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Role of *Rasayana Basti* in the Management of *Vandhyatva* (Female Infertility) w.s.r. to Anovulatory Factor

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ABSTRACT

Introduction:

Infertility is defined as a failure to conceive within one or more years of regular unprotected coitus. According to FIGO, ovarian factor contributes to 30-40% in causes of the female infertility. In the Ayurveda classics, description of *Vandhyatva* is available including *Nidana*, *Samprapti*, *Lakshana*, *Bheda*and *Chikitsa*. **Aim:** To evaluate the efficacy of *Rasayana Basti* in the management of female Infertility w.s.r to anovulatory factor. **Materials and Methods**: Total 17 female patients of infertility having an ovulatory factor, being diagnosed by TVS for two consecutive cycles were included in this study. *Rasayana Basti* was given for 16 days for two cycles through rectal route in dose of 426 ml before meals in the morning time. A special scoring pattern for subjective and objective parameter was adopted. **Results:** Ovulation was reported in 71.42% of the patients. **Conclusion:** *Rasayana Basti showed* good result in anovulation

KEYWORDS

Vandhyatva, Rasayana Basti, Infertility, Abeejotsarga Anovulation, Deepana

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INTRODUCTION

The incidence of infertility is increasing by changing life style in urban India i.e. irregular working hours, late marriage, age at first marriage, place of residence, standard of living, sedentary lifestyle, working status of women, professional and social stress on young couples, genetic disorders etc. According to FIGO manual, ovarian factor contribute 30-40% in causes of the female infertility[1]. Infertility reduces quality of life especially through the negative psychosocial consequences like marital instability, anxiety, depression, social isolation, deprivation, loss of social status, loss of gender identity, ostracism and abuse[2]. Therefore, it is the first common cause of infertility. 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. so many therapies are developed, but they have unsatisfactory results, enormous expenses and many side effects. In Gujarat, the fertility rate was 4.3 in 1981, 3.1 in 1991, 3.0 in 1999, 2.5 in 2009, and 2.2 in 2016. This shows that the fertility rate has very much decreased in last few decades. The fertility rank of Gujarat in India was 12 in 2015[3].

Acharya *Sushruta*[4] has mentioned four essential factors that are required for healthy conception that is proper fertile period, physiologically adequate and healthy internal organs of reproduction, the proper nourishment - to the developing zygote or fetus, the activated ovum and spermatozoa. Fulfilment of all the above essentials ensures the fullness of the motherhood. Among them *Beeja* is the core stone of the female reproductive process and in its absence, conception cannot be achieved despite of all the other factors. Here the *Beeja* is taken as *Antahpushpa* i.e. ovum. Therefore, anovulation can be included under *Beeja Dushti*.

Hence, the infertility especially due to ovarian factor needs an immediate attention from alternative medicines. Ayurveda may give a promising hand to cure this disease even though there is no specific treatment according to factors. Therefore, it is a time to convert the challenging problem of managing infertility into a rewarding one always.

Why *Basti*? Without *Vata Yoni* never gets vitiated[5], here the word "*Yoni*" refers to reproductive organs collectively. *Vata* is governing factor of the reproductive physiology. Therefore, any vitiation in *Vata* will certainly affect the ovulation. In this

aspect, "*Basti*" is considered the best treatment for *Vata*[6]. *Basti* cures all the diseases of *Vata*. *Basti Karma* controls *Vata* at its *Moolasthana Pakvashaya*, and thus all metabolic processes under the control of *Vata* are automatically regulated as, if the root of the diseased tree is destroyed; its branches, leaves, and flowers are automatically destroyed[7]. Thus, it may act on anovulation by normalizing the pelvic reproductive physiology. Therefore, keeping this aspect in mind *Rasayana Basti*[8] referred by the *Nava-Navaneetakam* has been taken here in the study. *Rasayana Basti* is *Balya, Brihana, Deepana, Vrishya,* and *Shukrala*. It is one type of *Yapana Basti,* which includes *Niruha* as well as *Snehana*. *Yapana Basti* is also indicated in Infertility[9].

So far, no scientific study on *Rasayana Basti* has been carried out related to female infertility. *Agni Dushti* is also one important cause of infertility and an ovulation. Therefore, combination of *Deepana, Pachana*, and *Anulomana* drugs may help on anovulation.

AIMS AND OBJECTIVES

To evaluate the efficacy of *Rasayana Basti* in the management of female Infertility w.s.r. to an ovulatory factor.

1. **Primary Outcome**

- Occurrences of Ovulation

2. **Secondary Outcome**

- Improvement in associate complains like menstrual abnormalities

MATERIALS AND METHODS

Selection of patients:

Patients were selected from the O.P.D. of the Dept. of Prasuti Tantra & StreeRoga, IPGT&RA, Gujarat Ayurved University, Jamnagar.

Inclusion Criteria:

1. Female Patients of Child bearing age from 20-40 years
2. Patients having active married life minimum 1 year with having an ovulatory cycle.
3. Married female patients of reproductive age group with at least two or more consecutive an ovulatory cycles.
4. Primary and secondary both types of infertile patients having an ovulatory cycle or with immature ovarian follicle.

Exclusion Criteria:

1. Female patients having age less than 20 years and more than 40 years.
2. Congenital deformities and infectious diseases of reproductive tract like tuberculosis, Sexually transmitted diseases and carcinoma

3. Chronic systemic diseases like Diabetes, Hypertension, HIV, TB etc.

Criteria for Diagnosis:

The Trans Vaginal Sonography (TVS) is basic and primary investigation for this study. It was done from day 8^{th} – 9^{th} day of menstrual cycle up to at least 22^{nd} day of cycle to diagnose anovulation. Diagnosed patients of anovulation for 2 consecutive cycles were taken in this study.

Ethical clearance:

The Study was started after getting clearance from Institutional Ethics Committee **IEC No. PGT/7/-A/Ethics/2017-18/2669 (dated 17/11/17)**and registration in **CTRI-Reg. No: CTRI/2018/01/011440).** Written informed consent was taken before starting the treatment.

Treatment Protocol (Table 1)

Before starting the treatment, *Deepana – Pachana*, for 3 days along with *Koshtha Shuddhi* was given for 3 days from the 3^{rd}day of menses.

Table 1 Treatment Modality

Treatment Modality	Drug	Dose	Duration
Deepana- Pachana	*Amapachana Vati*	2 Tablets (each of 500mg) b.i.d. with luke warm water after meal.	3 days
Koshtha Shuddhi	*Erandabhrishta Haritaki*	5 gm. or as per *Koshtha* with Luke warm water at H.S.	3days

Table 2 Posology

Drug	*Route*	*Dose*	*Duration*	*Time*
Rasayana Basti	Rectal	426ml	Total 16 days, After cessation of menses for 2 consecutive cycles	At morning 8:30am to 10:00am

After *Deepan Pachana, Rasayana Basti* (Table 2 and 3) was given through rectal route after cessation of menses for 2 consecutive cycles before meal in dose of 426 ml at morning time.

Table 3 *Rasayana Basti*

Kwatha Dravya(for 192 ml of Kwatha)				
No	***Drug (Yavakuta)***	***Latin Name***	***Part used***	***Quantity***
1	*Rasna*	*Pluchea lanceolata*L.	*Root*	*50gm*
Kalka Dravyas				
5	*Shatapushpa*	*Anethumsowa*linn.	*Beeja*	*12gm*
6	*Yashtimadhu*	*Glycyrrhiza glabra*linn.	*Root*	*12gm*
7	*Pippali*	*Piper longum*linn	*Phala*	*12gm*
8	*Madhu*	*Mal depuratum*	-	*96gm*
9	*Saindhava*	*Sodium chloridum*	-	*6gm*
10	*TilaTaila*	*Sesamum indicum*linn	-	*96ml*

Preparation of *Rasayana Basti*:

All raw drugs for *Rasayana Basti* were procured from Pharmacy of Gujarat Ayurved University, Jamnagar. *Madhu* was purchased from Khadigram Udhyog Bhandar, Jamnagar**.**

पूर्वंहिदद्यान्मधुसैन्धवंतुस्नेहंविनिर्मथ्यंततोऽनुकल्कम्||२३||

विमथ्यसंयोज्यपुनर्द्रवैस्तंबस्तौनिदध्यान्मथितंखजेन|२४|[10]

The classical method of *Niruha Basti* preparation was used for the preparation of *Rasayana Basti*. Initially 96ml *Madhu* was mixed with 6 gm. *Saindhava Lavana* uniformly in *Kharala*. After 96 ml, Luke warm *Tila Taila* was added to above mixture until it became homogenous. Then *Kalka Dravya* 36 gm. was added. Lastly, 192 ml of Luke warm *Rasna Kwatha* was added to the above mixture. Total dose of *Rasayana Basti* was approx. 426ml. *Basti Dravya* was made luke warm by keeping it into hot water. This mixture is poured into a *Basti Putaka* and fixed with *Basti Netra*(nozzle)

Investigations

Specific investigations:

- Trans vaginal sonography (TVS): - **B.T, D.T. and A.T.)**

Follow up of study

After completion of course patients were advised to report every 7 days for follow up study, which was carried out for 2 cycles. During the follow up study, ovulation study and occurrence of conception were recorded.

Criteria of Assessment:

Subjective Parameter: A special Proforma was prepared incorporating the associated complains related to anovulation like menstrual abnormalities. A special scoring pattern for Subjective Parameters was done and assessed on the basis of changes at end point in comparison to base line score.

Objective Parameter: On the basis of follicular study by Trans Vaginal Sonography and/or on the basis of conception. For that a special scoring method according to size of follicle was adopted.

- **Scoring Pattern of Follicle: -**

  0 =<12 mm

  1 = 12-19 mm

  2= >19-23 mm

  3 = Ovulated

Over All Effect of Therapy:-

Complete remission	100% Relief (Ovulation) were considered as complete remission.
Marked improvement	>75-≤99%Relief (>19-23mm size of follicle) were considered as marked improvement.
Moderate improvement	>50-≤75% Relief (12-19mm size of follicle) were

	considered as moderate improvement.
Mild improvement	>25-≤50% Relief (<12 mm size of follicle) were considered as mild improvement.
No improvement	≤ 25 (Not any change in size), i.e. immature follicle
Secondary outcome: Conception	Number of patients who conceived during or follow up period.

- **Statistical estimation of results:**

• Wilcoxon signed-rank test was applied to the nonparametric statistical data for evaluating the difference before and after treatment.

After preparing the master chart of all the required data in Microsoft excel work sheet statistical calculations were made with the help of Sigma stat 3.5software and in stat 3 software. The results were interpreted at;

- Insignificant >0.05
- Significant $p < 0.05$
- Highly significant $p < 0.001$

OBSERVATION

Total 17 patients were registered in this study, among them 03 patients dropped out for her personal reasons.

In this study, 64.70% patients had primary infertility and 35.29 % patients had secondary infertility. 47.05% patients belonged to age group of 20-25 years. 88.23% patients were Hindu. 47.05% patients had 1-5 years chronicity. 82.35% had taken hormonal treatment for infertility. 35.29% of patients were having irregular menses. 23.52% patients were having less quantity of menses. 17.64 % had painful menses. 05.88% were having duration of menstrual period of <2 days. 23.52% were having Duration of menstrual period of >5 days. 29.41% of patients were having >35 days interval of cycle. 05.88% of patients were having<21 days interval of cycle. 41.17% had marital life of 1-5 years. 47.05 % patients had *Vishamashana*. 47.05% patients were having *Lavanarasa* dominancy diet and *Katu Rasa* dominancy diet in 41.17% of patients. *Chinta* was present in 82.35% of patients. 58.82% patients had *Vatakapha Prakriti*. Constipation was present in 23.52% of the patients. 35.29% of patients were having Grade 2(21-25) BMI, 29.41% with Grade 3 (26-30) BMI and 23.52% were having Grade 4(>30) BMI. 76.47% male partners were reported with Normal semen report.

RESULTS

Effect of *Rasayana Basti* on Subjective Parameter:

35.71% had irregular menses before treatment, while after treatment 02 patients i.e. 14.28% had irregular menses.03 patients i.e. 21.42 % had scanty menses before treatment, while after treatment 02 patients i.e. 14.28% had scanty menses.02 patients i.e. 14.28 % had excessive menses before treatment, while after treatment 01 patient i.e. 07.14% had excessive menses. 02 patients i.e. 14.28% had painful menses before treatment, while after treatment 01 patient i.e. 07.14% had painful menses. Before treatment04 patients i.e. 28.57% had>35 days interval of menstrual period, while after treatment02 patients i.e. 14.28% had >35 days interval of menstrual period. 01 patient i.e. 07.14% had<21 days interval of menstrual period before treatment, while after treatment patient got relief.01 patient i.e. 07.14% had<2 days duration of menstrual period before treatment, which remained unchanged after treatment. 01 patient i.e. 07.14% had<2 days duration of menstrual period before treatment, which remained unchanged after treatment. 03 patients i.e. 21.42% had>5 days of duration of menstrual period before treatment, while after treatment, 03 patients i.e. 21.42%had >5 days of duration of menses.

Initial mean score of Duration was **1.0**which was **0.3** after the treatment. This improvement was **Statistically Significant (P=0.004).**

Initial mean score of Interval was **1.9**which was **1.0** after the treatment. This improvement was **Statistically Significant (P=0.008).**

Initial mean score of Quantity was **2.1**which was **1.3** after the treatment. This improvement was **Statistically Significant (P=0.002).**

Initial mean score of Pain was **0.2**which was **0.07** after the treatment. This improvement was **statistically Non-Significant (P=0.500).**

Effect of *Rasayana Basti* on Objective Parameter:

Before treatment, size of follicle was 0-12 mm in 13 patients(92.85%) and >12-19mm in 01 patient (07.14%).

In 1st cycle of during treatment, follicular size was 0-12 mm in 08 patients (57.14%), and rupture of follicle was found in 06 patients (42.85%).

In 2ndcycle of during treatment, follicular size was 0-12 mm in 08 patients (57.14%), and

rupture of follicle was found in 06 patients (42.85%).

After treatment 06 patients (42.85%) had ovulation. 07 patients (50.00%) had 0-12 mm size, follicle.1 patient (07.14%) had 19-23mm size of follicle.

The initial mean score of follicular size was 2.929 which was 1.143after the treatment. This improvement was Statistically Significant (P=0.004).

Follicular size in follow up period

First month follow up - 06 patients i.e. 42.85% had follicular size 0-12 mm. 57.14% of patients i.e. 08 patients had ovulation. In 2nd month follow up - 06 patients i.e. 42.85% had follicular size 0-12mm. 57.14% of patients i.e. 08 patients had ovulation

Overall Effects of Therapies

Complete remission i.e. (Ovulation) was found in 71.42 % of patients, while 07.14% of patients were moderately changed. 04 patients remained unchanged. Conception was achieved in 7.14% patient.

Probable Mode of Action:

Rasayana Basti[11] is a preparation of multiple drugs and most of them have the property of *Vata-Kapha Shamana* and *Ama pachana* that ultimately helps in *Samprapti Vighatana.* The drugs, which are used in preparation of *Rasayana Basti* helps in regulation of ovulatory cycle through their combine effect. Moreover, advantages of *Basti* are also achieved here. As mentioned earlier that *Rasayana Basti* is one type of *Yapana Basti*, *Yapana Basti* especially alleviates *Avarana* of *Vata* by *Sama Kapha*. Reduction in this *Avarana* was seen as there was improvement in symptomatology of *Kaphavrita Vyana* and *Kaphavrita Udana*. This may be due to effect of *Basti* as *Vatanulomana*, *Srotoshuddhi* and *Rasayana* properties of *Yapana Basti*. Thus, *Rasayana Basti* corrects *Avarana* of *Vata* and *Swanidanena Prakupita Vata* as well. As *Acharya Charaka* says it '*Sadyabalajanana'*, it promotes *Dhatu* and being considered as *Shukra Mamsa Balajanana,* which shows that the *Basti* can be used in all the conditions of provoked *Vata* i.e. *Dhatukshaya*, *Avarana* and *Swanidanena Prakopa.* The drugs of *Rasayana Basti* possess Anti-Oxidant[12], Anti-inflammatory[13], Analgesic, Anti – Depressant activity[14], Anti-cancer and Anti-tumor activity[15] ,Bio-availability enhancer[16], uterine relaxant etc. properties which may help in relieving the stress, age-decline etc. i.e. causes of anovulation. From *Ayurvedic* point of view, the drugs used in preparation of *Rasayana Basti* are having properties like *Balya, Brihana, Deepana, Vrishya,* and *Shukrala*[17], *Deepana-Pachana* with

*AmapachanaVati*helps to bring the *Niramata of Sama Doshas* and thus aids in bringing the *Shakhagata Doshas* or *Tiryaka Doshas* back to *Koshtha*, which can be easily removed by mild purgative like *Eranda Bhrishta Haritaki*. *Eranda Bhrishta Haritaki* also helps to alleviate constipation and thus may be helpful in bringing *Pratimola Apana Vayu* back to normalcy. The process of *Deepana-Pachana* also cures *Agnimandya* and thus prevents *Ama* formation which can further lead to the process of *Avarana or Srotorodha* which is main factor involving in the pathogenesis of an ovulatory cycle. *Madhu* is having *Yogavahi* properties thus it increases the potency of other drugs. *Saindhava*, by molecular, quick and smooth properties, reaches up to micro channels, breaks down morbid mala and liquefies dosha. *Tila Taila* counters all the properties of *Vatadosha*, by *Ushnavirya* and *Snigdh* and *Guruguna*. *Shatapushpadi kalk* is *Katu*, *Tikshna*, and *Laghuguna* it increases *Agni* and clear *Srotoavrodh*. *Rasna* doing *Amapachana* by *Tiktarasa* and *Ushnaveerya* and *Vatasaman* by *Snigdh* and *Guruguna*.

DISCUSSION

Abeejotsarga i.e. anovulation is the one of the major factors of female infertility, most of the infertile women suffer by this cause. The use of ovulation induction agents, insulin sensitizers and hormones leads to further aggravation of the pathological scenario of an ovulatory cycle. Due to today's lifestyle, incidence of infertility because of ovulatory dysfunction is increased. The results shows that the efficacy of *Rasayana Basti* on follicular growth and maturity as well as ovulation in mid cycle. Due to *Deepana, Pachana, Vatanulomana Guna* of *Shatapushpadi Kalka Srotovarodha* was clear and *Sanga* was removed. *Madhu* and *Saindhava* are having *Chhedana* effects that expelled out the *Mala* from *Srotas*. *Rasna* did *Amapachana* by *Tikta Rasa* and *UshnaVeerya*. *Vatashamana* by *Snigdh a*nd *Guru Guna*. *Tila Taila* also countered all properties of *Vata Dosha*. Thus, the function of the *Vayu (Apana Vata)* could be able to perform its function "*Vibhajana"*. Because of this *Vibhajana* property, the size of follicles might be increasing. By the same properties, the rupture of follicle might be occurred. Thus, the growth and rupture of follicles were observed in *Rasayana Basti* group. *Rasayana 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. *Rasayana Basti* after absorption reaches into systemic circulation and the concept of Central Nervous System (CNS) resembles Enteric Nervous System (ENS) the endogenous opioids in the ENS specially endorphins (β-endorphin) are influenced which will affect GnRH release regularizing HPO axis regulating ovarian cycle and ovulation[18]. *Beejashaya* are situated at the *Sthana* of *Apana Vata*, all the deformities or abnormalities related to these organs are either completely or partially due to *Apana Vaigunya*. *Basti* is the *Pradhana Karma* of *Vata Vaigunya*. As whole, *Rasayana Basti* performed *Shodhana* effect as well as *Yapana* effect. It nourished the *Dhatu* that are vitiated due to *Vata Prakopa*.

CONCLUSION

The study overall concluded that *Rasayana Basti* is highly effective to induce ovulation and achieving conception.

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