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# A Clinical study on the efficacy of *Udvardana* and *Nasya* on Ovulatory functions w.s.r. to Female infertility in Moderate Obese (*Sthula*) individuals

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## ABSTRACT

Childlessness and infertility are rising dramatically in cities. The increase may be due to many reasons like the way of living, coping with stress, job pressure, obesity, postponing parenthood, galloping urbanization, sexually transmitted infections and many others. Hence treating infertility is the challenging job for the doctors in present era. The failure to ovulate is the major problem in approximately 40% cases of female infertility. This can be anovulation or severe oligo ovulation. In the latter case even though the ovulation does occur, its relative infrequency decreases the woman's chance of pregnancy. Hence the infertility and especially ovarian factor induced female infertility needs an immediate attention from alternative medicines. Over last decades, fertility therapy has expanded more than any other field of medicine. Hormonal therapy, In vitro Fertilization (IVF), Embryo Transfer (ET), Gamete Intra Fallopian Transfer (GIFT) etc., all these have a minimal success rate. Additionally these procedures are associated with adverse effects & are not affordable to all. Ayurveda may give a promising hand to cure this condition with the various treatment modalities mentioned in the classics. For the present clinical study, an effort was made to study the efficacy of *Udvardana* and *Nasya* followed by *Shamanaushadhis* in reversing the pathology of this disease and giving a "Never-Ending Joy" of parenthood to the couples through the Ayurvedic treatment.

**Key words:** Female Infertility, Ovulation, Moderate Obesity, *Sthaulya*, *Vandhyatwa*, *Udvardana*, *Kulattha Churna*, *Nasya*, *Vishnu Taila*, *Varanadi Ghana Vati*, *Sukumara Kashaya*.

## INTRODUCTION

GOD "The Creator" has empowered every human being to reproduce itself. The function of Reproduction is the Noblest. God has given this beautiful gift only to Women. Motherhood is the

crowning act in the women's feminine role of life.

The very definition of *Stree* is "*Sthyayathi Garbha Yasyamithi Stree*" i.e. *Stree* means the one who possess womb (*Garbha*) or who has the capacity of conceiving a child. As per Ayurveda giving birth to a healthy offspring is dependent on four basic factors i.e. *Rutu*, *Kshetra*, *Ambu* and *Beeja*.<sup>[1]</sup>

According to WHO, "Reproductive Health is a state of Complete Physical, Mental and Social well being and not merely the absence of disease or infirmity in all matters relating to the Reproductive system and to its functions and processes."<sup>[2]</sup>

In olden days, Infertile couples were considered as shadeless, branchless, fruitless waste tree or like a lamp in a picture or portrait which will not emit any light or brightness. Life of such a couple was considered to be a mere waste. With the changing

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times the angle with which the problem is visualized has also changed.

Failure to conceive within one or more years of regular unprotected coitus by a couple of mature age is termed as Infertility. It is a medical problem that involves both the couples and both of them remain involved even if only one partner needs medical treatment. Primary Infertility denotes those patients who have never conceived. Secondary Infertility indicates previous pregnancy but failure to conceive subsequently.<sup>[3]</sup>

As successful pregnancy is a multi step chain of events, even if one of the events or conditions is not met in the right time, pregnancy may not happen or reach to birth. The increasing rate of Infertility has become a challenging issue in the current scenario. As the treatment suggested in modern science dwell upon Hormonal supplementation, Surgical procedures, Assisted Reproductive Technologies etc., has a minimal success rate. Additionally these procedures are associated with adverse effects and are not affordable to all.

Reasons such as diet, weight, smoking, medical conditions, environmental pollutants, medications and family medical history, infections might have an effect on conception in couples.

In the present era, Obesity (*Sthaulya*) has a great impact on Infertility. *Sthaulya* is the abnormal and excess accumulation of *Medodhatu*, occurring due to irregular dietic habits, sedentary lifestyle etc., where in only *Medo Dhatu* is nourished and other *Dhatu*s are deprived of nourishment.

*Acharya Sushruta* has mentioned, *Sthaulya* as a *Rasanimitaja Vikara* and *Artava* being an *Upadhatu* of *Rasa Dhatu* also gets affected. It is usually noticed that women with an increasing BMI value, there is increased risk of Anovulation. Its major effects include hormonal imbalance, reduction in ovulation rate, menstrual irregularities, decreased pregnancy rate.<sup>[4]</sup>

It is estimated that the prevalence of obesity in women with PCOS is 35-63%. It has also been shown that there is a relative risk of Anovulatory Infertility in amongst the obese population is 2.7%.<sup>[5]</sup>

*Acharya Sushruta* has mentioned that, to achieve a fruitful conception four factors are essential, those are *Rutu* (Fertile period), *Kshetra* (Healthy Reproductive organs), *Ambu* (Proper nutrient fluid ) and *Beeja* (Ovum / Sperm ). Defect in any one of these can cause *Vandhyatwa*. In these four factors, one of the important factor is '*Beeja*' which is directly related to Ovulation process. Any abnormalities in this *Beeja* might result into Ovulatory dysfunctions and the absence of this *Beeja* in women is termed as Anovulation. The main reason for ovulatory dysfunctions is considered to be the vitiation of *Artava* (afflicting menstrual / ovulatory phase) and vitiated *Artava* does not possess healthy *Beeja* (ovum).

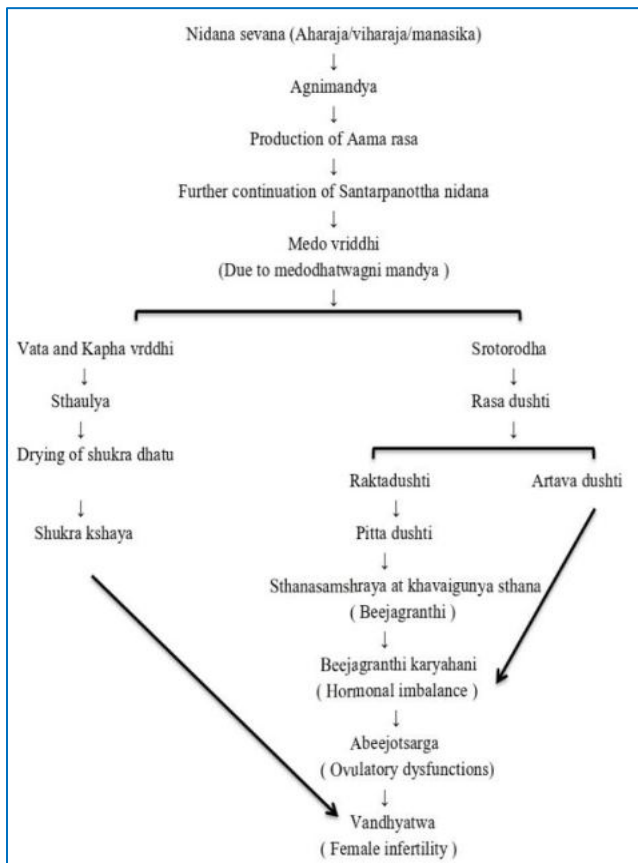
The treatment of ovulation defects in general practice mainly starts with hormonal treatment for ovulation, which might have some adverse effects. In this clinical study a non-hormonal, herbal, safe remedy to treat obesity, menstrual irregularities and ovulation defect was conducted.

In Ayurvedic classics the specific treatment method of administering drug through nasal route is mentioned called '*Nasya*' , as drug administered through *Nasa* goes to the brain and stimulates its functions by the verse, "*Nasa Hi Shiraso Dwaram*". As it is believed that the cells producing GnRH originates from the olfactory area and GnRH is a regulator of Gonadotrophin hormones and all the mechanism of Menstrual cycle is under the control of these Gonadotrophins secreted by Pituitary. Hence in this study an effort was made to assess the efficacy of *Nasya* in induction of Ovulation with *Vishnu Taila*.<sup>[6]</sup> For *Medohara Chikitsa*, *Udvartana* with *Kulattha Churna*<sup>[7]</sup> and *Varanadi Ghana Vati*<sup>[8]</sup> as *Shamana Yoga* was selected, as both have *Apatarpana* effect and *Kapha-Vata Shamaka* properties that may help in disintegrating the *Samprapti* of *Sthaulya*. *Sukumara Kashaya*<sup>[9]</sup> being an excellent remedy for Infertility was selected as an *Anupana*, that helps overcome Menstrual problems and thus regulating Hormonal imbalance.

**Samprapti Ghatakas in Obesity induced Female Infertility**

1. *Dosha: Kapha pradhana, Vata madhya, Hina Pitta*
  - a) *(Vata – Prana, Vyana, Samana, Apana)*
  - b) *(Pitta – Pachaka)*
  - c) *(Kapha – Kledaka)*
2. *Dhatu: Rasa, Rakta, Mamsa, Meda, Shukra*
  - a) *Upadhatu : Artava, Vasa*
3. *Agni: Manda at the level of Koshta and Dhatu*
4. *Srotas: Rasavaha, Raktavaha, Mamsavaha, Medovaha, Shukravaha, Artavavaha*
5. *Srotodushti: Sanga*
6. *Udbhavasthana: Ama - Pakvashaya*
7. *Adhishtana: Garbhashaya*
8. *Vyakta sthana: Yoni, Garbhashaya.*
9. *Sancharasthana: Rasayani*
10. *Rogamarga: Abhyantara*

**Flow chart of probable Samprapti of Sthaulya Janita Vandhyatwa**



**OBJECTIVES**

To study the comprehensive effect of *Apatarpana Chikitsa (Udvartana)*, *Shodhana Chikitsa (Nasya Karma)*, *Shamana Chikitsa (Varanadi Ghana Vati and Sukumara Kashaya)* in induction of Ovulation in obesity induced infertility.

**MATERIALS AND METHODS**

1. *Kulattha Churna for Udvartana Karma*
2. *Murchita Tila Taila for Mukhabhyanga.*
3. *Vishnu Taila for Nasya Karma.*
4. *Varanadi Ghana Vati as Shamanaushadhi.*
5. *Sukumara Kashaya as Anupana.*

**Intervention**

<b>Udvartana</b>	<i>Kulattha Churna</i> was carried out for 3 months / 3 consecutive cycles for 7 days.
<b>Nasya Karma</b> [Purva Karma, Pradhana Karma and Paschat Karma were Observed]	<i>Nasya</i> with <i>Vishnu Taila</i> was carried out for 7 days from the next day of cessation of menstruation for 3 months / 3 consecutive cycles respectively.
<b>Shamanoushadhi</b>	<i>Varanadi Ghana Vati</i>
Dose	1 tab TID (500mg) after food
Duration	3 consecutive cycles / 3 months
Anupana	<i>Sukumara Kashaya</i>

**Treatment Duration:** 3 Consecutive cycles / 3 months.

**Follow-up:** Once in 15 days.

**Study design:** Comprehensive Clinical Study.

**Sample size:** Minimum of 30 subjects fulfilling the Diagnostic and Inclusion criteria were selected for the study.

**Selection Criteria**

Patients suffering from Primary and Secondary Infertility along with Moderate Obesity fulfilling the inclusion criteria and willing to participate in the study were registered.

**Inclusion Criteria**

- Subjects who had no issues within 2-10 years of married life were included.
- Primary and Secondary infertility with or without Anovulatory cycles.
- Subjects belonging to Age group between 18-35 yrs.
- Subjects with Moderate Obesity and B.M.I between 25-30.
- Subjects suffering with a history of P.C.O.D.
- Subjects fit for *Udvardana* and *Nasya* were included for the study.

**Exclusion Criteria**

- Subjects who do not fulfill the inclusion criteria were excluded from the study.
- Subjects with Severe obesity with B.M.I > 30.
- Disorders of reproductive tract such as Congenital anomalies, Tuberculosis, Carcinoma.
- Subjects suffering with any Chronic illness, Uncontrolled Thyroid abnormalities and systemic diseases.
- Infertility due to tubal blockage, PID, Uterine polyp or Fibroids, Endometriosis.
- Subjects suffering with HIV/VDRL/HBsAG/STD's were excluded.

**Parameters of the study**

Following subjective and objective criteria were considered for the study.

**Subjective parameters**

1. Menstrual Irregularities.
2. Quantity of bleeding.

3. Vaginal Secretion.

**Objective parameters**

1. Follicular size.
2. Endometrial thickness.
3. Body mass index

**Investigations**

- USG Pelvis for follicular study will be done from 12th day of Menstrual cycle till the attainment of Ovulation on alternate days.
- Routine Blood Investigations : Hb%, TC, DC, ESR, HIV / HBsAG / VDRL.
- Trans - vaginal sonography (If needed)
- HSG (If needed)
- UPT (If needed)

**Assessment Criteria**

Subjective and Objective parameters Before, During and After treatment was analyzed and a final conclusion was drawn using appropriate statistical methods. The results were categorized as;

1. Marked relief : Above 75 % improvement
2. Moderate relief : 51% - 75% improvement
3. Mild relief : 25% - 50% improvement
4. No relief : Below 25% improvement

**RESULTS**

Effect of therapy on different parameters such as Subjective and Objective parameters were assessed and obtained results were Statistically analyzed by applying student paired “ t ” test.

**Effect of therapy on Subjective parameters**

**Table 1: Showing the effect on Menstrual irregularities**

Parameter	B T	A T	Me an	% Rel ief	SD	SE	t	p	Rema rks
Menstrual irregularity	11	2	0.3	81.82 %	0.47	0.085	3.53	< 0.01	Significant



**Table 2: Showing the Effect on Quantity of Bleeding**

Parameter	B T	A T	Mean	% Relief	SD	SE	t	p
Quantity of bleeding	9	3	0.2	66.67%	0.41	0.07	2.85	< 0.001
< 0.01 = Significant								

**Table 3: Showing the Effect on Vaginal secretion**

Parameter	B T	A T	Mean	% Relief	SD	SE	t	p
Vaginal secretion	8	3	0.16	62.5%	0.38	0.07	2.28	< 0.05
< 0.05 = Significant								

**Effect of therapy on Objective parameter**

**Table 4: Showing the Effect on Follicular size**

Parameter	B T	A T	Mean	% Relief	SD	SE	t	p
Follicular size	77	34.92	1.4	54.65%	0.47	0.08	17.5	< 0.001
<0.001 = Highly significant								

**Table 5: Showing the Effect on Endometrial thickness**

Parameter	B T	A T	Mean	% Relief	SD	SE	t	p
Endometrial thickness	54	19.56	1.14	63.78%	0.49	0.09	12.66	< 0.001
<0.001 = Highly significant								

**Table 6: Showing the Effect on Body mass index**

Parameter	B T	A T	Mean	% Relief	SD	SE	t	p
Body mass index	65	29.59	1.18	54.48%	0.41	0.07	16.85	< 0.001
<0.001 = Highly significant								

**Table 7: Showing the Overall effect of study on 30 subjects**

Relief	No of patients	Percentage	Remarks
Fertility	02	6.66 %	Conceived
Above 75 %	01	3.33 %	Marked relief
51 to 75 %	25	83.33 %	Moderate relief
25 to 50 %	04	13.33 %	Mild relief
Below 25%	00	00 %	No relief

**DISCUSSION**

**Probable mode of action of Udvartana Dravya (Kulattha Churna)**

Kulattha has Kashaya Rasa, Laghu, Ruksha, Teekshna and Ushna Guna, Lekhana and Bhedana Karma. By virtue of these properties, it acts as Kapha-Vata Shamaka as well as Medoghna, which may help in removing the Srotorodha and thereby normalizing the flow of Vata and at the level of Apana Vata it may help in regularizing the menstrual cycle and treats Sthaulya too.

**Probable mode of action of Udvartana Karma**

The reason for selecting Udvartana in Obesity induced Female infertility was because, it is a proven remedy for many of the metabolic and life style disorders. It

acts as *Kapha-Vatahara*, does *Medas Pravilayana* (Liquifies and mobilizes the stagnant morbid medas) thereby opens up the blocked channels (*Srotavarodha*), blood vessels and transport systems of the body, thus enables free circulation of nutrients in the body.

*Udvartana* with *Ruksha gunatmaka*, *Kashaya Rasapradhana Dravyas* would be more beneficial for *Sthaulya*. Thus the drug possessing these qualities i.e *Kulattha* was used and it could be a proven beneficial/remedial therapy for *Sthaulya Roga*.

In *Udvartana*, due to increased friction to all parts of the body, the increased *Meda* is depleted and the increased *Ushma* / heat generated during the *Udvartana Karma* digests the *Ama*, thus clearing the obstruction in the *Srotas* (*Srotoshodhana*) and hence correcting the *Agnimandhya* which in turn reduces the *Sthaulya*. By the virtue of the above said properties of *Kulattha Churna*, it helps in reducing the excess *Meda* and *Kleda*, and in *Udvartana Karma* as the *Churna* is rubbed in opposite direction of the hair follicles, Hyperthermia is induced and transdermal drug absorption takes place. Hyperthermia thus produced improves local blood and lymphatic circulation and thereby improving local tissue metabolism.

One of the function of *Udvartana Karma* is “*Sthirikaranam Angaanaam*” and in classics it is mentioned that *Garbhashaya* is one among the *Koshtangas* and probably by doing *Udvartana Karma* the Uterus is strengthened and it can hold a Pregnancy till full term and the risks of Miscarriages could be avoided.

#### Discussion on probable mode of action of Nasya Karma

The reason for selecting *Nasya Karma* for the present clinical study was that, the Ovulatory dysfunction is mainly related with the irregular menses, failure to ovulate consistently, and often excessive weight gain that is difficult to control. In Female infertility we mostly come across hormonal imbalance as the most

important cause and all the hormonal regulation is under the control of the brain, specifically the Pituitary and the Hypothalamus. Hence for the present study, *Nasya* was selected for the treatment to mainly target the hormonal control, as in Ayurvedic classics, *Nasa* (nose) is said to be the gateway to *Shiras* (brain) because of which the drug administered through nose reaches the brain there by normalizing the hormonal imbalance and improving the chances of Conception. And in modern science, it is given that the cell producing GnRH originate from the olfactory area and GnRH is a regulator of gonadotropin hormones. So considering this relation into the mind, it has been tried to see the effect of *Nasya Karma* on *Ovulation*.

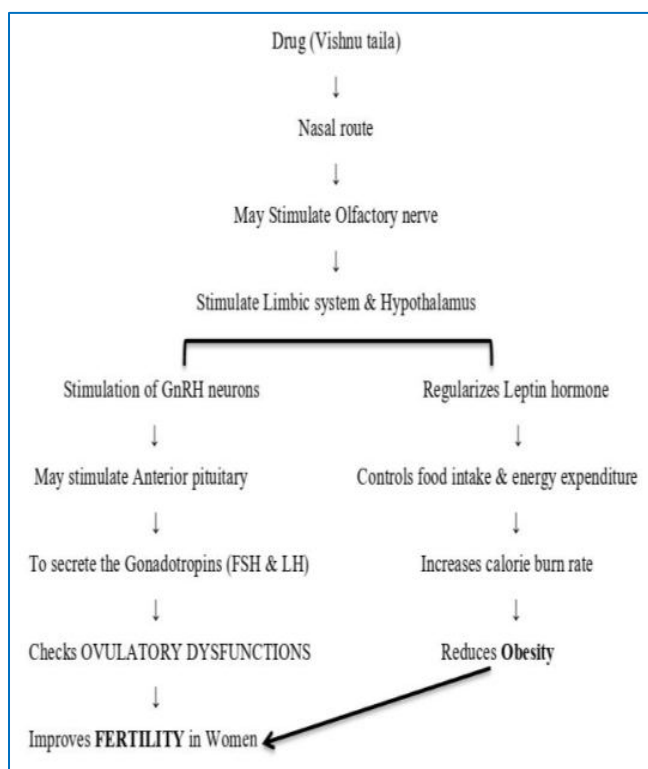
#### Discussion on probable mode of action of Nasya Dravya (Vishnu Taila)

*Taila* is also said to be *Vatakaphashamaka*. As in this condition there is *Vata Pradhana Tridoshaja Dushti*. *Taila* would be the best media for the treatment. So, here *Nasya* with *Vishnu Taila* was selected.

*Vishnu Taila* is more of *Katu Rasa Pradhana* which is *Agni and Vayu Mahabhuta Yukta* and secondly *Madhura Rasa Pradhana* which is *Prithvi Aap Mahabhutayukta* that might help in breaking up the *Samprapti* of *Sthaulya Janita Vandhyatwa*, that is *Katu Rasa* takes care of vitiated *Kapha* and *Madhura Rasa* checks *Vatadushti*. Apart from this, it acts by the virtue of its *Guna* which is more of *Laghu, Ruksha* and *Teekshna Gunas* that helps in clearing the *Srotoshodhana* at the level of *Rasavahasrotas* which in turn corrects the *Rakta Dushti (Uttarottara Dhatu)* and *Artava Dushti (Upadhatu of Rasa Dhatu)* by counter acting on *Guru* and *Snigdha Guna* of *Kapha*.

Maximum drugs in *Vishnu Taila* are of *Ushna Veerya* that acts as *Vatakaphahara* like *Eranda, Brhati, Kanthakari, Chirabilva, Shalaparni, Prshniparni* which might act at the level of *Prana Vata* and checks the Hormonal imbalance hence, regularizing the Leptin hormone<sup>[10]</sup> which hampers the normal functioning of the reproductive hormones (FSH and LH).

### Schematic representation of probable Mode of action of Vishnu Taila



### Probable mode of action of Varanadi Ghana Vati as Shamanaushadhi and Sukumara Kashaya as Anupana

In Ayurveda, the main line of treatment explained for any *Santarpanottha Vikara* is *Apatarpana Chikitsa* where *Ushna* (hot potency), *Teekshna* (penetrating), *Kaphahara*, *Medohara* drugs are administered. Ayurveda classics have quoted the use of *Varanadiganaprayoga* in the management of *Sthaulya*.

Considering the *Doshaghna Karma* of the drug, majority of the drugs in the *Yoga* are *Kaphavatahara* in nature. Drugs like *Varana*, *Chitraka*, *Brihati*, *Pootikaranja*, *Pathya Kantakari* etc. are having *Deepana - Pachana* properties. As *Sthaulya* is a *Kapha Pradhana Vyadhi*, *Varanadi Ghana Vati* having the above said properties helps in *Samprapti Vighatana* of *Sthaulya*.

In *Sthaulya*, both *Jatharagni* and *Dhatvagnis* are affected and *Ama* formation takes place. Due to the *Ushna*, *Teekshna* and *Deepana-Pachana* properties of

the drug, the *Agni* gets normalized, Proper *Dhatu Pachana* takes place, and it reduces the chances of excess *Meda* formation thereby preventing the chances of *Sthaulya* and also there is proper nourishment to all the other *Dhatu*s because of which they perform their normal physiological functions.

*Sukumara kashaya* was selected as *Anupana* for the present study. As *Anupana* enhances the properties of the medicine and helps in circulation of the drug, *Sukumara Kashaya* when administered with *Varanadi Ghana Vati* would probably correct the *Agni Dushti* and does *Srotoshodhana*. It contains drugs like *Punarnava*, *Dashamoola*, *Aaragvatha*, *Eranda*, *Darbha*, *Sara*, *Kasha*, *Ikshumoola*, *Mundi* along with *Saindhava* and *Guda*. Majority of drugs are *Madhura Rasa*, *Pitta* and *Vata Shamaka* in nature. It might also help in regulating *Apana Vata*, thereby improving the functions of *Artava* and ultimately correcting the Menstrual and Ovulatory functions.

### CONCLUSION

Female Infertility is the common global problem and is the leading cause of marital upset, personal unhappiness and ill health. It is seen that one third of the infertile population seeking advice from the infertility clinics shows ovulatory dysfunctions. In the present era, Obesity has become a leading cause for infertility in couples. Its major effects include Hormonal imbalance, Reduction in ovulation rate, Menstrual irregularities, Decreased pregnancy rate etc. About 40% women suffering from infertility due to ovulatory dysfunction can be considered under *Beeja Dushti* (Most essential factor is *Beeja*, amongst four factors described by *Acharya Sushruta*). All *Yonirogas* (including *Vandhyatva*) are due to *Vata Dosh*a, but in the present study as infertility is being studied in moderate obese individuals, the vitiation of *Kapha* and *Medovridhi* is also evidenced which are mainly responsible for *Rasa* and *Artava Dushti*, thus the Menstrual and the Ovulatory functions are deranged. *Udvartana* done with *Kulattha Churna* has *Kapha - Medohara* properties and *Vishnu Taila* used as *Nasyartha* has *Tridosha Shamaka* properties as well as *Rasayana*, *Balya*, *Vrushya* effect, so it is very much



effective in infertility. Hence both these therapies and the drugs used were helpful in reverting the *Samprapti* of *Sthaulya Janita Vandhyatwa*. Very encouraging results were found on Subjective parameters such as Menstrual irregularities, Quantity of bleeding, Vaginal secretions and also on Objective parameters i.e. Follicular size, Endometrial thickness and Body mass index with the therapies advocated.

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