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Research Article

A Clinical Study To Evaluate The Efficacy Of *Kashmaryadi Ghrita* And *Baladi Churna* In *Vandhyatwa* W.S.R. To Female Infertility

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ABSTRACT:

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Infertility is a global health issue which affect approximately 8-10% of couples worldwide. Infertility is defined as failure to conceive within one or more year of regular unprotected coitus. It is a common rising problem of society. Women, who are able to conceive but they 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* can give a promising hand to cure this disease. So as to find out effective treatment without any side effect *Kashmaryadi ghrita* and *Baladi churna* oral treatment was selected in present study. 15 patients were selected randomly for present clinical trial study. Extremely significant results are observed in follicular study, Very significant results shown on fern test and spinnbarkeit test. Based on the observations it can be concluded that *Kashmaryadi ghrita* and *Baladi churna* is an effective drug for the management of female infertility.

Key words: *Vandhyatwa*, *Kashmaryadi ghrita*, *Baladi churna*.

INTRODUCTION:

Having a child completes the most desirable issue of a married couple.

Without child marriage does not come true. A woman gets born two times in her life one when she is born second when she gives birth to her child. Women is the root of child. A woman completes her family after giving birth to her child.

Putraishana - aspiration of child is the strongest desire of all the married couple.

Grihasthashrama- is one of the *ashrama* among four *ashrama* of life, which allows to have child to complete its definition. All married couples feel complete after having child. Infertility is a global issue. Ten to fifteen percent of marriages prove to be childless.

Women who are able to conceive but then have repeated miscarriages are also said to be infertile. Infertility is of two types—

1. Primary—Primary infertility denotes those patients who have never conceived.

2. Secondary—It indicates previous pregnancy but failure to conceive subsequently.

AIMS and OBJECTIVE:

- To evaluate the effect of *Kashmaryadi Ghrita* oral therapy along with *Baladi churna*, in order to search for a non surgical, affordable, and safe treatment for female infertility.

MATERIALS and METHOD:

Selection of patient: Total 16 clinically diagnosed and confirmed cases of *Vandhyatwa* were registered for the present clinical trial. Out of which 15 patients completed the course of treatment. The cases were selected from the O.P.D. / I.P.D. of P.G. Department of *Prasuti Tantra & Stri Roga*, National Institute of Ayurveda (N.I.A.) Hospital, Jaipur after taking informed written consent.

Criteria for Selection of patients -

a) Inclusion Criteria:

- ❖ All cases of primary & secondary infertility.
- ❖ Age group between 20 to 40 years.
- ❖ Male counterpart should be normal.
- ❖ One fallopian tube must be patent.

b) Exclusion criteria:

- ❖ Patients suffering from pelvic pathology including fibroid uterus, cervical polyp etc.
- ❖ Congenital anatomical defect.
- ❖ Patient suffering from severe infection or chronic systemic diseases.
- ❖ Bilateral tubal blockage.
- ❖ Infertility due to peritoneal factors.

c) Withdrawal Criteria:

- ❖ During the course of trial if any serious condition arises which requires urgent treatment.
- ❖ Patient herself wants to withdraw from the clinical trial.
- ❖ Irregular follow up and non compliance.

Laboratory investigations -

Before treatment:

1. Blood test- Hb%, TLC, DLC, ESR, HBsAg, VDRL, HIV, MONTOUX Test (if needed), RBS, T₃, T₄, TSH, LFT, RFT
2. Urine test - Routine & Microscopic
3. Cervical mucus (1) Spinnbarkeit Test (2) Fern Test
4. Post coital test
5. USG-Uterus & Adenexa
6. HSG

7. Anti-sperm Anti body test (if needed)

8. Pap smear- (if needed)
9. Follicular study (if possible)
10. Hormonal assays- S. FSH, S. LH, S. Progesterone, S. Prolactin (If possible).
11. Husband's semen analysis

After Treatment:

1. Cervical mucus (1) Spinnbarkeit (2) Fern test
2. Follicular study (If possible)
3. Urine Pregnancy detection test
4. USG- To Confirm Pregnancy

Table 1: INGREDIENT OF KASHMARYADI GHRITA:

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

Table 2: INGREDIENT OF BALADI CHURNA

Drug name	Latin name	Part used
<i>Bala</i>	<i>Sida cordifolia Linn.</i>	<i>Moola</i>
<i>Atibala</i>	<i>Abutilon indicum Linn.</i>	<i>Moola</i>
<i>Mulethi</i>	<i>Glycyrrhiza glabra Linn.</i>	<i>Moola</i>
<i>Sharkara</i>

Administration of drugs:

Kashmaryadi ghrita-

Dose- 5ml twice a day with lukewarm milk (200ml) for 3 consecutive cycles.

BALADI CHURNA-

Dose- 5gm BD with *Ghrita* and *Madhu* as *sahapana* and *ksheera* as *anupana*, for 3consecutive cycle.

Follow up study:

Patients were followed up fortnightly for 2 months after completion of trial.

Assessment Criteria:

The following criteria were developed to assess the efficacy of therapy, which is based on the improvement in subjective and objective criteria. To facilitate the statistical analysis of the efficacy of therapy, scoring system was adopted as follows:

Overall effect of treatment

The score of Subjective and Objective parameters were obtained before and after treatment and the total effect of therapy was assessed accordingly in terms of:

- Conception
 - Improvement in Subjective parameters
 - Improvement in objective parameters
 - Unchanged

Statistical Analysis:

Various observations were made and the results obtained were computed statistically using Student’s t – test, Wilcoxon matched-pairs signed-ranks test, Mann-Whitney test by using Graphpad-instat software to find out the significance of the values obtained and various conclusions were drawn accordingly.

P value :

- P> 0.05 - Not significant or not quite significant
- P< 0.05 -Significant
- P< 0.01 - Very significant
- P<0.001 - Extremely significant

Result:

Table 3 Improvements in Subjective Parameters

S. No.	Symptoms	Mean		Diff.	% of Relief	SD	SE	P	Significance of Results
		BT	AT						
1.	Interval of menstrual cycle	0.467	0.200	0.267	57.15	0.458	0.118	0.125	N.S.
2.	Duration of menstrual cycle	1.333	0.467	0.867	65.02	0.834	0.215	0.005	V.S.
3.	Amount of menstrual bleeding	2.600	1.333	1.267	48.73	0.884	0.228	0.0005	E.S.
4.	Pain during menses	1.067	0.533	0.533	49.98	0.516	0.133	0.008	V.S.
5.	Dyspareunia	0.200	0.067	0.133	66.65	0.351	0.091	0.500	N.S.
6.	Psychological stress	1.000	0.600	0.400	40.00	0.507	0.131	0.031	S.

Graph 1-Effect of Therapy on Subjective Parameter

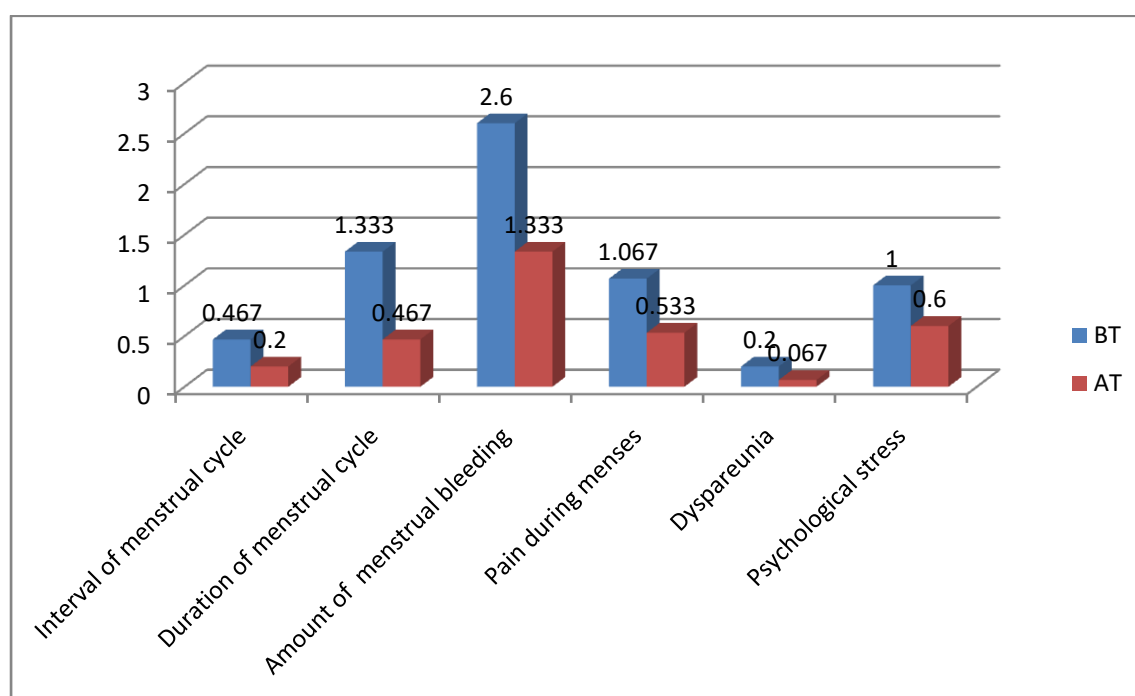
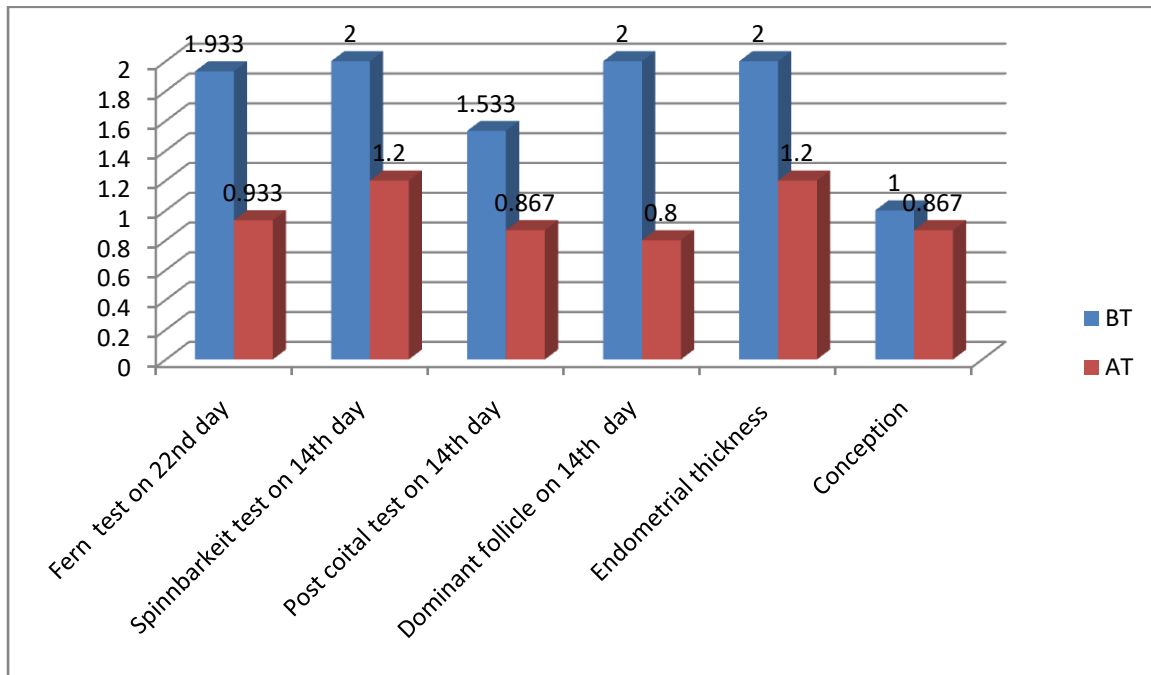


Table 4 Improvement in Objective Parameters

S. No	Variable	Mean		Dif.	% of Relief	SD	SE	't'	P	Significance of Results
1.	Fern test on 22 nd day	1.933	0.933	1.000	51.73	0.535	0.138	7.246	<0.0001	E.S.
2.	Spinnbarkeit test on 14 th day	2.000	1.200	0.800	40.00	0.676	0.175	4.583	0.0004	E.S.
3.	Post coital test on 14 th day	1.533	0.867	0.667	43.49	0.724	0.187	3.568	0.0031	V.S.
4.	Dominant follicle on 14 th day	2.000	0.800	1.200	60.00	0.676	0.175	6.874	<0.0001	E.S.
5.	Endometrial thickness	2.000	1.200	0.800	40.00	1.014	0.262	3.055	0.0086	V.S.
6.	Conception	1.000	0.867	0.133	13.33	0.352	0.091	1.468	0.164	N.S.

- ❖ Statistically extremely significant results (p<0.001) were found in Fern test, S.b. test, Dominant follicle.
- ❖ Statistically very significant result (p<0.01) was found in PCT test, E.T. test.
- ❖ Statistically non significant results (p>0.05) were found in Conception.



Graph-2 Effect of Therapy on Objective Parameters

EFFECT OF THERAPY ON CONCEPTION

S. No.	Total no. of pts.	Effect based on conception		
		Conception	No conception	% relief
1.	15	02	13	13.33%

In the study during or after treatment **13.33%** patients conceived.

Discussion:

Probable Mode of Action of Kashmaryadi Ghrita-

➤ The ingredients of *Kashmaryadi Ghrita* are *Gambhari, Triphala, Draksha, Kasmard, Parushak, Punarnava, Haridradvaya, Kaknasa, Sahachar, Shatavari, Guduchi, Goghril* etc. Majority of the drugs are *Madhur, Tikta* and *Kashaya rasa pradhan, Ushna veerya, Madhur*

vipaak, Laghu and *Ruksha guna pradhanya.*

- *Kashaya* and *Madhur rasa, Sheet veerya* may increase the muscular strength of reproductive system.
- Majority of the drugs having *Tridosha shamaka, Deepana, Pachana, Anuloman, Vrishya, Rasayana, Shothhar, Balya, Yonidoshahara, Garbhasthapaka* properties.

- *Gambhari* has *Tikta, Kashaya, Madhura rasa, Guru guna, Ushna veerya* and *Katu vipaka*.
- *Madhura rasa* increases secretion and decreases degeneration of cervical epithelial cells. *Madhura Rasa* has *Prithvi, Jala Mahabhuta Pradhanata* and *Brimhana* property which is responsible for *Upachaya* thereby improves the endometrial thickness.
- Due to its *Shothhar* actions, it treated inflammations and helps in conception.
- It is ***Garbhasthapak***, so helps in conception.
- *Haritaki* has *Kashaya, Madhura, Amla, Katu and Tikta rasa, Laghu, Ruksha, Sara guna, Ushna veerya* and *Madhura vipaka*.
- *Tridosha-shamaka* property of drugs along with *Madhura vipaka*
- *Haritaki* has *Prajasthapan* and *Yonidosahar* properties, it pacify local inflammation and infection and helps in conception and prevent the abortion as it is mentioned in our classics that conception only occurs in *Shuddha Yoni*.
- Due to its *Vatanulomak karma* it normalises *Vata doshas* and helps in *Beejotsarg* and conception as *Acharya Charak* said that all the gynaecological disorders are due to vitiation of *Vata*.ⁱ
- *Vibhitaki* has *Kashaya Rasa, Laghu, Ruksha, Sara guna, Ushna veerya* and *Madhura vipaka* and *Tridoshashamak* actions.
- *Amalaki* contains *Amla, Madhura, Katu, Tikta, Kashaya rasa, Guru, Ruksha, Sara guna, Sheeta veerya* and *Madhur vipaka* and it is *Tridosha shamak*.
Because of *Kashaya rasa* it increases muscular strength of reproductive organs.
- Its actions are *Rasayan, Yonidosahar* and *Garbhasthapan*.
- *Draksha* has *Madhura rasa, Snigdha, Guru, Mridu guna, Sheeta veerya* and *Madhur vipaka* and *Vata- pitta-shamaka* properties.
- *Draksha* is *Soumanasya-janana* and *Saumnasya* is said to be important factor to normalise *Vata dosha*.
achieve pregnancy.ⁱⁱ
- It has *Madhura rasa, Prithvi, Jala Mahabhuta pradhanata* and *Brimhana* property which is responsible for *upachaya* thereby improves the endometrial thickness as well as quality of cervical mucous and muscular strength of reproductive system.
- *Madhura rasa* increases secretion and decreases degeneration of cervical epithelial cells. It also contains carbohydrate in abundance and less protein which is very important for cervical mucus.

Madhura rasa and *vipaka* nourish *Rasa, Rakta, Mamsa Dhatu* and give them strengthⁱⁱⁱ.

- *Shatavari* nourishes and cleanses the blood and the female reproductive organs causing it to be very effective in enhancing the fertility.
- It is *Garbha poshaka*. It nourishes the uterus and ovum and prepares the female organs for pregnancy and prevents threatened miscarriage. *Shatavari* contains phyto- estrogens, the precursor of estrogen. Due to its phytoestrogenic effect^{iv} increases amount of cervical mucus, spinnbarkeit, ferning, motility and density of sperms in cervical mucus.
- Punarnava has *Madhura, Tikta, Kashaya rasa, Ruksha, Laghu guna, Ushna veerya, Madhura vipaka* and *Tridosh-shamaka* actions.
- It posses *Lekhan* action and by this it may remove *Sang* and *Aavarana* of *Vata doshas* by *Kapha dosha* and may help to break pathogenesis.
- Because of its *Shothhar* actions, it treated inflammations of reproductive tract.
- Haridra-dvaya has *Tikta rasa, Ruksha, Laghu guna, Ushna veerya, Katu vipaka* and *Kaphapitta-*

shamak actions.

- It has *Deepan-Pachan* and *Amadosha-nashak* properties and thus correct *Agnimandya* and *Srotoshodhan* by removing *Ama*.
- It has *Yonidoshahara* action, so corrects all the doshas of *Yoni* and helps in conception.
- It also has anti-inflammatory actions, so it act on inflammation of reproductive tract, and helps in conception.
- *Gambhari, Triphala, Haridradvaya, Kasmard, Guduchi, Punarnava* etc. have *Deepana, Pachana* and *Amadosha-nashak* properties so that it regulates *Jatharagni, Dhatvagni* and *Bhutagni* which corrects metabolism at cellular level, which results in proper formation of *Dhatus* and *Upadhatus (Artava)* and *Srotoshodhan* by removing *Ama*.
- ❖ *Haritaki, Vibhitaki, Amalaki, Draksha, Gambhari, Parushak* have the *Sara guna* and *Virechak* action so that they regulates *Doshas* by *Sanshodhana Karma*. The vitiation of *Vata* may be due to *Margavrodha (Avrita Apana Vayu)* with *Kapha Dosha*. *Acharya Charaka* has mentioned *Triphala* for *Virechana* in *Pakvashyagata Doshav and *Pakvashaya* is the main *sthana* of *Vata Dosha* 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*.

- ❖ *Amalaki, Guduchi, Daruharidra* etc. drugs have antioxidant property which decrease oxidative stress.
- ❖ *Triphala, Haridra, Daruharidra*, have *Yonidoshahara* action i.e it pacify local inflammation and infection and it is mentioned in our classics that conception only occurs in *Shudhdha Yoni*.
- ❖ **BALADI CHURNA:**

Acharya Vangsen has mentioned *Baladi churna* as ***Garbhapradam*** *yoga* in *Mahila rogadohikar adhyaya*.^{vi}

Probable mode of action-

- Contents of *Baladi churna* are ***Bala, Atibala, Madhuyashti*** and ***Sharkra***.
- All ingredients have *Madhur rasa, madhur vipaka, sheet virya, and vatta –pitta shamaka* property.
- Due to *madhura rasa & vipaka, sheet virya* and *snigdha guna* it act on *Kshayajanya vata prakop* and regulates *vata dosha*.
- *Madhura rasa*, itself has *Prithvi, Jala, Mahabhuta Pradhana* and *Balya, Brimhana, Rasayana*

properties are responsible for *Upachaya* thereby improves the endometrial thickness and helps in folliculogenesis.

- Due to *balya, vrishya, and rasayan* property it act as Antistress and CNS depressant stimulant and regulate the function of HPO axis because due to stress endogenous opioids are increase, which suppress both the dopamine and GnRH pathway leading to increase in prolactin secretions.
- *Madhura rasa* increases secretion and decreases degeneration of cervical epithelial cells.
- The process of new cells division and regeneration from basal layer of endometrium is said to be due to *Vata*, as differentiation or cell division are the functions of *Vata*. So the pacified *Vata dosha (Apanavayu)* lead to *Artavjanana*, downward *pravritti* of *Artava*.
- *Pitta* is responsible for all type of *Paka Karma* in the body, so here, the role of *Pitta* can be understood as ovarian Steroidogenesis where two cells (theca cells and granulosa cells) produce different hormones under the influence of two gonadotrophins (LH and FSH) . *Pitta* is responsible for production of adequate level of

hormones. By its proper action on Dhatupak and Rasadisamyak Dhatunirman.

- The function of *Kapha* is *Upachayakarma* leads to *Dhatuprasadan prakriya*, which means development. So, here it is responsible for further development of endometrial cells by proliferative and secretary changes through estrogen and progesterone respectively.
- The adequate level of hormones during follicular and luteal phase is responsible for proper function by proliferation and secretary changes in endometrium.
- Proper function of *Vata-Pitta* enhances regular function of HPO axis results in proper *Upchaya* action of *Kapha* leads to proliferative and secretary changes in endometrium. Menstrual cycle regulates and endometrial thickness increased by proper action of *tridosha* thus, the amount of menstrual blood increased, there is proper ovulation.
- *Bala* has *Madhur rasa, Laghu, Snigdha, Pichchila guna, Sheeta veerya Madhur vipaka* and *Vatta Pitta shamak* properties. Due to its *Madhur rasa* having

Prithvi, Jala, Mahabhut Pradhanta there is proper *Upchaya karma* which improves the endometrial thickness.

- It has *Garbhashaya daurbalya, Vattavikara nashak* property so it provide strength to female reproductive system and normalize *Yonigata Vatta*.
- *Atibala* has *Madhur rasa, Laghu, Snigdha, guna, Sheeta veerya Madhur vipaka* and *Vatta Pitta shamak* properties.
- Due to its *Rasayana karma* it act as anti stress agent, which regulate HPO axis.
- Due to its *Madhur rasa, Vatahara*, it acts on *Yoni gata Vatta* which get pacified and regulate all normal function of *Apanavayu*.
- *Madhuyashti* has *Madhur rasa, Guru, Snigdha, Pichchila guna, Sheeta veerya Madhur vipaka* and *Vatta Pitta shamak* properties.
- It has *Vatavikar, Dahashamak, Raktavikarnashak* property so, it normalize the *Vattadushti* and also improves the *Pitta dosha* quality so *Apanavayu* and *Pitta Dosha* function will be regulated like *Artavajanana, Beeja nirmana, Beejotsarga* and proper *Dhatu paka* leading to *Rasadidhatu nirman, artavautpatti*.

- The general property of *Sharkara* is *Pitta-shamaka*. Other properties of *Sarkara* are:^{vii},^{viii} *Daha Prashmana* and *Rakta-pitta Shamana* in nature.^{ix} So yoni gata Pitta get pacified.
- It has *Madhura Rasa, Snigdha, Guru Guna, Sheeta Virya, Madhura Vipaka, Vata- pitta-shamaka Doshakarma*.
- It has *Shramahara, Dahahara, Rechaka, Balya* properties and it is laxative, anti-inflammatory, so it provide strength and pacify inflammation of genital tract, and helps in conception.

Conclusion:

- ❖ Infertility is caused by dushti of *Gati* of *Apana Vayu* due to the obstruction in the *Artavavaha Srotas* and any deviation in the normalcy of *Garbha-sambhava-Samagri*.
- ❖ For *Avrita Apana Vayu (Margavarodha)* with *Kapha Dosh*, the treatment should be *Srotoshodhana, Agnideepaka, Vatanulomak* and *Pakvashaya Shuddikaran*.

- ❖ *Kashmaryadi ghruta* (combination of *Gambhari, Triphala, Draksha, Kasmard, Parushak, Punarnava, Haridradvaya, Kaknasa, Sahachar, Shatavari, Guduchi, Goghrita*) has properties of *deepana, pachana, vata-kaphashamak, srotoshodhaka, Yonidoshahara* and *Garbhasthapana*. *Baladi churna* has *Balya, Brimghana, Rasayana, Vrishya, Vata-kapha-shamaka* and *Garbhasthapaka* properties.
- ❖ Ingredients of *Baladi churna* are *Bala, Atibala, Madhuyashti* and *Sharkra*. All ingredients have *Madhur rasa, madhur vipaka, sheet virya, and vatta –pitta shamaka* property. Due to *madhura rasa & vipaka, sheet virya* and *snigdha guna* it act on *Kshayajanya vata prakop* and regulates *vata dosha*. Thus it helps in conception.
- ❖ Thus, Based on this study *Kashmaryadi ghruta* along with *Baladi churna* can be recommended safely for the management of infertility with success.

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