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## SAFETY & EFFICACY OF VIRGARBHAKAR YOGA W.S.R TO ITS EFFECT ON FERTILITY

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### ABSTRACT:

*Ayurveda* being an oldest medical system of the world serves the mankind by curing the sufferings & miseries and even helps in extending the life span by maintain and promoting the health. Pre- *Vedic* period and *Vedic* period emphasizes not only on the use of metals for preparing weapons and ornaments but also for some medicinal values that of Gold, Silver and Copper etc in the treatment of disease. *Charaka Samhita* and *Susruta Samhita* describe tonic values of a number of Metals/Minerals and even the scholars of Rasa Shastra have pledged to free the entire world from disease by using processed Mercury. The manufacture of nontoxic drugs from the metals like gold, Silver, Copper and Iron had begun and the processes were improved with the increasing understanding of the Safety & Efficacy issues. *Bhasmas* prepared according to classical methods never contains a metal in free form. The question of toxicity arises in only those manufacturers who are resorting to short cuts in the preparation of *Rasaushadhies*. The ancient Indians have very well cautioned against improper processing of heavy metals and have warned that these may harm the vital organs like liver, kidneys etc. and even it may cause the death. Here in this article an attempt is made to clarify the safety and toxicity effect of *Virgarbhakar Yoga* which is specially indicated in infertility is studied with aim of standardizing the drug and to see the fertility. Pharmaceutical, analytical and experimental study was the materials and methods and evidence of these claims that *Virgarbhakar Yoga* can be used safely to get fertility result.

**Key words:** Fertility, Marana, Shodhana, Virgharbhar Yoga,

## INTRODUCTION

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Ayurveda is the science of life which originated from the Vedas. It aims at achieving perfect health, through physical, mental and spiritual well-being. According to Ayurveda good health is considered as a prerequisite for achieving the goals of life i.e. Dharma, Artha, Kama and Moksha. A person gets these benefits by giving an offspring, which resort these qualities. Even in Upanishads Putraishana is mentioned as one of the primary desires of mankind. Infertility is one of the human problems having a social and emotional aspect. Herbal, mineral and animal products were used in therapeutic form by this ancient medical system. Among them treatment using metal and mineral products gained an upper hand due to the peculiar properties like their quick action, decreased dose etc. *Charaka Samhita* and *Susruta Samhita* describe medicinal values of a number of Metals/Minerals and even endeavor to free the entire world from disease by using processed Mercury. The manufacture of non-toxic drugs from the

metals like gold, Silver, Copper and Iron had begun and the processes were improved with the increasing understanding of the Safety & Efficacy issues. The ancient Acharyas have very well cautioned against improper processing of heavy metals and have warned that these may harm the vital organs like liver, kidneys etc and even it may cause the death. Present study was undertaken to assess the effectiveness of *VirgarbhakarYoga* on hormonal status of albino rats and to trace out mechanism by which drug is acting on reproductive system. *Virgarbhakar Yoga* is named after *Virgarbhakarikriya* mentioned in Ph.D thesis of Prof.Lakshami Kant Dwivedi entitled *Rudrayamala parad kalpa* which had been quoted from the manuscript of *Rudrayamala Tantra* 84<sup>th</sup> *Patalajalasiddhikalpa*. The process is mentioned for the treatment of *vandhya*. Mineral content of the drug include the ingredients of *Chaturmukha Rasa*<sup>1</sup> and herbs from *Charaka Samhita* and animal products from *Nayansukha*.

### AIMS & OBJECTIVES:

1. To standardize the herbomineral preparation: *VirgarbhakarYoga*.
2. To access the effect of the herbomineral formulation on infertility of female albino rats

3. To trace out the mechanism by which drug is acting on the reproductive system

### **SAFETY ISSUES IN ANCIENT PERIOD**

A search through classics reveals that the ancient scientists who unveiled the treasure of Ayurveda have also given due importance for Safety & Efficacy issues. Some of the areas where they have given diligence while the preparation of medicines are as follows.

1. Selection of Raw Material
2. Properties of Raw Metals/Minerals
3. Properties of Drugs
4. Process / Preparation (SOP & SMP)
5. Dose / Kalpa Karma
6. Sahapana / Anupana (Vehicle for medicine)

**a. Metals:**

*b. <sup>2</sup> “Grahya tadeva Kanakam Mridu Rakta Peetam” (Ay. Pra. 3/26)*

**c. Minerals:<sup>3</sup>**

*“Jatwabham Mridumritsnachham Yanmalam Tatchilajatu”*

*“Yastu Guggulukabhasastiktako Lavananvitah” (Cha. Chi.1/3/23)*

**c. Herbals:** In case of herbal drugs a lot of specifications were given regarding the time of collection, Region, Season, Soil, Place and Maturity of Plant etc.

Though diligence was kept in selection of raw materials some of the metals and minerals or their associated metallic chemicals might have shown toxicity which would have later lead to the detail description of elaborated processing methods like shodhana. At the same time

7. Pathya (Do's), Apathya (Don'ts)
8. Method of Administration of Medicine
9. Management of Untoward effects
10. Drug absorption ,Drug Metabolism, Indications of Medicine

Regarding the Selection of Raw Material Acharyas have given due care in maintaining the quality of raw materials used for the preparation of various dosage forms. In case of metals and minerals the best quality among the group were described by the grahya lakshana and those raw materials which comply with the characteristics mentioned in grahya lakshana were to be procured. A number of such descriptions of the best quality of materials can be collected from the classics. A few examples are quoted below.

these metals and minerals needed to be converted to inassimilable form for their therapeutic effect in the body. Thus arises procedures like shodhana, marana etc. to convert them to effective dosage forms free of toxic effects.

### **IMPORTANCE OF SHODHANA & MARANA: <sup>4</sup>**

Among the various methods devised by Acharyas to render the metals and minerals

free of toxicity Shodhana was the first step. It is a purification process to remove impurities (toxic-substances) and make them for suitability of the next Marana process. Samanya Shodhana was done for a group of drugs while Visheshha Shodhana was done to remove specific Doshas For e.g. Samanya Shodhana of metals is carried out by heating them up to red hot and dipping them in liquids like- Til Tail, Takra, Gomutra, Kanji and Kulattha Kashaya for seven times.

The process of converting the pure metals and minerals into Bhasma form by triturating with specific liquids and subjecting to contact with Agni is known as Marana. It consists of two basic stages – Bhavana and Puta paka. During bhavana shodhita metal in powder form is triturated with certain herbal juices and decoctions. This process mainly makes conversion of non toxic metallic compound into inorganic or organo-metallic forms due to addition of herbal juice/ liquids and makes the particle finer by making their Sanghatabhedhana (Change in the chemical bond) and enhances the properties of the drugs. During putapaka the substances is closed in a Sharava samputa (crucible) and heating is done at different temperature This process is repeated as many times as prescribed for each preparation. Hence, we have a Dasa puta (10 cycles) Sata puta (100 cycles) Sahasra puta (1000 cycles) etc.

The colours of the final Bhasmas have also been described by our ancient scientists. For examples. The perfectly prepared Kantalauha bhasma resembles the colour of ripen Jambu fruit. The science of Ayurveda itself specifies certain tests to ascertain the quality of metals/minerals in Bhasmas. There are many such tests to establish the quality of the metal like Rekhapurnata, nishchandrata, apunarbhavatwa, varitaratwa etc.

It is believed that Metal and Minerals in Ayurvedic Preparations exist in complex Tonic form due to unique heat processing and herbal treatment. The Rasaushadhies are broadly divided in to the following.

1. Khalveeya Rasayana: Medicines prepared in Khalva Yantra.
2. Kupipakwa: Medicines prepared by heating drugs in bottle.
3. Parpati: Prepared in thin scaly forms.
4. Pottali: Medicines prepared with mountain like shape by heating in Sulphur
5. Lauha: Medicines containing Loha bhasma as chief ingredient.
6. Mandoora: Medicines prepared mainly with Lohakitta.
7. Pisti: Drugs made very fine by triturating with few distilled herbal liquids.
8. Bhasma: Various Minerals and Metals.

Besides describing elaborate procedures for converting these metals and minerals in to non toxic assailable form the acharyas have also mentioned dose of the

various rasoushadhies along with strict regimen to be followed while administering these bhasmas. Along with that a concept called kshetrikarana (Process of Making the body suitable for use of Rasoushadhies) is also mentioned.

**MATERIAL & METHODS:**

The herbo mineral compound *VirgarbhakarYoga* was prepared in the department of Rasa Shastra and

Bhaishajya kalpana, N.I.A, Jaipur. To assess the safety and efficacy of virgharbhakar yoga, Two samples of *VirgarbhakarYoga* were prepared – *VirgarbhakarYoga* 1 and *VirgarbhakarYoga* 2 (eliminating mineral drugs) and analysis were carried out. The ingredients of the compound along with the chemical analysis are given in the table 1.

**Table 1 Showing ingredients of Virgarbhakar Yoga**

Sl.No.	Content	Sl.No	Content
1	Shuddha Parada	10	Ksheeravidari <sup>8</sup>
2	Shuddha Gandhaka	11	Atibala
3	Abhraka Bhasma	12	Jivaka
4	Swarana Bhasma <sup>5</sup>	13	Apamarga <sup>9</sup>
5	Lauha Bhasma <sup>6</sup>	14	Vata Shunga
6	Haritaki <sup>7</sup>	15	Naga keshar
7	Mandukaparni	16	Ashwagandha <sup>10</sup>
8.	Durva	17	Gorochana
9	Guduchi		

Preparation of *VirgarbhakarYoga* as per the textual references.

Study was conducted in three phases.

- Anti-fertility studies for assessing the anti-fertility effect of *Vidanga* extract.
- Fertility studies for assessing the effect of *VirgarbhakarYoga*
- Study on immature rats to assess the effect of *Virgarbhakar Yoga* on reproductive maturity.

**Phase 1 study**

Albino rats of either sex 8-10 weeks weighing 70-80g were obtained from animal house of Dept. of zoology Rajasthan University Jaipur. Total 8 male and 30 female albino rats were taken and kept in separate cages for 15 days to let them acclimatize with the environment. After fifteen days female rats were divided in to 2 Groups. GroupA n=9 (control) and Group B n=21(experimental).Group A was



kept on normal diet and water. Group B were given alcoholic extract of Vidangain a dose of 10mg/100g bow/rat/day in a single dose of 2ml having oil as vehicle for 30 days. After 30 days 3 animals each of groups were sacrificed.

**Phase 2 study**

For second phase trial animals left in the first phase were taken. Group B animals were again divided in to 3 groups C, D, E. Group C was taken as infertile control group. Group D,E were given two different samples of *Virgarbhakar Yoga* 10mg/100g for 30 days for honey and water. After 30 days 3 animals each from A, D, E, C were sacrificed. Remaining animals of the four groups were left for mating with male rats. Female rats supposed to be pregnant after observing the vaginal mucous plug were kept in separate cages and observed regularly and autopsied on 21<sup>st</sup> day of gestational age when they did not deliver litters except group A females who delivered litters on 21<sup>st</sup>day.

**Phase 3 study**

**Table 2 showing result of phase 1(antifertility) study in control group A and Vidanga extract treated group B**

Hormone Studies	Group A	Group B	t value	P value	Significance
	Mean ± S.E	Mean ± S.E			
LH	4.37±2.80	4.83±1.62	0.25	-	Insignificant
Estrogen	133.5±19.03	67.40±30.99	3.15	0.05*	Significant
Progesterone	4.77±0.15	6.50± 4.07	0.74	-	Insignificant

For third phase of study 12 immature healthy female rats were divided in to 3 groups containing 4 rats each. The groups were named as F, G and H. F and G were given samples of *Virgarbhakar Yoga* while H was kept as control. Biochemical parameters studied include Estrogen, Progesterone, FSH and LH. All animals were observed for morbidity and mortality twice daily. General clinical observations were made twice a day at the same time throughout study Animals were sacrificed on 21<sup>st</sup> day and ovary and uterus were send for histopathological studies.

**Results**

The gross behavior of all animals remained normal throughout the study. There was increase in body weight in all groups which was statistically insignificant as compared to control group.

**Hormonal changes**

**Changes in phase 1:** The LH and Progesterone hormone in group B animals didn't show any significant changes while estrogen level was significantly increased.

**Changes in phase 2:** On administration of Virgarbhakar Yoga 1 in group D the highly elevated Estrogen level come down to the normal limits like that of control group, while level persist highly elevated in group C.

**Table 3 Showing result of phase 2(fertility) study**

Hormone Studies	Group A	Group D	Group E	Group C
	Mean ± S.E	Mean ± S.E	Mean ± S.E	Mean ± S.E
LH	0.1±0.0	0.63±0.61	15.57±24.64	0.40±0.44
Estrogen	86.73±11.72	73.73±11.88	83.38±14.22	13.4±19.4
Progesterone	19.33±3.11	16.10± 11.78	13.70±8.23	11.17±8.11

**Changes in phase 3:** The increase in LH hormone level was significant in F group treated with Virgarbhakaryoga 1. The group G showed increase in LH level which was also significant.

**Table 4 Showing result of phase 3 study**

Hormone Studies	Group F	Group G	Group H	t value	t value	p value	P value
	Virgarbhakar 1	Virgarbhakar 2	( Control)	F-H	G-H	F-H	F-H
	Mean ± S.E	Mean ± S.E	Mean ± S.E				
LH	5.12±1.78	4.52±2.02	0.95±1.57	3.51	2.79	0.02	0.05*
Estrogen	31.35±4.81	29.23±20.6	33.95±11.50	0.42	0.40	-	-
Progesterone	1.25±0.59	2.88± 0.48	1.60±1.49	0.44	1.63	-	-

**Histopathological Changes:**

**Changes in phase 1**

The histopathological study showed a number of changes in ovary and uterus after Vidanga administration.

**Ovarian changes-** The ovary of control group A showed normal structure having follicles of all sizes from nest of oocytes to large griffin follicles, theca external and internal, normal vascularity and normal corpus lutium cells. Ovary of group B showed conspicuous follicular atresia, increased vascularity and necrosis of corpus lutium cells.

**Uterine changes-** The uterus of Group A showed wide lumen lined up with columnar

epithelial cells, 3 distinct layer of basal, myometrium and endometrium, normal endometrial glands with visible glandular epithelium having small lumen and outer periphery was smooth lined up with epithelial tissue. Group B show changes in uterine tissue as the vascularity was highly increased, the myometrium show noticeable shrinkage, the endometrial glands were undergoing hypotropic changes showing regression, the outer lining was disturbed and the lumen was narrow and slit like.

**Changes in phase 2**

The histopathological study of ovary of group D and E showed that the changes were returning towards normal as

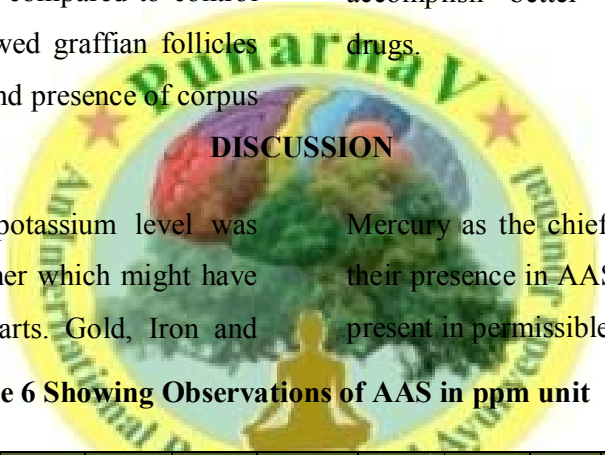


graafian follicle were again seen in developing stages and corpus luteum having healthy cells as compared to group C in which changes of necrosis were persisting. The uterine structure of group D and E showed decreased vascularity, normal endometrial glands with epithelial lining as compared to group C.

**Changes in phase 3**

Study on immature rats showed that there were early changes in ovary and uterus of F and G as compared to control group H. Ovary showed graafian follicles in developing stage and presence of corpus

leutium which were absent in group H. Groups C, D, E didn't delivered litters after mating so they were autopsied to see resorption on 22 nd day. Absence of implantation indicated that none of them conceived .Study showed that though structural changes caused by Vidanga were returning to normal strategy after administering samples of *VirgarbhakarYoga* but needed much longer time to let them become normal to conceive. Further study is needed to accomplish better results of prepared drugs.



**DISCUSSION**

In the AAS study potassium level was found higher than other which might have come from herbal parts. Gold, Iron and

Mercury as the chief constituents showed their presence in AAS. Heavy metals were present in permissible limit.

**Table 6 Showing Observations of AAS in ppm unit**

Sample	Au	Fe	Hg	K	Na	Ca	Al	As	Pb	Cd
Virgarbhakar Yoga-1	1634	3294	3857	34070	3195	5114	306	4.471	9.029	0.247

In phase 1 study where alcohol. Extract of Vidanga were administered, the level of Estrogen hormone was significantly increased in Vidanga treated animals as compared to control the increase was further confirmed by changes seen in section of ovary and uterus. Changes in hormonal level of Progesterone and LH were insignificant. In phase 2 study, hormonal assay showed that elevated Estrogen level returned to normal.

The ovary showed that changes were reversing as graafian follicles were seen in developing stages. The changes were similar in *VirgarbhakarYoga* 1 and 2 but were more advanced in *VirgarbhakarYoga* 1 suggesting that it might be due to the presence of gold Bhasma and other minerals in *VirgarbhakarYoga* 1. In phase three study there were significant increase in level of LH as compared to control group suggesting that the drug might be influencing the hypo pituitary axis for

early release of gonadotropins which further stimulate changes in gonads. Over all the study showed that the proposed drug might stimulate pituitary as well as gonads to secrete hormones essential for fertility in the normal range and thus enhancing fertility rates.

Proposed mechanism of action: The drug showed effect on hormonal level mainly on Estrogen. From Ayurvedic view we can say that the ingredients of the drug mainly possess *Madura* rasa and *vipaka*, *shitaveerya* and *vata pitta shamaka* properties and show *prajasthapaka* property.

### CONCLUSION

The study revealed that the *Virgarbhakar Yoga* can be safely used to enhance the activity

of reproductive system in cases of unexplained infertility. The trial drug is also beneficial

in patients where Estrogen level is elevated as in cases of PCOD, endometriosis etc. Thus

the present study add to the evidence base data which reveals that herbo-mineral Compounds are safe and effective when prepared and administered strictly adhering to the rules of the classic texts.

- The manufacture of non toxic drugs from the metals like gold, Silver, Copper and

Iron had begun and the processes were improved with the increasing understanding of the Safety & Efficacy issues.

- Merely testing heavy metal levels is inconclusive and to look that calcined or purified metals /Minerals are safe and effective at higher levels in the body. It would be useful to learn at what level these become safe & toxic. Strictly adhered state of art safety practices till advancement practices come.
- There must be ensuring that fully certified organic vendors (due to presence of heavy metals in the plant).

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