	0 (0%)	15 (100%)	15 (100%)	15 (100%)
2	No. of women in which endometrial thickness is more than 7mm	15 (100%)	0 (0%)	0 (0%)	0 (0%)

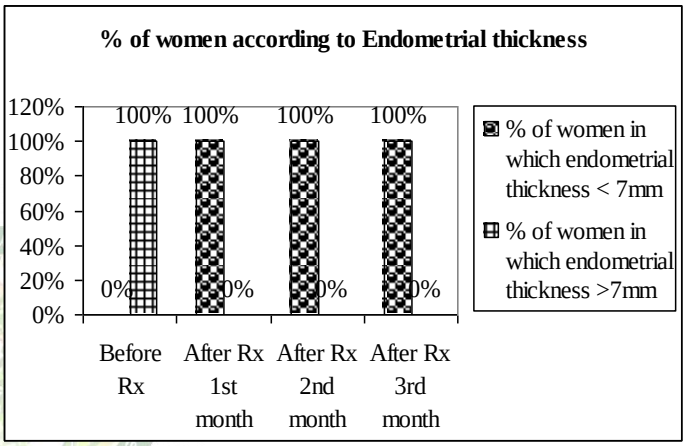
Graph-change in the appearance Graph-Change in the Endometrical of Dominant Follicle before and after thickness before and after treatment (Rx) in group I. (n=15) treatment (Rx) in group I (n=15)





Graph -Change in the appearance of Graph - Change in the Endometrial Dominant Follicle before and after thickness before and after treatment (Rx) treatment (Rx) in group I (n=15) in group II. (n=15)





DISCUSSION

The combination of *Shodhita Gairika* and *Talispatra* churna was administered with cold water on the 4th day of menstrual cycle acts as a contraceptive, has been explained in Yoga-Ratnakar. Hence an attempt was made in this clinical study to assess the contraceptive effect of the formulation. 30 women were selected considering inclusive and exclusive criteria during the period from June 2007 to August 2008. Detail history, clinical examination of the women was conducted. All the women were asked to come on 11th-13th day of menstrual cycle before the administration of drug for follicular study by Transvaginal Scan (TVS) for confirmation of Ovulatory cycles & to rule out pathological disorders in group I, mixture of *Talispatra* and *Gairika* (10 gm) administered on 4th day of menstrual cycle with cold water single dose in one cycle only. In group II, 15 women were selected and Mala-D one tablet daily administered from 5th day of menstrual cycle 21 days for 3 cycles and asked them to come on 11th -13th day of menstrual cycle for follicular study by Transvaginal scan for 3 cycles.

In Group I: Before the drug administration it was noted by transvaginal scan that 15 women had dominant follicle and endometrium thickness was more than 7mm. Then mixture of *Talispatra* and *Gairika* (10gm) was administered on 4th day of menstrual cycle, single dose and observed for 3 consecutive menstrual cycles without administration of this test drug or any other contraceptive drug.

After the drug administration on 4th day of menstrual cycle, 11th day the reports of tranvaginal scan in 1st month it was noted that 14 women had no Dominant Follicle but in only one woman Dominant Follicle was observed. In 10 women endometrial hypoplasia was noted. No any other problems with their menses and other complications were noted.

Then again all the women were asked to come on 11th – 13th day of menstrual cycle in second month without taking any contraceptive medicine and Follicular study was done by Transvaginal scan. In second month out of 15 women Dominant Follicle appeared in 8 women and DF not appeared in 7 women and endometrial hypoplasia was noted in 4 women. None of the women had menstrual problem or any other complication.

Then again all the women were asked to come on 11th-13th day of menstrual cycle in third month without taking any contraceptive medicine. Follicular study was done by TVS. In 3 women no Dominant Follicle but 12 women had Dominant Follicle. In 12 women endometrial thickness was increased but in 3 women endometrial thickness was <7mm.

Statistical analysis was carried out by applying $\chi 2$ test which shows $\chi 2 = 16.607$ for Dominant Follicle

appearance and $\chi 2$ = 8. 130 for endometrial thickness. P values were calculated, which revealed p=0. 000 for Dominant Follicle and p= 0. 0017 for endometrial thickness which is highly significant.

In Group II : Before the drug administration it was noted by transvaginal scan that 15 women had dominant follicle and endometrium thickness was more than 7mm. Then tablet Mala-D daily one was administered from 5th day of menstrual cycle, for 21 days for 3 menstrual cycles (every month) and observed for 3 consecutive cycle (with drug).

After the drug administration Transvaginal scan done on 11th day of menstrual cycle in 1st, 2nd & 3rd months respectively. It was observed in follicular study by TVS that none of them had Dominant Follicle and endometrial thickness was not favorable for conception. It is expected with regular drug administration, once the drug is stopped the result will be like before treatment.

No any side effects were noted in study group I, while in standard group II some women had complaints of gastric irritation, burning chest and nausea etc.

As for as the probable mechanism of the action is concerned, *Talispatra* is having antiovulatory, anti-implantation activity as well as it is uterine contractor. Antiovulatory activity is achieved may be due to the inhibition of ovulation and by producing endometrial hypoplasia. Inhibition of ovulation by preventing the release of ovum from ovary may achieved by blocking the pituitary secretion of gonadotropin which is necessary for ovulation. Oestrogen is necessary for maturation of follicle, the drug may be having anti-oestrogenic activity, it may act as an anti-oestrogenic by:- 1) Inhibition of oestrogen synthesis. 2) Due to Blockage of receptor binding.

Thus the release of gonadotropin releasing hormones from the hypothalamus may be prevented through the negative feedback mechanism, so there may be no sufficient release of FSH and LH from the anterior pituitary thus follicular growth may be inhibited. This activity may also disturb the estrogen androgen ratio. Collectively it may result into inhibition of maturation of follicle. In experimental study also histological study slides indicated suppressed of the maturation of graffian follicle, [7] it may also provide the sound base for assessment of its anti-Ovulatory activity.

The study shows endometrial hypoplasia takes place, due to its anti-progestional activity. In experimental study it was proved that *Talispatra* & *Gairika* had anti-implantation activity[7], due to its anti progestinal activity. May be drug makes both the hormones to act synergistically on hypothalamo-pituitary axis, thus follicular growth may not initiated or if initiated recruitment does not occur. In this way inhibition of ovulation takes place.

Garbhashayasankocha takes place due to *Tiktapradhana* (Bitter, dominant) rasa of *Talispatra* and *Kashaya rasa* (astringent) of mixture of *Talispatra* and *Gairika*. This property of *Sankocha* (Contraction) may contribute more if taken with cold water. *Gairika* with *Talispatra* has demonstrated (Synergistic effect) 100% anti-implantation activity in albino rats. Based on this clinical study was undertaken[7].

Gairika is red oxide of Iron, chemically the mineral is Fe_2O_3 corresponding to Fe 70% and Oxygen 30%. Iron is necessary for regulation of body temperature. It may prevent the increase of body temperature, necessary for ovulation and contributing in the anti-ovulatory activity along with *Talispatra*.

So due to its combined effect of anti-ovulatory, anti-implantation, uterine contractor it may acts as a contraceptive. Mixture of *Talispatra* and *Gairika* (10gm) shown significant contraceptive activity.

In the study it was observed that after administration of single dose anti-ovulatory effects were reversed gradually in II & III month indicating induction of functional sterility. So the drug may act as temporary contraceptive only not as permanent contraceptive.

All modern oral contraceptive drugs are suppose to consume daily for 21 days and recent some drugs are introduced twice in a week. But this Ayurvedic formulation can be consumed only once in a month gives significant contraceptive activity than modern drugs without any side effects.

CONCLUSION

30 women formed the study population. 15 women were administered mixture of *Talispatra* & *Gairika* with cold water on 4th day of menstrual cycle in group I. 15 women were administered Tab. Mala-D at night daily from 5th day of menstrual cycle in Group II. All the women were observed for a period of 3 cycles. Before the administration follicular study was done by transvaginal scan in group I & II. All women had dominant follicle and endometrial thickness was more than 7mm. Transvaginal scan was done on 11th – 13th day for 3 consecutive menstrual cycles.

In 1st month it was noted that in only one woman had Dominant Follicle But she had regular menstrual cycle. and 10 women had endometrial hypoplasia (less than 7mm). In 2nd month in 7 women had Dominant Follicle & in 4 women had endometrial hypoplasia but all women had regular menstrual cycle.

In 3rd month 4 women had Dominant Follicle & in 3 women had endometrial hypoplasia, but they had regular menstrual cycle. In 20% women Dominant Follicle was not observed but endometrial hypoplasia was observed. Thus the study drug had shown significant contraceptive activity.

At the 1st cycle 93. 33% & at the end of study in group I, 20% women had no Dominant Follicle & endometrial thickness was <7mm. In group I & II all the women had regular menstrual cycle indicating its contraceptive activity. Single dose of this Ayurvedic formulation shown significant contraceptive activity than modern contraceptive without any side effects, but gastritis, nausea, burning chest were noted in group II. The mixture of *Talispatra* with *Gairika* shown significant contraceptive activity and may contribute to the main stream of national health programme like family planning.

Due to its single dose the risk of forgetting pills leading to undesirable pregnancies was avoided. It does not require medical supervision and checkup. No any allergic manifestation appeared during study. During study

Dominant Follicle appeared in few women in 2nd and 3rd months indicating return of fertility, so it acts as a reversible and temporary method of contraception. The study drug is much cost effective, safe and effective method of contraception. It is a drug of choice for women who cannot tolerate oral pills, Intra-uterine devices and afraid of surgical aid. All modern oral contraceptive drugs are suppose to consume daily for 21 days and recent some drugs are introduced twice in a week. But this Ayurvedic formulation can be consumed only once in a month gives significant contraceptive activity than modern drugs without any side effect

Scope for study

- This study has given scope for a long period of drug administration on larger population to get still more clinical data.
- This clinical study has given scope to think still more on new parameters like hormonal assay to prove its clinical efficacy, safety after longer period of drug administration.

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