

CLINICAL STUDY TO EVALUATE THE EFFICACY OF *KASHMARYADI GHRITIN VANDHYATWA* W.S.R. TO FEMALE INFERTILITY

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ABSTRACT

Motherhood is a boon to a women's existence. This blessing from God is being interfered by the fast paced life-style of modern world affecting the female health adversely. As a result, infertility has been observed as an emerging health issue. Infertility is defined as failure to conceive within one or more years of regular unprotected coitus. Women who are able to conceive but then have repeated miscarriages are also said to be infertile. In present era *Vandhyatwa* has been one of the major clinical challenge which is yet to be resolved. *Ayurveda* may give a promising hand to cure this disease. So to find effective treatment of *Vandhyatwa*, without any side effect, *Kashmaryadi ghrif* oral treatment was selected. 15 patients were selected randomly for present clinical trial study. Highly significant results are observed in follicular study, Very significant results are shown on fern test and spinnbarkeit test. Based on the observations it can be concluded that *Kashmaryadi ghrif* is an effective drug for the management of female infertility.

Keywords: *Vandhyatwa*, *Kashmaryadi ghrif*

INTRODUCTION

Infertility is defined as a failure to conceive within one or more years of regular unprotected coitus. Primary infertility denotes those patients who have never conceived. Secondary infertility indicates previous pregnancy but failure to conceive subsequently¹. Infertility does not threaten physical health but has a strong impact on psychological and social well-being of the couples. Hence, infertility is of public health importance, especially in developing countries because of its high prevalence and its serious psychological, financial and social implications.

Conception depends on the fertility potential of both the male and female partner. The male is directly responsible in about 30-40%, the female in about 40-55% and both are responsible in about 10% cases. The remaining 10% is unexplained in spite of thorough investigations with modern technical knowhow.¹

In *Ayurveda* infertility is termed as '*Vandhyatwa*' According to *Acharya Susruta*, four main factors required for the proper conception are:²

1. *Ritu* (Fertile period)

2. *Kshetra* (Healthy uterus)
3. *Ambu* (Proper nutrient fluid)
4. *Beeja* (Viable ovum & sperm)

Presence of any abnormality in any of the above said factors causes Infertility.

In modern science causes are-³

1. Male-25 %
2. Ovulatory— 27 %
3. Tubal/Uterine—22%
4. Other—9%
5. Unexplained-17%

Nowadays acceptability of *Ayurveda* as mode of therapy and treatment for infertility is increasing and people endorsed their faith in this branch of medicine, which occupies its prominence in the naturally available herbs. *Ayurveda* may give a promising hand to cure this disease. As the subject matter discussed in *Ayurveda*, it becomes necessary to study, understand and prove them particularly in light of modern scientific parameters in the present era.

AIMS AND OBJECTIVES: To evaluate the effect of *Kashmaryadi Ghrit* orally in female infertility in order to search for a safe, affordable and non-surgical treatment for female infertility.

MATERIAL AND METHODS:

Selection of the patients- Total 17 clinically diagnosed patients of infertility from OPD & IPD of NIA, Jaipur were selected for the present clinical trial and informed consent was obtained. Out of which 15 patients completed the course of treatment.

Method of research: The method adopted in present study was open randomized clinical trial.

Drug: The drug *Kashmaryadi Ghrit* for the present study has been selected from *Charak samhita chikitsa sthan* 30/52-53 and it was prepared according to classical reference in the Pharmacy of National Institute of *Ayurveda*, Jaipur.

Criteria for selection of patients

Inclusion criteria:

1. All primary & secondary cases of infertility.
2. Age group between 20 to 40 years.
3. Male counterpart should be normal in all aspects.

4. Infertility due to PCOD.
5. Infertility due to cervical factors.
6. One fallopian tube must be patent.

Exclusion criteria:

1. Surgical factors including fibroid uterus, cervical polyp, cervical stenosis etc.
2. Congenital anatomical defect.
3. Patient suffering from severe infection or chronic systemic diseases.
4. Infertility due to tubal factors (if both tubes are blocked).
5. Infertility due to peritoneal factors.

Withdrawal criteria:

1. During the course of trial if any serious conditions or serious adverse effect develops which requires urgent treatment.
2. Patient herself wants to withdraw from the clinical trial.
3. Irregular follow up.

Criteria for diagnosis

Investigations: Before treatment-

- Medical history & physical examination
- Pelvic Examination to look for abnormalities or infections
- Blood test- Hb %, TLC, DLC, ESR, HIV, HBsAg, VDRL, RBS, T3, T4, TSH
- Montoux test (if needed)
- Urine test -Routine & Microscopic
- Cervical mucus (1) Spinnbarkeit (2) Fern Test
- Post coital test
- USG-Uterus & Adnexa
- HSG
- Antisperm & Antibody Test (if needed)
- Pap smear- if needed.
- Follicular study (if possible)
- Hormone assay- FSH, LH, Progesterone, Prolactin (If possible)

After treatment-

- Follicular study
- Cervical mucus – Fern test, Spinnbarkeit Test
- Urine pregnancy detection test.(After 7days of missed period)
- USG- To confirm pregnancy

Table 1: Ingredients of *Kashmaryadi Ghrit*⁴:

Drug name	Latin name	Parts used
<i>Gambhari</i>	<i>Gmelina arborea</i> Roxb	Fruit
<i>Haritaki</i>	<i>Terminalia Chebula</i> Retz.	Fruit
<i>Bibhitak</i>	<i>Terminalia bellirica</i> Roxb.	Fruit
<i>Amalaki</i>	<i>Emblica officinalis</i> Gaertn.	Fruit
<i>Draksha</i>	<i>Vitis vinifera</i> Linn	Fruit
<i>Kasmard</i>	<i>Cassia occidentalis</i> Linn	Fruit
<i>Parusak</i>	<i>Grewia asiatica</i> Linn	Fruit
<i>Punarnava</i>	<i>Boerhavia diffusa</i> Linn	Mula (Root)
<i>Haridra</i>	<i>Curcuma longa</i> Linn	Kand
<i>Daru haridra</i>	<i>Berberis aristata</i> DC	Mula
<i>Kaknaasa</i>	<i>Asclepias curassavica</i> Linn	Mula
<i>Sahachar</i>	<i>Barleria prionitis</i> Linn	Patra(Leaf)
<i>Shatavari</i>	<i>Asparagus racemosus</i> Willd.	Kand
<i>Guduchi</i>	<i>Tinospora cordifolia</i> Willd.	Kaand
<i>Goghrit</i>		

Table 2: Administration of drug-

DRUG	<i>Kashmaryadi ghrit</i>
DOSE	5 ml twice a day with hot milk (200 ml)
ROUTE	Oral
DURATION	3months

Follow up study – Follow up was done after each cycle during trial & up to two months after the completion of trial.

Overall effect of treatment-The score of individual symptoms were obtained before and after treatment. The total effect of therapy was assessed accordingly in terms of-

- Conception.
- Increased in size of ovarian follicle
- Improvement in the character of cervical mucus
- Improvement in menstrual parameters
- Unchanged

Criteria of assessment-The improvement in the parameters were assessed mainly on the basis of relief in the signs and symptoms of the disease. To assess the effect of therapy all the signs and symp-

toms were scored depending upon their severity. Scored as following grading's- 0,1,2,3.

Statistical analysis- Various observations made and results obtained were computed statistically using Wilcoxon matched-pairs signed-ranks test, Paired 't'test for conception to find out the significance of the values obtained and various conclusions were drawn accordingly. All the Results calculated by using Online InStatGraphPad software.

P value

- $P > 0.05$ - Not significant or not quite significant
- $P < 0.05$ – Significant
- $P < 0.01$ - Very significant
- $P < 0.001$ – Highly significant

RESULTS-

Table 3: Effect of therapy on Subjective parameters--

S.N.	Parameter	N	Mean		Mean Diff.	%	S.D. (±)	S.E. (±)	‘W’	P	Result
			BT	AT							
1	Amount of menses	15	0.533	0.266	0.266	49.9	0.704	0.182	3	>0.05	N.S.
2	Interval of menses	15	0.467	0.067	0.400	85.65	0.507	0.131	21	<0.05	S
3	Duration of menses	15	0.600	0.066	0.533	88.83	0.915	0.236	10	> 0.05	N.S.
4	Dysmenorrhoea	15	0.933	0.266	0.666	71.38	0.48	0.12	55	< 0.01	V.S.
5	Dyspareunia	15	0.666	0.200	0.466	69.96	0.639	0.165	21	< 0.05	S

Very significant results are shown in Dysmenorrhoea. Significant results are observed in Interval of menses and Dyspareunia.

Table 4: Effect of therapy on Objective parameters-

S.N.	Parameter	N	Mean		Mean Diff.	%	S.D. (±)	S.E. (±)	‘W’	P	Result
			BT	AT							
1	Follicular study	15	1.867	0.933	0.933	49.97	0.704	0.18	66	≤0.001	HS
2	Endometrial thickness	15	1.000	0.467	0.533	53.30	0.74	0.19	21	<0.05	S
3	Fern test	15	2.133	0.933	1.200	56.25	1.474	0.385	56	<0.01	VS
4	Spinnbarkeit test	15	1.267	0.600	0.667	52.64	0.617	0.159	45	<0.01	VS
5	Post coital test	15	0.266	0.200	0.066	24.81	0.258	0.066	1	> 0.05	NS

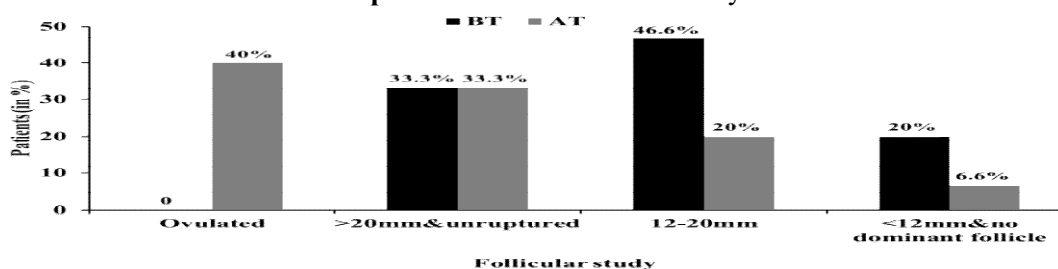
Highly significant results are observed in follicular study. Very significant results are shown in Fern test and SB test. Significant results are shown on endometrial thickness.

Table 5: Effect of therapy on conception-

Total no. of pts.	Effect based on conception		
	Conception	No conception	% relief
15	03	12	20.00

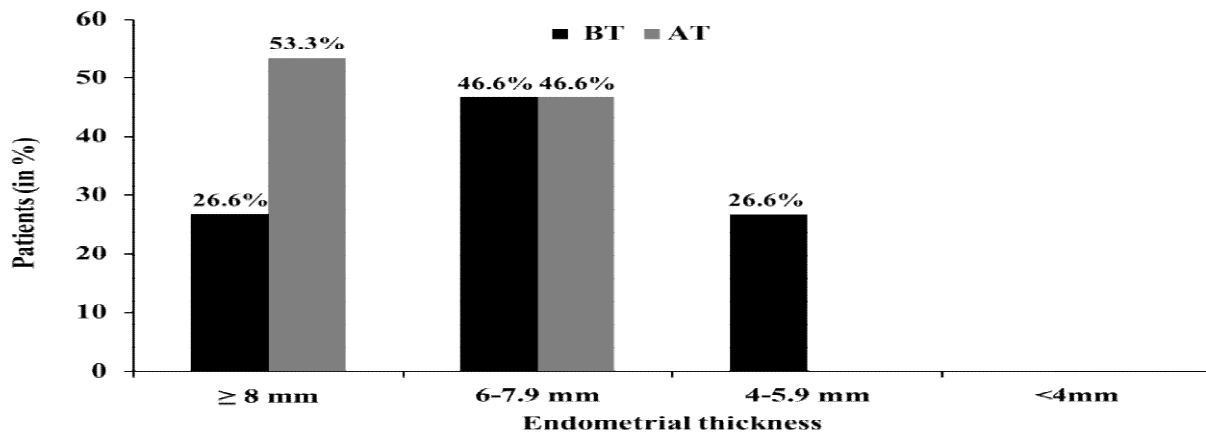
During or after treatment 20.00% patients conceived.

Graph 1: Effect on Follicular study-



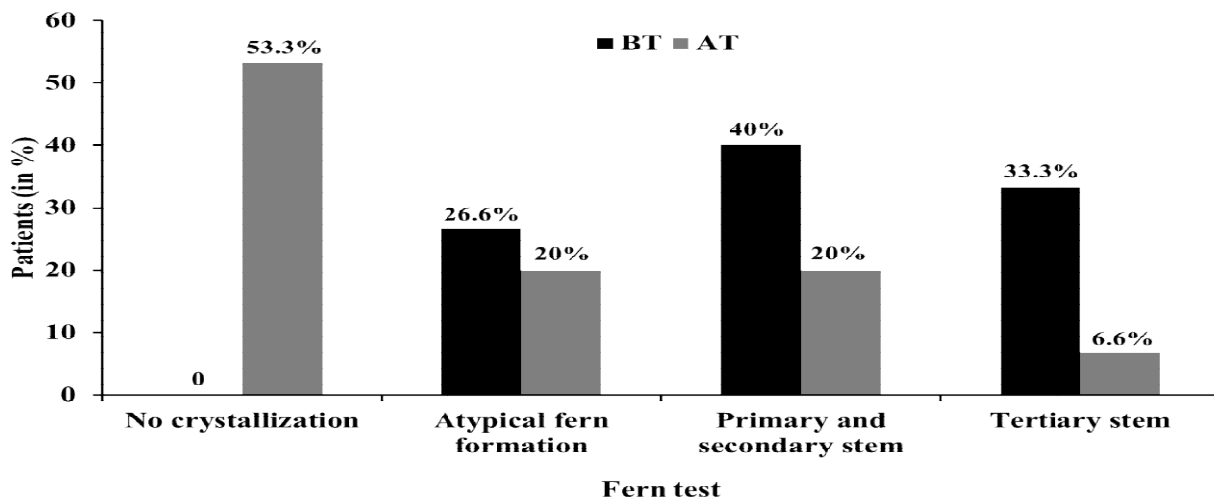
(BT-Before treatment, AT-After treatment)

Graph 2: Effect on Endometrial thickness



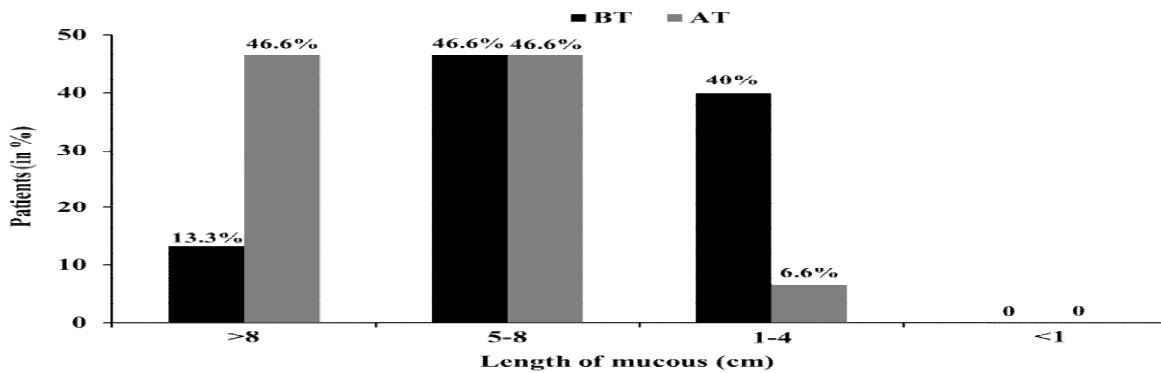
(BT-Before treatment, AT-After treatment)

Graph 3: Effect on Fern test-



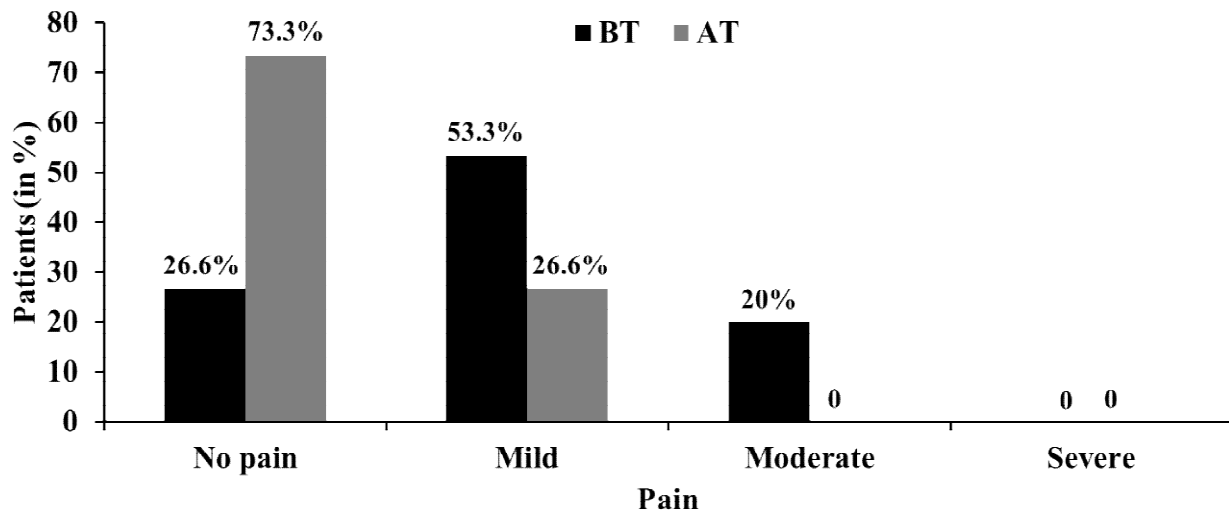
(BT-Before treatment, AT-After treatment)

Graph4: Effect on Spinnbarkeit test-



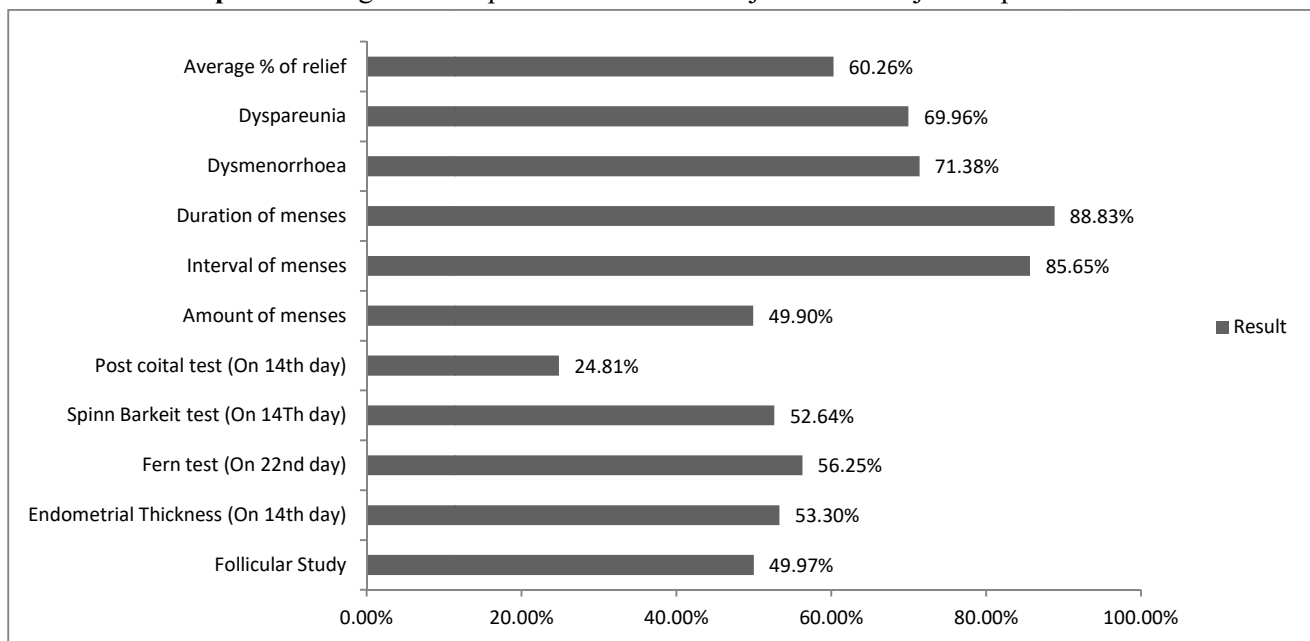
(BT-Before treatment, AT-After treatment)

Graph 5: Effect on Dysmenorrhoea-



(BT-Before treatment, AT-After treatment)

Graph 6: Average % of improvement in both subjective and objective parameters—



(BT-Before treatment, AT-After treatment)

DISCUSSION

Probable Mode of Action of Kashmaryadi Ghrit-

➤ The contents of *Kashmaryadi Ghrit* are *Gambhari*, *Triphala*, *Draksha*, *Kasmard*, *Parushak*, *Punarnava*, *Haridra-dvaya*, *Kaknaasa*, *Sahachar*, *Shatavari*, *Guduchi*, *Goghrit* etc. Most of the drugs are *Madhur*, *Tikta* and *Kashaya rasa pradhan*, *Ushna*

Veerya, *Madhur Vipaka*, *Laghu* and *Ruksha guna pradhanya*.

- *Gambhari* is *Garbhasthapak*⁵, so helps in conception.
- Some drugs like *Amalaki*, *Haritaki*, *Guduchi* and *Kaknasa* are *Rasayana* drugs⁵. These drugs are beneficial for proper nourishment of all *Dhatu*s and *Upadhatu*s. By improving

strength of all *dhatu*s including *Rasa* and its *Upadhatu* may be formation of *Beeja* is improved by proper nourishment.

- *Gambhari*⁵, *Triphala*, *Haridra-dvaya*, *Kasmard*⁶, *Guduchi*⁵, *Punarnava*⁶ etc. have *Deepana*, *Pachana* properties so that it regulates *Jatharagni*, *Dhatvagni* and *Bhutagni* which corrects metabolism at cellular level, which results in proper formation of *Dhatu*s and *Upadhatu*s (*Artava*) and *Srotoshodhana* by removing *Ama*.
- The vitiation of *Vata* may be due to *Margavarodha* (*Avrita Apana Vayu*) with *Kapha Dosh*a. *Acharya Charaka* has mentioned *Triphala* for *Virechana* in *Pakvashyagata Dosh*a⁷ and *Pakvashaya* is the main *Sthana* of *Vata Dosh*a so it regulates vitiated *Vata* along with *Kapha* and *Pitta*. Thus *Sanshodhana Karma* clears the *Srotas* and regulates the function of *Tridosha* specially *Avrita Apana Vayu*.
- *Draksha* is indicated in *Grabhashay-daurbalya*.⁸ Because of *Madhur rasa* and *Sheet veerya* it may increase the muscular strength of reproductive system. *Draksha* is *Soumanasyajanana* and *Acharya Charak* said that *Soumnasya garbhadharnaam*.⁹
- *Triphala*, *Haridra*, *Daruharidra* have *Yonidoshahara* action¹⁰ so that it pacify local inflammation and infection and it is mentioned in our classics that conception only occurs in *Shuddha Yoni*.
- *Gambhari*⁵, *Kasmard*⁶, *Punarnava*¹¹, *Kaknasa*, *Sahachar*⁶, *Haridra* have *Shothahara* actions, it cures inflammations.
- *Gambhari*, *Draksha*, *Parushak*, *Kasmard*, *Sahachar*, *Shatavari*, etc. drugs and *Ghrit* itself have *Madhura Rasa*, *Prithvi*, *Jala Mahabhuta Pradhanata* and *Brimhana* property which is responsible for *Upachaya* thereby improves the endometrial thickness. *Madhura rasa* in-

creases secretion and decreases degeneration of cervical epithelial cells. *Madhura rasa* and *Vipaka* nourishes *Rasa*, *Rakta*, *Mamsa Dhatu* and give them strength.¹²

- *Shatavari* totally nourishes the female reproductive organs causing it to be very effective in enhancing the fertility. It nourishes the womb and ovum and prepares the reproductive organs for conception and prevents threatened miscarriages. *Shatavari* contains phytoestrogens, the precursor of estrogen. Due to this effect increases amount of cervical mucus, motility and density of sperms in cervical mucus.¹³
- The causative factor of infertility is mainly vitiation of *Vata*. *Acharya Charak* says that all the gynecological disorders are due to vitiation of *Vata*¹⁴ and maximum drugs of *Kashmaryadi ghrit* having *Vatashamak* and *Vatanulomak* action. By normalize *Dosh*as it may ensure proper functioning of *Dhatu*s.
- *Ghrit* has property of *Samskaranuvartan* i.e. it can imbibe the properties of ingredient without losing its natural properties. It is *Yogavahi* so it carries active principles of the drugs to increase the potency of the compound drug.¹⁵
- *Goghrit* has *Agnivardhak*, *Rochaka*, *Rasayana*, *Vrishya* properties.
- In general, the blood cerebrospinal fluid and the blood brain barriers are highly permeable to water, carbon dioxide, oxygen, and most lipid soluble substances, and slightly permeable to electrolytes such as sodium chloride and potassium. The more lipophilic the drug is, the more likely it is to cross the blood-brain barrier^{16,17} and acts on central nervous system i.e hypothalamus and pituitary gland and may correct hormonal imbalance. *Ghrit* contains cholesterol which is responsible for the synthesis of steroid hormones i.e. estrogen and progesterone.

Mode of Action of Kashmaryadi Ghril- On Cervical Factor-

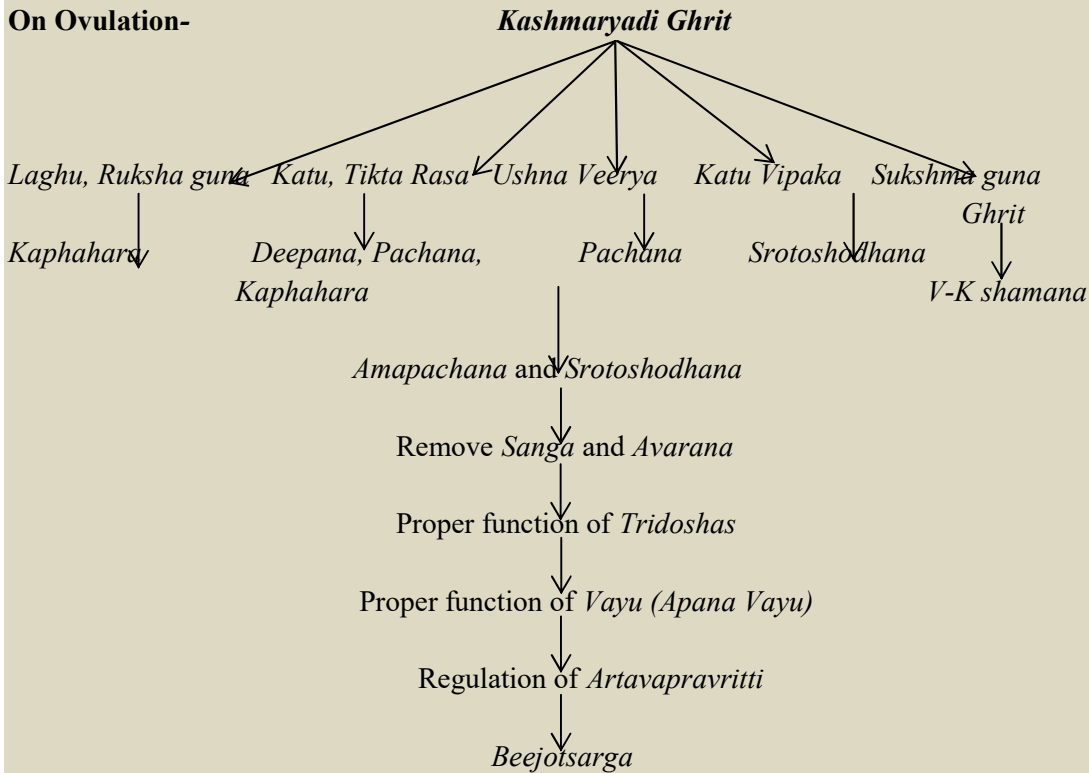
Laghu Guna → ↓ Pichchhilata of Kapha → ↓ Viscosity & Spinnbarkeit ↑

Madhura Rasa → Anabolic action → ↑ Secretory units → ↑ Amount

Deepana, Pachana, Anulomana → Proper function of receptor mechanism → Ferning
(+++)

Sheeta and Mridu Guna pacify the Ushna and Tikshna Guna of Pitta and decreases acidic mucous.

On Ovulation-



CONCLUSION

- As a result of the clinical trial done on total 15 patients of infertility total 3 patients conceived i.e. 20.00% result.
- No adverse effect or complications were produced with the use of this treatment. So this treatment is found to be safe, economic, non-surgical and effective and can be recommended for the management of unexplained cases of Vandhyatwa.
- Considering the time bound duration of study with small sample size and limited resources for conducting this clinical trial, drawing concrete and precise conclusions would be premature so number of patients in large scale will be more valid in suggesting efficacy of the drug.

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Source of Support: Nil

Conflict Of Interest: None Declared

How to cite this URL: Baranwal Deepika & Dave Hetal H: Clinical Study To Evaluate The Efficacy Of Kashmaryadi Ghrit In Vandhyatwa W.S.R. To Female Infertility. International Ayurvedic Medical Journal {online} 2018 {cited March, 2018} Available from: http://www.iamj.in/posts/images/upload/529_537.pdf