

Effect of *Brihatyadi Yapana Basti* and *Shivalingi* (*Bryonia laciniosa* Linn.) seed powder in the management of female infertility (*Vandhyatva*) due to anovulatory factor: An open-labelled randomized clinical trial

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Abstract

Back ground: Infertility is a global problem that has impact on quality of life, especially through the negative psycho-social consequences. One-third of infertile population attending infertility clinics are reported with anovulation. According to Acharya Sushruta, among four essential factors required for conception, *Beeja* (ovum) is the core stone of the female reproductive process and conception can not be achieved in its absence, despite of other factors. **Aims and Objectives:** To evaluate and compare the efficacy of *Brihatyadi Yapana Basti* (therapeutic enema) and *Shivalingi* (*Bryonia laciniosa* Linn) seed powder in the management of female infertility w.s.r to the anovulatory factor. **Materials and Methods:** Total 30 female patients suffering from infertility due to anovulation confirmed by trans vaginal sonography were enrolled in the present study and randomly divided in two groups i.e., in group A ($n = 15$), *Brihatyadi Yapana Basti* (400 ml) was administered for 15 days after menstruation for 2 consecutive cycles. In group B ($n = 15$) *Shivalingi* seed powder was administered in dose of 3 gms twice in a day with cow milk on empty stomach for 2 months with 2 months followup. The efficacy of the therapy was assessed on the basis of follicular study by trans-vaginal sonography (TVS) on the 12th, 14th, 16th and 18th days of menstrual cycle and/or on the basis of conception achieved. The obtained data was analyzed for statistical significance using Student's *t*-test. **Result:** In the *Brihatyadi Yapana Basti* group, ovulation was found in 80% of the patients and conception rate was 26.66% and in the *Shivalingi* seed powder oral group, ovulation was found in 64.28% patients and conception was not reported. **Conclusion:** It was concluded that *Brihatyadi Yapana Basti* is more effective in follicular growth, ovulation and also achieving conception than that of *Shivalingi* seed powder orally.

Keywords: Anovulation, *Brihatyadi Yapana Basti*, infertility, *Shivalingi* seed powder

Introduction

Infertility is failure to conceive within 1 or more years of regular unprotected coitus.^[1] The male is directly responsible in about 30%-40% and the female in about 40%-55% and both are responsible in 10% in the cases of infertility. According to the FIGO manual (1990), causes of infertility are tubal and peritoneal factor (25%-35%), ovulatory factor (30%-40%) and endometriosis (1%-10%).^[2] Infertility varies across the regions of the world and it has been estimated to affect 8%-12% couples world wide. The WHO has estimated the overall prevalence of primary infertility in India to be between 3.9% and 16.8%^[3] It is of two types: primary infertility refers to couples who have not conceived after at least 1 year having sex without using birth control

methods and secondary infertility refers to couples who have been able to conceive at least once but are unable later. In *Ayurveda*, Acharya Sushruta describes four essential factors for healthy progeny such as *Ritu* (ideal time for conception), *Kshetra* (uterus), *Ambu* (proper nutrition to foetus) and *Beeja* (healthy gametes)^[4] Fulfillment of all the above essential factors ensures motherhood.

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Deficiency in the above factors impedes the conception. Among them, *Beeja* is the core stone of the female reproductive process and in its absence, conception can not be achieved in spite of all the other factors. Here, *Beeja* is taken as *Antahpushpa* i.e., ovum. Hence, anovulation is considered as absence of *Beeja*. The act of ovulation is regulated by *Vata*, especially *Apana Vayu* (mechanism responsible for proper expulsion of ovum). Hence, in *Ayurveda* classics, *Basti* is indicated for correction of *Apana Vayu* which is the main vitiating factor of the reproductive system. *Yapana Basti* is indicated in infertility by Acharya Charaka in *Siddhisthana*.^[5] *Shivalingi* seed powder is having properties like *Balya* (giving strength), *Brihaniya* (nourishing/increasing body strength), *Deepana* (appetizer), *Pachana* (digestive), *Putrajanana* (responsible for reproduction), *Yonishodhana* (regulate female reproductive system), *Rutupravartana* (induce menstruation) and *Prajasthapana* (promotes conception). It also has hepato-protective and anti-oxidant properties, which ultimately helps in regulation of ovarian cycle. Hence, in this study *Brihatyadi Yapana Basti* and *Shivalingi* seed powder were selected.

Aims and objectives

1. Primary objective of the study was to evaluate and compare the efficacy of *Brihatyadi Yapana Basti* and *Shivalingi* seed powder administered orally in the management of female infertility w.s.r to anovulatory factor
2. Secondary objective was to evaluate the efficacy of *Brihatyadi Yapana Basti* and *Shivalingi* seed powder on menstrual abnormalities such as irregular menses or dysmenorrhea.

Materials and Methods

- The females attending the OPD of Prasuti Tantra and Stree Roga, IPGT&RA, Jamnagar, with the history of infertility and fulfilling the criteria of selection, were registered in the study irrespective of caste and religion. Before starting the clinical trial approval was taken from Institutional Ethics Committee vide letter no. PGT/7/-A/Ethics/2016-17/2676
- Before starting the clinical trial approval was taken from Institutional Ethics Committee vide letter no. PGT/7/-A/Ethics/2016-17/2676 (dated 16/11/2016). The study has been registered in CTRI (CTRI/2017/04/008360). Informed written consent from each patient willing to participate before starting the study was taken. The detailed history was filled up in the specially prepared proforma.
- Ingredients of *Brihatyadi Yapana Basti* were procured from pharmacy of Gujarat Ayurved University, Jamnagar and *Shivalingi* seed was purchased from Ayurvedic store of local market of Jamnagar and identified in the pharmacognosy laboratory of IPGT&RA, Jamnagar.

Inclusion criteria

1. Married females having age between 20 to 40 years and having active married life of minimum of 1 year with at least 2 or more consecutive anovulatory cycles.

2. Female with primary or secondary type of infertility due to anovulatory cycle or with immature ovarian follicle
3. Patients eligible for *Basti*.

Exclusion criteria

1. Females having age less than 20 years and more than 40 years
2. Patients suffering from systematic disorders such as hypertension, diabetes mellitus, hypo or hyper-thyroidism and severe anemia, reproductive tract disorders such as tuberculosis, carcinoma, congenital deformities or having sexually transmitted diseases were excluded.
3. Patient not eligible for *Basti*.

Investigation

1. General investigations
 - Hematological – Hemoglobin%, total leucocyte count (TLC), different leucocyte count (DLC), erythrocyte sedimentation rate and packed cell volume were carried out before and after the treatment
 - Random blood sugar was also done before and after the treatment
 - Serological – HIV (human immunodeficiency virus), venereal disease research laboratory and HBsAg (hepatitis B surface antigen) were done before treatment only
 - Urine (routine – microscopic) examination was done before and after the treatment.
2. Specific investigations:
 - Transvaginal Sonography (TVS) for the diagnosis of anovulation was done on 12th, 14th, 16th and 18th days of menstrual cycle
 - Tests for Serum follicle-stimulating hormone, luteinizing hormone, prolactin and thyroid-stimulating hormone were done before treatment and after the treatment.

Treatment protocol

- In the present study, the patients were randomly divided into two groups (group A & group B) as per the computer generated randomization chart. Before starting the treatment for the purpose of improving appetite and proper digestion (*Deepana – Pachana*) and for bowel cleaning (*Koshtha Shuddhi*), *Amapachana Vati* (2 *Vati* thrice daily before meal) and 5gm of *Erandabhrishtha Haritaki* powder once at bed time with warm water was given for initial three days.

Basti was stopped on the day of ovulation, that was confirmed by series of TVS done from USG report

Posology

- Group A: 400ml of *Brihatyadi Yapana Basti* was administered per rectum after the completion of menstrual cycle for 15 day in the morning for two consecutive cycles.

- Group B: *Shivalingi* seed powder was administered 3gm twice a day (8:00 am and 8:00 pm) with cow milk for 2 month before meal.

Basti preparation

For the preparation of *Basti*, 60 ml of *Madhu* (Honey) was taken in mortar and then *Saindhava* (rock salt) 10gm was added and was mixed well for 10 min. Thereafter *Tila Taila* (Sesamum oil) -60ml, *Go-Ghrita* (cow ghee)-60ml, cow milk- 240ml, paste of *Pippali* (*Piper longum* linn), *Madanaphala* (*Randia dumetorum* lam), and *Yashtimadhu* (*Glycyrrhiza glabra* linn.)-15gm, was added and in the end decoction of *Brihati* (*Solanum indicum* linn.), *Kantakari* (*Solanum xanthocarpum* schrad. & wendle), *Guduchi* (*Tinospora cordifolia* (willd) miess), and *Shatavari* (*Asparagus recemosus* willd)-60ml was added and mixed well. This warm mixture was used in the *Basti*.

Basti procedure

- Pre-operative** - Before *Basti* procedure massage with *Bala Taila* and *Nadi Swedana* was done on abdomen and back for 15-20 min in all the selected patients.
- Operative** - Patient were asked to lie down in left lateral position after evacuating the urine and stool and then *Basti* was administered slowly and steadily This, 400ml of *Brihatyadi Yapana Basti* per rectum was given with the help of *Basti Netra* (nozzle) and *Basti Putaka* (canula). after the completion of menstrual cycle for 15 day in the morning for two consecutive cycles.
- Post-operative** - Patient was asked to lie down in supine position for at least 30 minutes and hot water bag was given to keep on abdomen and back of the patient for fomentation purpose.

Pathyapathya (Do's & dont's)

- Intercourse during *Rutukala* (ovulatory period)
- To avoid mental stress
- To take simple food such as *Mudga* (green gram), *Yava* (barley), *Raktashali* (*Oryza punctata*), *Shigru* (drumsticks), *Shasthishali* (*oryza sativum*) and *Paraval* (*Trichosanthes dioica*)
- To have taken more cow milk
- To perform *Yogas* postures and *Prayanamas* such as *Bhramari Pranayama*, *Hastapadasana*, *Janu Shirasana*, *Baddha Konasana* etc.
- Lukewarm water was advised for drinking and bathing.

Follow-up

- Follow-up was done after the completion of treatment for 2 months on 12th, 14th, 16th and 18th days of menstrual cycle

Criteria of assessment

- The efficacy of the therapy was assessed on the basis of follicular study by TVS on the 12th, 14th, 16th and 18th days of menstrual cycle and/or on the basis of conception achieved.
- To assess the overall response of therapies, a special scoring method according to size of follicle was adopted. [Table 1]

Over all effect of therapy

Overall effect of therapy was assessed on the basis of parameters as mentioned in [Table 2].

Statistical estimation of results

The obtained data was analyzed for statistical significance using Student's *t*-test. The level of "*P*" between 0.05 to 0.01 and *P* < 0.001 was considered as statistically significant and highly significant, respectively. If the calculated "*t*" value was more than 0.05 (*P* > 0.05), results were taken as insignificant.

Observation on demographic data

In this present study, 30 patients were registered and effect of therapy was assessed on 29 patients as one of the patient dropped out in group B.

In group A, out of 15 patients 15 patients completed the treatment and in group B out of 15 patients 14 patients completed treatment along with the follow-up. In group A, maximum number of the patients, i.e., 53.33% were from the age group of 26 to 30 years while in group B 40% were from this age group. In group A, 33.33% of the patients had primary infertility and 66.66% of the patients had secondary infertility and in group B, 60% of the patients had primary infertility and 40% of the patients had secondary infertility. In group A, 53.33% of the patients had chronicity of infertility of 1–5 years and in group B, 93.33% of the patients had chronicity of infertility of 1–5 years. In group A and group B none of the patients had the family history of infertility and all had proper development of secondary sex characters with timely onset of menarche. None of the patients had history of taking contraceptive pills.

In group A, 33.33% of the patients had regular menstrual cycle with moderate flow of menstrual. The 40% of the patients, did not have any pain during menstruation with duration of menstruation of 2–5 days in 53.33% of the patients, with an interval of >35 days in 46.66% of the patients and in group

Table 1: Scoring Pattern for follicle size

Sr. No	Score	Follicle size
1	0	0 - 12 mm
2	1	>12 - 19 mm
3	2	>19 - 23 mm
4	3	Ovulated

Table 2: Overall effect of therapy

Complete remission	Ovulation occurred
Marked improvement	Ovulation did not occur but improvement in the size of follicles up to full maturation, i.e., >19 mm
Moderate improvement	Improvement in size of follicles, i.e., 12-19 mm
Unchanged	No change in size, i.e., immature and cyst
Secondary outcome-conceived	Number of patients who conceived during or follow-up period

B, 40% of the patients had regular menstrual cycle with moderate flow of menstruation in 46.66% of the patients, most of the patient did not have any pain during menstruation, with duration of menstruation of 2–5 days in 53.33% of the patients, with an interval of >35 days in 46.66% of the patients.

In group A, intercourse for <2 times/week was found in 73.33% of the patients, irregular menstrual history was reported in 66.66% of the patients, 46.66% of the patients had Body Mass Index of 26–30 (Grade 3) while in group B, intercourse for <2 times/week was found in 86.66% of the patients. Irregular menstrual history was reported in 60% of the patients. Body Mass Index of 21–25 (Grade 2) was found in 46.66% of the patients.

The anteverted & anteflexed position of the uterus was found in 86.66% patients and in group B, 93.33% of the patients, whereas all the patients in both the groups had normal-sized uterus, with mobility and clear fornices.

Effect of therapy

In group A

Before treatment, the size of follicle was 0–12 mm in nine patients (60.00%) and >12–19 mm in five patients (33.33%), whereas one patient, i.e., (6.66%), had >19 – 23 mm size [Table 3].

In the first cycle of the treatment, the follicular size was 0–12 mm in one patient (6.66%) and >12–19 mm in three patients (20%), two patients (13.33%) had >19–23 mm size follicle, whereas rupture of follicle was found in nine patients (60%).

In the second cycle of the treatment, the follicular size was 0–12 mm in none of the patient and >12–19 mm in three patients (20%). Two patients (13.33%) had >19–23 mm size follicle, whereas the rupture of follicle was found in ten patients (66.66%).

After treatment (follow up), 13 patients (86.66%) had ovulation. One patient (6.66%) had >12–19 mm and one patient (6.66%) had >19–23 mm size follicle. None of the patients had follicle size of 12 mm.

In group B

Before treatment, the size of follicle was 0–12 mm in nine patients (46.66%) and >12–19 mm in two patients (20.00%), whereas four patients, i.e., (33.33%), had >19 – 23 mm size [Table 4]. During first cycle of the treatment, four patients (28.57%) had 0–12 mm size, three patients (21.42%) had >12–19 mm size, two patients (14.28%) had >19–23 mm size follicle, whereas rupture of follicle was found in seven patients (35.17%).

In the second cycle of the treatment, two patients (14.28%) had 0–12 mm size follicle, three patients (21.42%) had size >12–19 mm, two patients (14.28%) had size >19–23 mm size follicle, whereas rupture of follicle was found in seven patients (50.00%). After treatment, nine patients (64.28%) had ovulation, two patients (14.28%) had >12–19 mm and three patients (21.42%) had >19–23 mm size follicle.

Table 3: Effect of Brihatyadi Yapana Basti on follicular growth and ovulation (Group A) (n=15)

Size of follicle (mm)	Number of patients, n (%)			
	BT	DT (1 st cycle)	DT (2 nd cycle)	AT
0-12	9 (60.00)	1 (6.66)	0 (0.00)	0 (0.00)
>12-19	5 (33.33)	3 (20.00)	3 (20.00)	1 (6.66)
19-23 cystic	1 (6.66)	2 (13.33)	2 (13.33)	1 (6.66)
Ovulation	0 (0.00)	9 (60)	10 (66.66)	13 (86.66)

BT: Before treatment, DT: During treatment, AT: After treatment

Table 4: Effect of Shivalingi Beeja powder on follicular growth and ovulation (n=14) (Group B)

Size of follicle (mm)	Number of patients, n (%)			
	BT	DT (1 st cycle)	DT (2 nd cycle)	AT
0-12	9 (46.66)	4 (28.57)	2 (14.28)	0 (0.00)
>12-19	2 (20.00)	3 (21.42)	3 (21.42)	2 (14.28)
>19-23 cystic	4 (33.33)	2 (14.28)	2 (14.28)	3 (21.42)
Ovulation	0 (0.00)	5 (35.17)	7 (50.00)	9 (64.28)

BT: Before treatment, DT: During treatment, AT: After treatment

Comparative effect of therapy in group A and group B

In group A, the initial mean score of follicular size was 2.533 which was 0.267 after the treatment and was statistically highly significant ($P < 0.001$) [Table 5] Whereas, in group B, the initial mean score of follicular size was 2.429 which was 0.429 after the treatment and was statistically highly significant ($P < 0.001$).

In group A, 12 patients (80%) had rupture of follicle, i.e., ovulation occurred, whereas three patients (20%) had unruptured follicle after the treatment [Table 6]. In group B, nine patients (64.28%) had ovulation and five patients (35.72%) did not have ovulation after the treatment. In group A, ten patients, (66.66%), had irregular menses before treatment, whereas after treatment, three patients, (20%) had irregular menses.

This above data reveals that in group A, 70%, relief was found in irregular menses. Whereas, in group B, nine patients, (64.28%) had irregular menses before treatment, whereas after treatment, four patients, (28.57%) had irregular menses. In the present study, the 26.66% achieved conception in group A while it was nil in group B. In group A, after follow-up of 1st month, one patient (6.66%) had follicular size >12–19 mm and three patients (20%) had follicular size >19–23 mm or cystic formation. 73.33% of the patients i.e., 11 patients, had ovulation, In the 2nd -month follow-up, one patient (6.66%) had follicular size >12–19 mm and one patient (6.66%) had follicular size 19–23 mm or cystic formation and 86.66% of the patients, i.e., 13 patients, had ovulation.

In group B, after 1st month follow-up, two patients (14.28%) had follicular size >12–19 mm and two patients (14.28%) had follicular

size >19–23 mm. 71.42% of the patients, (10 patients) had ovulation. In the 2nd -month follow-up, one patient (7.14%) had follicular size >12–19 mm and one patient (7.14%) had follicular size >19–23 mm and 85.71% of the patients, (12 patients) had ovulation.

Data reveals that in group A (*Brihatyadi Yapana Basti*), 26.66% of the patients could conceive. Excellent response, i.e., ovulation, was found in 80.00% of the patients, whereas 13.33% of the patients had marked response and 6.66% of the patients had moderate response. In group B [*Shivalingi* seed powder] none of the patients conceived. In this group excellent response, i.e., ovulation, was found in 64.28% of the patients, whereas 21.42% of the patients markedly improved and 14.28% of the patients had moderate improvement.

Discussion

Nowadays, infertility is a problem of global proportion, affecting on an average 8%–12% couples worldwide.^[6] In Ayurveda classics, *Vandhyatva* has not been described as a separate disease, but all the gynecological disorders are included in twenty *Yonivyapadas* (vaginal disorders). Hence, *Vandhyatva* can be understood from the point of view of *Yonivyapada*.

Vandhyatva is described in classical texts with a wide view including etiology and management; however, the etiological factors held responsible for infertility according to modern science cannot be correlated with etiology factors mentioned in Ayurveda. Similar, is the case of treatment. Hence, many treatments have been given in Ayurvedic texts for *Vandhyatva*, but in which type of infertility or on which factors of infertility it will be effective is not mentioned clearly. Hence, it is the need of time to evaluate the role of drug specifically in this regards. So, to study the effect of *Brihatyadi Yapana Basti* and *Shivalingi* seed powder on anovulatory factor, which is the most common cause of infertility in females was under taken. To assess the abnormal state, one must know the normalcy of the same.

In *Ayurveda*, *Tridosha* are the basic pillars of the physiology of the human body. Most of the authors of Ayurveda gynaecology consider the ovulation as a result of physiological action of *Pitta*, while the growth of the follicle as a function of *Kapha*. *Kapha* is considered responsible for follicular growth, while *Pitta* for the rupture of matured follicle [Figure 1].

Drug discussion

Probable mode of action of *Deepana - Pachana* and *Vatanulomana*

Deepana-Pachana (appetizer-digestives) property of *Amapachana Vati* helps to bring the normality of

Dosha and thus aids in bringing *Dosha* to their sites i.e., *Koshtha* from which can be easily removed by mild purgation like *Eranda Bhrishta Haritaki*. The process of *Deepana-Pachana* (appetizer-digestives) also correct *Agnimandya* and thus prevents *Ama* formation which can further lead to the process of *Avarana* or *Srotorodha* (obstruction of action of *Apana Vayu*) which is the main factor involving in the pathogenesis of anovulatory cycle.

Abhyanga and Swedana

Abhyanga and *Swedana* (oil massages and hot fomentation) are very important procedures and are used as both the *Pradhana Karma* (main procedure) as well as *Poorva Karma* (pre-operative procedure) of several *Panchakarma* procedures. Although classics have not specifically emphasized much upon *Snehana* (oleation) and *Swedana* (fomentation) before *Yapana Basti*, this approach seems to be genuine and appropriate. The drugs, which are used in preparation of *Brihatyadi Yapana Basti*, help in the regulation of ovulatory cycle through their combined effect. Moreover, the advantages of *Basti* are also achieved [Figure 2].

Probable mode of action of *Brihatyadi Yapana Basti* according to modern concept

To understand the possible mode of action, the route of administration, its absorption, concept of enteric nervous system (ENS) that stimulate the central nervous system (CNS) and endogenous opioids, and systems biology concept can be considered [Figure 3].

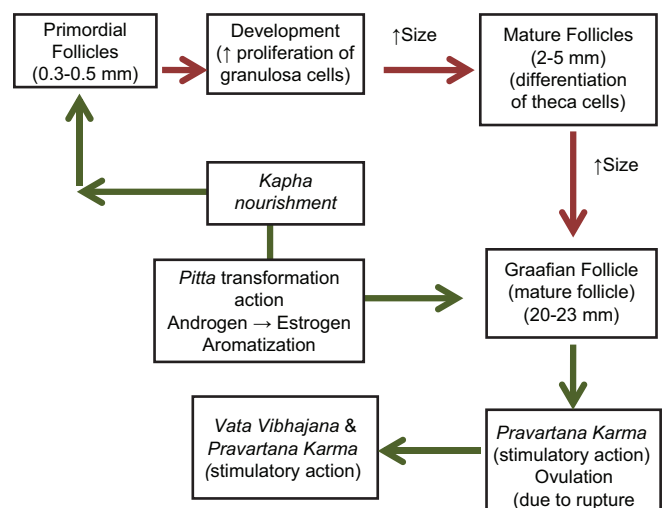


Figure 1: About etiology - pathology of probable *Tridoshika* involvement in the ovarian cycle

Table 5: Effect of therapies on follicular size

Group	N	Mean		X (AT–BT)	SD	SE	T	P
		BT	AT					
A	15	2.533	0.267	2.267	0.704	0.182	12.475	<0.001
B	14	2.429	0.429	2.000	1.177	0.314	6.360	<0.001

AT: After treatment, BT: Before treatment, SD: Standard deviation, SE: Standard error

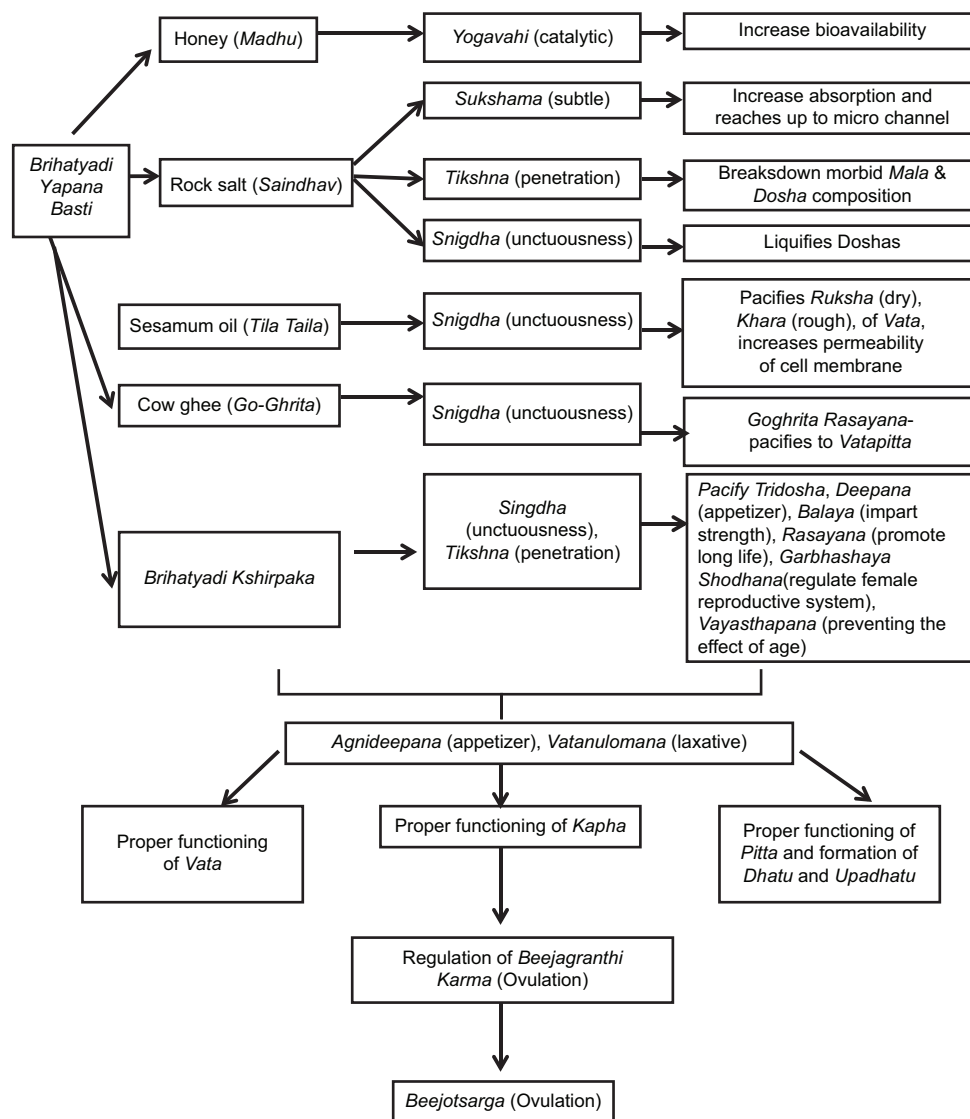


Figure 2: Probable mode of action of *Brihatyadi yapana basti*

Table 6: Total effect of therapy on ovulation

Status of follicle	Number of patients, n (%)	
	Group A	Group B
Ruptured	12 (80.00)	9 (64.28)
Unruptured or immature	3 (20.00)	5 (35.72)

Basti is not merely the enema one which exerts local cleansing effect; rather, it is a highly complex, sophisticated and systemic therapy having a wider range of therapeutic actions and indication. It exerts its action by endcolonic (action inside the colon), encolonic (action on tissues of the colon) and diacolonic (for systemic action) ways.

Probable mode of action of Shivalingi seed powder

Shivalingi seed in the form of powder was administered in group B. *Agnimandya*, production of *Ama* at the tissue level, vitiation of *Vata*, *Srotorodha* (obstruction of the channels), *Avarana* of *Vata*

by *Kapha* and *Pitta* and *Dhatukshaya* resulting in poor state of nourishment of *Dhatu* may be the major events in the pathogenesis of *Vandhyatva* w.s.r to *anovulation*. While considering *Rasa* (taste), *Veerya* (potency), *Vipaka* (transformation), *Guna* (quality) and *Doshaghata* (pacifying effect) collectively, it has *Tikta Rasa* (bitter taste), *Sheeta Veerya* (cold potency), *Madhura Vipaka* (sweet transformation), *Laghu Guna* (light property), *Deepana* (appetizer) and *Tridoshaghna* (pacifying effect on *Tridosha*) action. This drug is having hepatoprotective and antioxidant properties, which ultimately help in the regulation of ovarian cycle.

Conclusion

From the present study, it can be concluded that *Brihatyadi Yapana Basti* is comparatively more effective in promoting the growth of graafian follicle to its target size, inducing ovulation and in achieving conception than the *Shivalingi* seed powder. Thus, it is a promising intervention for future practices of

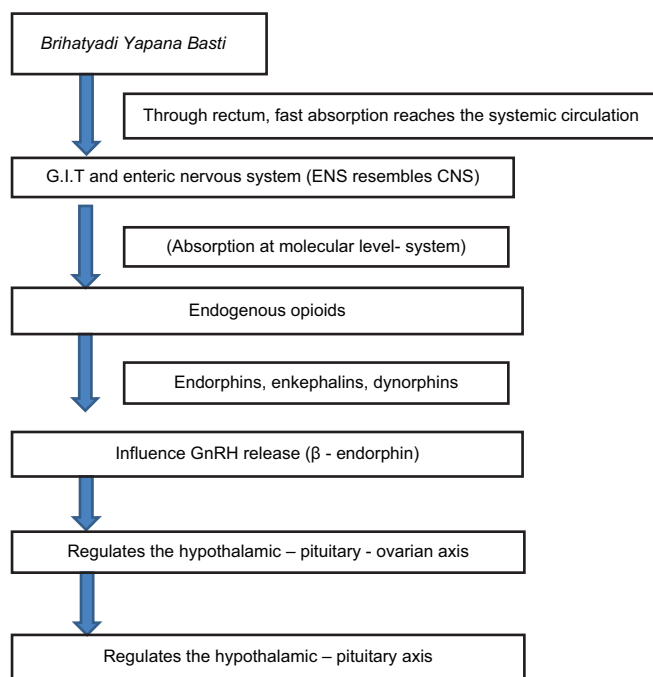


Figure 3: Probable mode of action of *Brihatyadi Yapana Basti* according to modern concept

Ayurvedic gynaecologists for managing female infertility due to anovulatory factor.

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Conflicts of interest

There are no conflicts of interest.

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