



# A RANDOMIZED CONTROLLED CLINICAL STUDY ON THE EFFECT OF *ASHWAGANDHA* *TAILA MATRA BASTI* IN *NASHTABEEJA* (ANOVULATION)

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## ABSTRACT

Ovulation refers to the physical act of rupture of the follicle with extrusion of the oocyte. When follicle does not rupture then ovulation failed and that is called anovulation or *Beejopaghata* or *Nastabeeja*. Ovulation failure is not only headache of this era but also was a problem in the ancient period. All Acharyas have mentioned *Beeja dosha* with *Beejopaghata* is a factor for *Vandhyatva*. *Revati jatharini (pushpaghani)*, *ashtartava dusti*, *avarana*, *beeja dusti*, *Shandhi yonivyapad*, *vandhya yonivyapad*, *mitya aahara*, *vihara*, *Use of tikshana virechana in mridukoshtha*, *artavaha sroto viddhata* are the causes of *beejopghata*. *Artava Kshaya* and its treatment which described in ayurvedic texts indicates both for menstrual cycle and ovulation.

Ayurveda is a proven age-old science of life and it has its own natural scientific approach regarding to line of treatment. Lots of causes of *Vandhyatva* is given in Ayurvedic text including *Nastabeeja* or Anovulation. Ovulation is regulated by *Apana vata*. *Basti* is the main treatment for *Vata shamana*. Among the *Dravyas* which does *Vata shamaka*, *Taila* is best for *Vata*. In Kashyapa Samhita in the *Phala shruti* of *Anuvasana basti* it is mentioned as "*Alpapushpa Nashtapushpa Nashtabeeja Akrmanyabeeja pareeta anuvasya iti*". *Aswagandha taila* is explained in *Bhaishajya Ratnavali*, *vajeekarana adhyaya* as *Stana linga vardhana*. The effect of *Tila taila Matra Basti* has been proven already. So, it is taken in Controlled group.

**Key words:** Nashta beeja; Anovulation; Matrabasti; Vandyatwa; Aswagandha; Beejadosha

## INTRODUCTION:

Infertility is a global reproductive issue that affects both males and females, but it is rarely discussed in public and is often overlooked. It has been neglected in the context of a health issue, and it is also a topic for social science research in South Asia, or more broadly in the developing world.

The word "Artava" denotes two meanings, one of them is "Bahirpushpa" and another one is Antahpushpa. Both Bahirpushpa and Antahpushpa are interrelated. Bahirpushpa is outward manifestation of appropriate work of Antahpushpa, which is necessary for conception. Here the present study deals with "Antahpushpa" ie; Ovum. From the four essential factors for garbha i.e. Rutu, Kshetra, Ambu, and Beeja, the woman is responsible for the

two important factors i.e. Kshetra and Beeja. Rutu also related to the Rutukala of the woman. The union of Beeja of the both side i.e. Shukra and Artava (ovum) with Atma inside the kukshi is called garbha. So, the Beeja is the core stone of the female reproductive process and absence of this factor, Garbha cannot occur inspite of the proper Rutu, Kshetra and Ambu.

Now it is seen that one third of the infertile population seeking advice of infertility clinics show ovulation failure, means absence or delayed or premature rupture of Stree Beeja (ovum) in Rutukala. Ovulation refers to the physical act of rupture of the follicle with extrusion of the oocyte. When follicle does not rupture then ovulation failed and that is called anovulation or Beejopaghata or nastabeeja. Ovulation failure is not only headache of this era but also was a problem in the ancient period. All Acharyas have mentioned Beeja dosha with Beejopaghata is a factor for Vandhyatva. Artava Kshaya and its treatment which described in ayurvedic texts indicates both for menstrual cycle and ovulation. Acharya Kashyapa has described that Revatigraha, misuse of Pancha Karma and manasika vayadhis as cause for nastabeeja.

Various conventional techniques are presently used to overcome female infertility due to ovulatory failure. Application of ovulation-inducing drugs depends on the type of anovulatory disorder; for example, in the case of hypogonadotropic hypogonadism, gonadotropins and pulsatile gonadotropin-releasing hormone (GnRH) therapy is preferred. Previously, human menopausal gonadotropins, a mixture of follicle-stimulating hormone (FSH) and luteinizing hormone (LH), were used. However, at present, more expensive but purer forms of recombinant gonadotropins are recommended. Over last decades, fertility therapy has expanded more than any other field of medicine. Hormonal therapy, In vitro Fertilization (IVF), Embryo Transfer, (ET), Gamete Intrafallopian Transfer (GIFT) etc so many therapies are developed, but they have unsatisfactory results, enormous expenses and lots of side effects like ovarian hyper stimulation, frequent abortion, multiple gestations and major long-term possibility of ovarian cancer. Even after recent progress in ART, many couples are unable to parent healthy babies except through gamete donation or adoption. In this respect, stem cells have shown new hope to overcome the issues related to infertility in the form of cell-based therapies in various experimental preclinical and clinical models.

In this scenario comes the esteem importance of ayurveda science. Ayurveda is a proven age-old science of life and it has its own natural scientific approach regarding to line of treatment. Lots of causes of Vandhyatva is given in Ayurvedic text including Nastabeeja or Anovulation. Now a days people have accepted Ayurveda and endorsed their faith in this branch of medicine, which occupies its prominence in the naturally available herbs. These untouched therapies and medicinal concepts are lying idle in Samhitas and wanting to be tapped in today's highly scientific world of medicine. The drug of choice has explained as stana linga vardhana but the effect of the drug shows its action on arthava also and matrabasti and its effect in ovulation can also be studied in detail. In this study moorchitha tila taila matrabasti is taken as controlled group as its efficacy is already proven and studies have been done on that . So here patients with nashtabeeja are selected and administered Ashwagandha Taila matrabasti to prove its efficacy and also to compare its efficacy with Tila taila matrabasti.

## AIMS AND OBJECTIVES

- To evaluate the efficacy of *Aswagandha taila Matra Basti* in *Nastabeeja* (Anovulation)
- To compare the efficacy of *Aswagandha taila Matra Basti* with *Tila taila Matra Basi* in *Nashtabeeja* (Anovulation)

## METHODOLOGY

### Study design

A Randomized Controlled Clinical Trial

### Ethical clearance

Ethical clearance was obtained from the ethical committee constituted in Alva's Ayurveda Medical college, Moodbidri. The aims, objectives and methodology were explained to the committee and the clearance was obtained

**Informed consent**

Written consent was obtained from each patient who has participated in the study after explaining the details

N o	DRUG	BOTANICAL NAME	RASA	GUNA	VIRYA	VIPAKA	DOSHA KARMA	OTHER KARMAS	PART USED
1	ASWAGANDHA	Withania somnifera	Katu Tikta Kashya	Snigdha, laghu	Usna	Katu	Vata kapha hara	Balya, rasayana, sukrala	Root/leaf
2	SHATAVARI	Asparagus racemosus	Madhu raTikta	Guru,snig gdha	Sita	Madh ura	Vata pittahara	Rasayana, vrsya, stanaya janana	Tuberous root
3	KUSTHA	Sausseria lappa	Tiktha Katu Madhu ra	Laghu, ruksha	Usna	Katu	Vata kapha hara	Lekhanya vrsya	Root
4	JATAMANSI	Nardostach ys jatamansi	Tikta, Kashay amadh ura	Laghu, snigdha	Sita	katu	Tridosha hara	Medhya Balya	Rhizome
5	BRUHATI	Solanum indicum	Katu, tiktha	Laghu Ruksha, Tiksna	Usna	Katu	Kapha vata hara	Mutrala sukra rechaka	fruit

**Sample size:** Minimum of 40 patients fulfilling the diagnostic criteria were selected.

**Sampling method:** Simple Random Sampling (Lottery method)

**Selection criteria:** The cases were selected according to inclusion and diagnostic criteria.

According to the inclusion and diagnostic criteria subjects were assigned randomly into two groups, Group A and Group B.

**Drug source:** Raw drug required were collected from the local market and Alva's pharmacy, under the supervision of Dravya Guna experts and medicine was prepared at Alva's pharmacy, Mijar.

**Table no 1 : Showing properties of Ashwagandha taila**

**DIAGNOSTIC CRITERIA**

1. Anovulation for at least 2 previous consecutive cycles
2. Primary or Secondary infertility

**INCLUSION CRITERIA**

1. Age group: 20 – 40 years.
2. Anovulation for at least 2 previous cycles
3. Primary or secondary infertility with anovulatory factor

**EXCLUSION CRITERIA**

1. Patient on oral contraceptive pills
2. Patients who are taking medications for ovulation induction
3. Bleeding p/v
4. Active pelvic infections
5. Disorders of reproductive tract – Cervical tumours, Polyps, Tuberculosis, Carcinoma, Congenital deformities
6. Endometriosis
7. Patients suffering from other Chronic illness, Cardiac diseases, Thyroid disorders
8. Infertility associated with other factors like Tubal blockage, Uterine factors, Cervical factors, Vaginal factors.

**INTERVENTION**

The subjects who have been screened and have met the diagnostic and inclusion criteria,

**Table no 01: Intervention of drug**

	<b>GROUP A</b>	<b>GROUP B</b>
<b>Medicine</b>	<b>Tila taila</b>	<b>Ashwagandha taila</b>
<b>Dose</b>	72 ml	72 ml
<b>Time of administration</b>	After food	After food
<b>Mode of administration</b>	Rectal route (Matra basti)	Rectal route (Matra basti)
<b>Duration of medication</b>	Starting from 6 <sup>th</sup> day of menstruation,  8 days, for 2 consecutive cycles	Starting from 6 <sup>th</sup> day of menstruation,  8 days, for 2 consecutive cycles

**ASSESSMENT PARAMETERS****Table 2; Assessment parameter 1 (IRREGULAR PERIODS)**

<b>IRREGULAR PERIODS</b>	
NO	0
YES	1

**Table 3; Assessment parameter 2 (INTERVAL BETWEEN THE CYCLES)**

INTERVAL BETWEEN THE CYCLE	
criteria	score
<21 days	1
21-35 days	0
>35 days	1

**Table 4: Assessment parameter 3 & 4 (FOLLICLE SIZE & ENDOMETRIAL THICKNESS)**

USG			
Follicle size (mm)		Endometrial thickness (mm)	
Criteria	Score	Criteria	Score
<12	0	<7	0
12-19	1	7-9	2
19-23	2	10-14	3
Ovulated	3	>14	1

**PROCEDURE OF MATRA BASTI****POORVA KARMA**

- Preparation of patient
- Local *Abhyanga* and *Swedana* done
- Patient is asked to evacuate bladder
- Patient is Asked to have food
- Patient is made to lie in the left lateral position with the right leg flexed and left leg straight.

## Preparation of medicine

- 72 ml of *Ashwagandha taila* is taken and made little hot (water bath) and kept.

## PRADHANA KARMA

- Lukewarm oil taken in syringe of appropriate size
- The tip of the syringe is smeared with oil
- The anal orifice is lubricated with oil
- Tip of the syringe is then introduced into the anal canal
- When all the oil is pushed into the rectum, the syringe is gently pulled out.

## PASCHAT KARMA

- *Sphik Tadana* is done
  - Patient is made to lie on supine position
- Patient is made to rise the legs by flexing the hip 3-4 times

**STATISTICAL ANALYSIS**

- Central tendencies and dispersions were measured using Mean, Median, Standard Deviation, Standard Error and Quartiles.
- Test of significance was done using Wilcoxon signed-rank test and independent t test

**Assessment of total effect of therapy****Table 5: Comparative results of Group A and Group B**

Overall Result After follow-up							
Parameters	GROUP A		GROUP B		TEST STATISTICS		
	Mean Score	±SD	Mean Score	±SD	Z	P	Remarks
Irregular periods	0.30	0.470	0.20	0.410	0.72	0.471 (>0.05)	NS
Interval of cycles	0.25	0.444	0.15	0.366	0.78	0.435 (>0.05)	NS
Follicle size	2.25	0.550	2.50	0.688	1.51	0.131 (>0.05)	NS
Endometrial thickness	7.40	1.211	7.48	0.758	0.25	0.804 (>0.05)	NS

**Table no 6: The overall effect of treatment in Group A and Group B**

Overall Response After Treatment					
Response Grouping	Response	GROUP A		GROUP B	
		No. Of Subjects	%	No. Of Subjects	%
(0%-25%)	Poor Response	2	10%	1	5%
(26%-50%)	Mild Response	3	15%	2	10%
(51%-75%)	Moderate Response	6	30%	4	20%
(76%-100%)	Marked Response	9	45%	13	65%
Total		20	100%	20	100%

## DISCUSSION AND RESULTS

According to acharya Charaka, Basti is the best treatment for vata prakopa, *Bastivataharanam sreshtam* and there is no stree roga where involvement of vata dosha is not there. Matra Basti is one of the type of Anuvasana Basti which is Balya, Bruhmana, Vatarogahra and can be used without any complications Sneha basti is indicated in *Alpapushpa, Nastapushpa, Nastabeeja Akarmanayabeeja* conditions.

According to modern, Rectal administration of drugs partially avoids hepatic first pass metabolism. The superior rectal vein which peruses the upper part of the rectum drains into the portal vein and subsequently into the liver whereas the middle and inferior rectal veins drains the lower part of the rectum and enter into the inferior vena cava and bypass the liver before entering the general circulation so rectal administration of medicines are much beneficial.

### Properties of *Aswagandha taila*:-

Aswagandha taila is explained in Bhaishajya Ratnavali, vajeekarana adhyaya as Stana linga vardhana. Garbhasaya has direct connection with Urdhwagami Dhamanis. These Dhamanis carries Artava throughout the life except during lactation. So Stana Vardhaka dravyas has direct effect on Artava also. The drug used for Aswagandha taila nirmana are mostly of Madhura-Katu rasa, Ushna virya and having Katu Vipaka with Laghu and Snigdha Guna. It can be said that due to Laghu guna is easily absorbable and it can enter every part of the cells easily. So by these qualities, it nourishes the body. It has also regeneration capacity. Due to proper nutrition and *vatanulomana* follicle starts to get mature as we observed increase in size of follicle and after getting maturity rupture of follicle also occurs. This is the probable mode of action of drugs because *Acharya Charaka* said that-dravya can acts by its *rasa, guna, virya, vipaka* and *prabhava* also.

### Probable mode of action of tila taila

Tila taila has several properties that beneficial for artava janana. Its having Madhura rasa, snigdha guna, and vata hara karma

It has Sukshma guna which helps to dilate channels and allow for normal menstrual blood flow. Tila taila nourishes and strengthens all dhatus and thus alleviates vata.

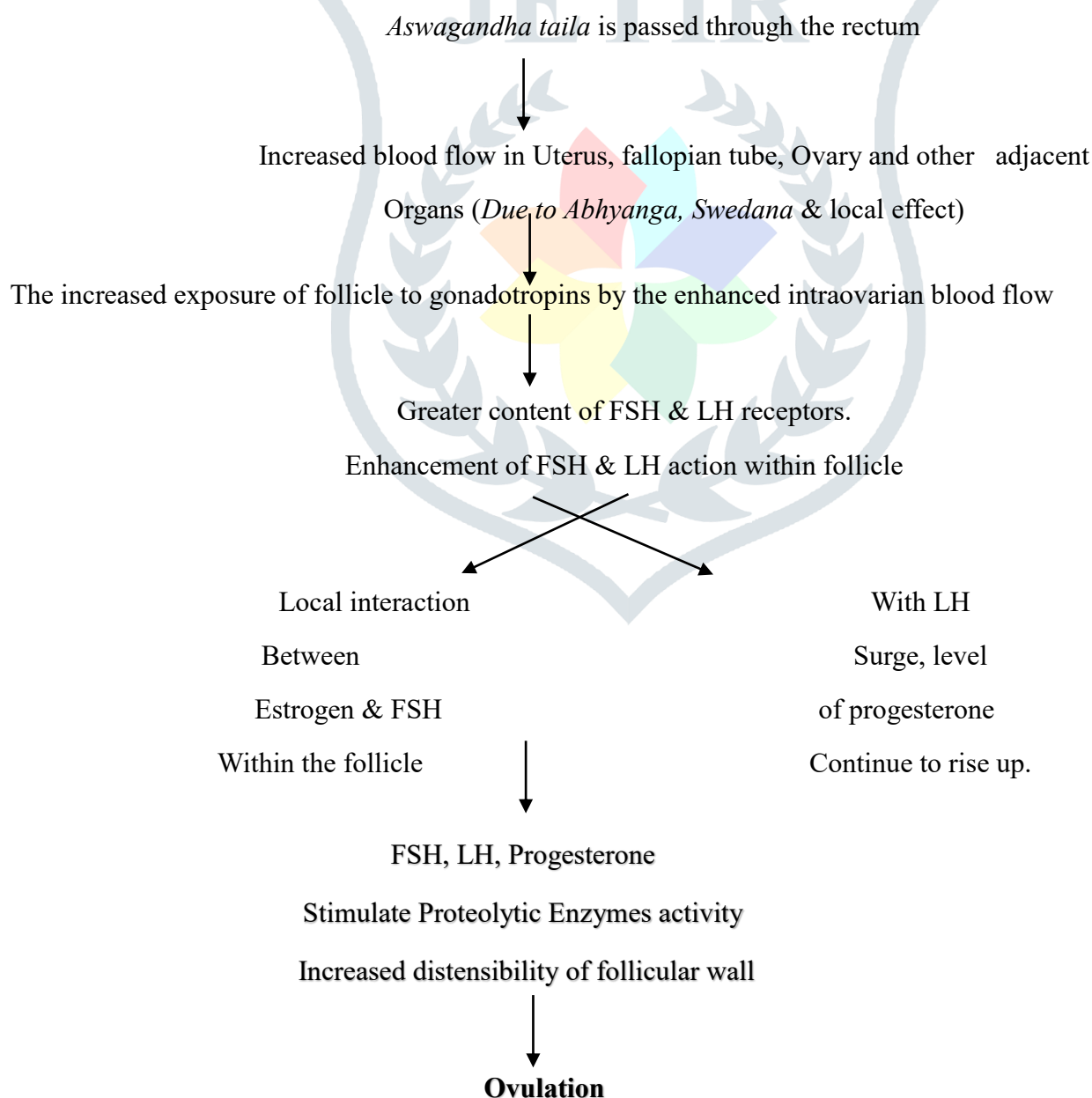
It also possess Snigdha and Guru guna which decreases Rukshata. Tila taila is having proven actions on *Artava janana, Garbhasaya shodhana, Vrushya, Yonishoolahara karmas*.

Tila Taila's efficacy in anovulation stems from its rich chemical constituents:

1. Sesamin and sesamolin (lignans): Estrogenic properties, enhancing follicular growth and ovulation.
2. Vitamin E (tocopherol): Antioxidant, protecting ovarian tissue from oxidative stress.
3. Fatty acids (oleic, linoleic, and palmitic): Nourishing reproductive tissues, regulating hormone production.
4. Phytosterols (beta-sitosterol): Hormone regulation, improving ovulatory function.
5. Sesquiterpenes: Anti-inflammatory, reducing inflammation-related ovulatory dysfunction.

Tila Taila's chemical constituents work synergistically to:

- Regulate estrogen-progesterone balance
- Enhance follicular growth and maturation
- Stimulate ovulation
- Reduce oxidative stress and inflammation
- Nourish and rejuvenate reproductive tissues



Flow chart 1: Mode of action on Ashwagandha taila in matrabasti form

**PROBABLE MODE OF ACTION OF ASWAGANDHA TAILA (BY MATRA BASTI)**

Vata is mainly responsible for all types of Yonirogas and Artava Vikaras. Nastabeeja is Vata pradhana tridoshaja vyadhi. Basti is considered as best Chikitsa of Vata. According to Acharya Kashyapa for Nastabeeja, Anuvasana basti should be given, *Alpapushpa Nastapushpa Nastabeeja Akarmanayabeeja pareetaa Anuvaasya iti*. Aswagandha taila has tridosha shamaka specially Vatashamaka, Artavajanana, Deepana, etc properties hence Aswagandha taila is effective in this condition.

According to Acharya Parashara, "Guda is the root of the body". So, drug which is given by anal route having local and general effect. Apana Vayu is situated at Shroni (Pelvic organ like anal canal, Utero vaginal channel etc., urinary bladder, penis etc.) and it excretes the Dhatu, Upadhatu and Mala from respective Ashayas. There by Matrabasti along with properties of drug i.e. Madhura Rasa, Guru, Snigdha Guna, Ushna Virya etc. favours Vata shamana, Anuloma gati of Vata. Basti directly pacifies Apana Vayu which in turn brings back the Agni in normal condition and also controls the Samana Vayu and also because of Vata shamana, Apana Vayu functions normally and helps in proper Pravritti of Artava.

Due to Vatashamana and Anuloma gati of Vata, Pitta and Kapha comes to equilibrium in its place. Agni is improved due to Deepaneeya, Pachaneeya function of Tikta Rasa, Ushna Virya drugs. Proper function of Agni leads to Samyaka ahara pachana and Rasa Raktadhatu Nirmana. Samyaka, utpatti of Rasaraktadi dhatu favors samyaka utpatti of Upadhatu Artava.

On the other hand when basti veerya is spread all over body and sneha because of its sukshma guna, it spreads macro and micro channels of Srotasa, then it pacify all doshic vitiation along with Vyana Vayu. That's why total Rasa Rakta Chankramana will be done properly, so its upadhatu Artava also functions properly. Matra Basti given through Guda (rectal route) normalizes Apana Vayu leading to Vatanulomana and physiological functioning of Vata, which may help in turn for the extrusion of ovum from the follicle and ovulation. Basti Dravya spreads all over the body, pacifies the aggravated Dosha along with Vyana Vayu leads to Samyaka Rasa Raktadi Dhatu Nirmana. Sukshma Bhaga of Rasa reaches the Beejagranthi, which regularizes the Beejotsarga with the help of normal Apana Vayu.

Matra Basti after absorption reaches into systemic circulation and the Central Nervous System (CNS) & Enteric Nervous System (ENS). The endogenous opioids in the ENS specially endorphins ( $\beta$ -endorphin) are influenced which will affect GnRh release regularizing HPO axis regulating ovarian cycle and ovulation. Endogenous opioids are a group of peptides, which play an important role in the ovarian cycle through the inhibitory effect on GnRH secretion. Other pituitary hormones are also modulated by opiates.  $\beta$ -endorphin has been best known of the opioid related to the reproductive system regulating variety of pituitary hormones including gonadotrophins.  $\beta$ -endorphin has a role in the regulation of the normal ovarian cycle

**CONCLUSION**

*Nashtabeeja*, or anovulation, is a common reproductive disorder characterized by the absence or irregularity of ovulation, affecting approximately 10-15% of women of reproductive age worldwide. Defined as a disruption in

the normal ovulatory cycle, anovulation hinders fertility and increases the risk of hormonal imbalances, polycystic ovary syndrome (PCOS), and other endocrine disorders.<sup>i</sup>

According to ayurvedic medicine, *Nashtabeeja* is attributed to imbalances in the *tridosha*, particularly *vata* and *kapha*, which govern reproductive health. This study investigated the efficacy of *Ashwagandha taila*<sup>ii</sup> *matrabasti*, in managing *nashtabeeja* and restoring ovulatory function and compared its efficacy with *Tila taila matrabasti* which has already proven in ovulatory dysfunction.

The treatment adopted in both Group A i.e, *Tila taila matrabasti* and Group B *Aswagandha taila matrabasti* were found to be effective but when compared to Group A (control group), Group A (trial group) shows better results in normalizing the menstrual abnormalities & ovarian dysfunction clinically,

Statistically both the groups didn't show any significant differences after the course of treatment.

Although the study found no statistically significant difference between the two groups in terms of ovulatory function, menstrual regularity, and hormonal balance ( $p > 0.05$ ), a clinically significant advantage was observed in the Ashwagandha Taila group.

Despite the absence of statistical significance, the Ashwagandha Taila group demonstrated:

1. Higher ovulation rates (88% vs 76% in *Tila Taila* group)
2. Improved menstrual regularity (54% vs 69% in *Tila Taila* group)
3. Enhanced hormonal balance (reduced FSH and increased estrogenic levels)

These clinically meaningful differences suggest that *Ashwagandha Taila Matrabasti* may be a more effective treatment option for *Nashtabeeja*, particularly in patients with mild to moderate symptoms. The method of treatment applied in both the groups was simple, economical and required no hospitalization and could be done at OPD level.

After treatment it was found that most of the patients had ovulation & many patients relived of menstrual symptoms. The more pharmacological action of the drug may be fully established with a large sample size in further research.

So here, **The Null hypothesis is accepted and Alternate hypothesis is rejected**

There is neither statistical significant difference between *Aswagandha taila Matrabasti* and *Tila taila Matrabasti*, nor *Aswagandha taila Matrabasti* is better than *Tila taila Matrabasti* in *Nashtabeeja* (Anovulation).

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