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THE COMPARATIVE STUDY OF RASONA TAILA UTTARBASTI AND RASONA SIDDHA KSHIRPAN WITH MODERN MEDICINE IN THE MANAGEMENT OF VANDHYATVA WITH SPECIAL REFERENCE TO ANOVULATORY CYCLE

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ABSTRACT

Introduction: The consequences of infertility are plenty and can include social impact and personal suffering. The most common cause of female infertility is failure to ovulate. In the modern medicine. The crucial factors in the process of conception, as described in Ayurveda are, *Rutu* (fertile period), *Kshetra* (Healthy reproductive organs), *Ambu*(proper nutrient fluid), *Beeja*(ovum/ sperm). Abnormality in any one of these can cause infertility. **Aims & Objectives:** 1.To study the effects of the study drug on the ovulation *Beejotsarga*) and endometrium (*Garbhashayya)*along with probable mechanism of action on the anovulatory 2.To provide herbal, cost effective, better alternative in the management of anartavata in the patients of vandhyatva.

Discussion & Result: *Rasonataila uttarbasti* and *kshirpaan* has significant results on all the parameters. It found to be effective in reducing the pain of menstrual phase and increase the menstrual flow. It is seen that the results of the therapy in both groups, in case of ovulation/follicle size are equally effective. *RasonaTaila Uttarbasti* and *Siddha Kshirpan* are as effective as Clomiphene Citrate. However trial group formulation proves to be an alternative, cost effective, herbal treatment for anovulatory menstrual cycles.

Keywords: *infertility, vandhytwa, rutu, beeja, uttarbasti, garbhashaya, kshetra.*

INTRODUCTION

A very famous saying “A Mother is born to love her child with every single beat of her heart” reminds about the importance of motherhood in a woman’s life. But still a vast number of women are disturbed in their married life due to ‘infertility’. This infertility has a deep impact on individual’s physical and mental health and this disturbs her family life.

The consequences of infertility are plenty and can include social impact and personal suffering. The most common cause of female infertility is failure to ovulate. In the modern medicine, most commonly used treatment for an ovulation is the administration of Clomiphene citrate. Though it has got a good successful rate, still it has adverse effects like ovarian hyperstimulation

syndrome, ovarian cyst, multiple pregnancies and resistance to treatment etc. Besides it merely induces ovulation and has no effect on endometrium. Again for the preparation of womb, patients have to be given other drugs like oestrogen preparations which possess other adverse effects. The crucial factors in the process of conception, as described in Ayurveda are, *Rutu* (fertile period), *Kshetra* (Healthy reproductive organs), *Ambu*(proper nutrient fluid),*Beeja* (ovum/ sperm).Abnormality in any one of these can cause infertility. The term '*Beeja*' can be correlated with the spermatozoa in men and ova in women. The saying, "As you sow, so shall you reap" signifies the importance of the seed. It is the seed which gives the fruit and so it is the *Beeja* which yields the *garbha.* And the absence of this *beeja* in women is termed as an ovulation.[1,2] Infertility in Ayurveda has been termed as *Vandhyatva. Aacharaya kashaypa* has mentioned the usage of *rasona* in the treatment of infertility and has dedicated the one whole chapter to the drug *Rasona.* He has described the usage of rasona for shonitjanana and pushpa related i.e.*beeja* related *vyadhis* in *vandhyaas*, in all the available forms viz., either as a constituent of meals or as a medicine.[3]

Aims & objectives:

1. To study the effects of the study drug on the ovulation (*Beejotsarga*) and endometrium (*Garbhashayya).*
2. To propose the probable mechanism of action of the study drug on the anovulatory cycle.
3. To provide herbal, cost effective, better alternative in the management of *anartavata* in the patients of *vandhyatva*.
4. To study the complications if any during the course of treatment.

Materials & Methods:

Study design: - An Open Randomized Clinical Trial.

Sample size: In each group 30 patients were enrolled, totally 60 patients were recruited in this study.

Place of Study: M.A. Podar Ayurveda Hospital, Mumbai.

Ethical Clearance: Ethical clearance was sought from the institutional ethical committee.

Well informed Consent: An understanding of the procedure was given to the patients about the trial and a well informed written consent was taken from the patients in the language best understood by them, prior to participation in the trial.

Clinical study:

Inclusion Criteria:

 Married patients (Age group 18-45yrs)
 Infertility patients
 PCOD (Polycystic Ovarian Disease)
 Irregular menses / scanty menses due to an ovulatory cycle, delayed ovulation

Exclusion Criteria:

 Unmarried patients.
 Bleeding P/V (per vagina)
 Cervical tumor, polyp, Ca cervix, Uterine fibroid.
 Congenital anomalies in female genital tract.
Tubercular endometritis, HIV/VDRL/ HbsAg positive.
 Malignant diseased patients and cytotoxic patients.

Pathological Investigations: Following investigation were done to rule out other disorders, to assess patient's hematological status and the prognosis of the patient's general condition.

a. **Hematological investigations:** CBC, ESR, Blood group, B.T., C.T., HIV/ VDRL/ HbsAg, BSL F/PP, Urine R/ M
b. USG pelvis
c. Follicular study- A serial vaginal or abdominal sonography was done from 10th day of menstrual cycle, till after ovulation. According to size of follicle it was done on alternate day. Ovulation was

presumed to have occurred when there is a sudden reduction in size or complete disappearance of the dominant follicle measuring 18 to 25 mm prior to its rupture and minimal fluid collection in Pouch of Douglas.

Group Managements:

Particulars	Group A	Group B
Drug	*Rasona Taila* (*Rasona Taila Uttarbasti*)	Tab. Clomiphene citrate
Duration	5 days in a month for consecutive 3 cycles.	5 days in a month for consecutive 3 menstrual cycles.
Aushadh Kala	*Rutukala* (from 5th day of menstrual cycle),	from 2nd day of menstrual cycle
Dose	80 ml/day for 10 successive days	50 mg (once in a day)
Follow up	every menstrual cycle for consecutive 3 cycles	every menstrual cycle for consecutive 3 cycles

Drugs: Raw materials were purchased directly from the market. The drugs were checked for the authenticity. *Rasona Taila* and *Rasona siddhakshir* was prepared by the standard method given in the *Kashyapa samhita* and *Sharangdharsamhita* respectively. The proportion of the ingredients of *Rasonataila* and *siddha kshir* were as follows:[4]

Ingredients of *Rasonataila:*

Rasona *4 kg,*
Sesame oil *2.5 liter*
Cow's milk *2.5 liter*
Dashmoolabharad *10 gms*
Water 51 liter

Ingredients of *Rasonakshirpan*:

Crushed Rasona bulb *1 part*
Godugdha *8 parts*
Water *32 part*

Study Procedure: Detailed history with findings was recorded on the self designed CRF. Haematological stability of the patients was assessed before the treatment.

Group A: In this group 30 patients were treated with *Rasona Taila Uttar Basti* and *Rasona Siddha KshirPaana.*

Procedure of *Uttarbasti*: *Uttar basti* was given to the patients in the *ritukala* from 5th day of menstrual cycle in the dosage of 4,6,8,10,12 ml respectively for successive 5 days for consecutive 3 cycles. *Kshirapan* was given orally to all the patients of group A in the dosage of 80 ml for consecutive 10 days during every menstrual cycle for consecutive 3 cycles.

Group B : Tab. Clomiphene citrate was given to the patients of this group in dose of 50 mg once a day from 2nd day of menstrual cycle for consecutive 5 days for consecutive 3 cycles. Follicular study was done before and after every cycle of the treatment, to assess the results on the ovulation and endometrial thickness.

Follow up was taken during every menstrual cycle for consecutive 3 menstrual cycles.

Assessment Criteria: To assess the improvement in symptoms, gradations on the basis of severity were given which have been stated here. The changes in the gradation of symptoms indicated the effect of drug under the clinical trial.

A) Subjective Criteria:-

1) Menstrual Cycle Pain: Internationally accepted Pain Mobility Gradation Chart (Based on Visual Analogue Scale i.e. VAS)

Grade	Criteria	Scale on VAS
0	No Pain	- 0 on VAS

1	Mild Pain	- 1 – 3 on VAS
2	Moderate Pain	- 4 – 7 on VAS
3	Severe Pain	- 8 – 10 on VAS

2) Quantity of Bleeding:

Grade	Amount of bleeding	Pad Requirement
0	Spotting	No pad require
1	Scanty	1-2 pads/day
2	Moderate	2-3 pads/day
3	Excessive	4-5 pads/day

B) Objective Criteria:-

1) Follicular Size:

Grade	Follicular size
0	<12 mm
1	12 – 20mm
2	>20 mm
3	Ovulated

2) Endometrial Thickness

Grade	Endometrial thickness
0	< 5 mm
1	5-7 mm
2	7-9 mm
3	>9 mm

A. Observations & results:

Table No.1: Age wise distribution of patients

Age group(in years)	Group A (n)	Group B (n)	Total	Percentage
18-20	0	0	0	00.00
21-30	08	12	20	33.33
31-40	16	14	30	50.00
41-45	06	04	10	16.66

Age group was divided into four groups. 20 patients out of 60 (33.33%) belonged to the age group of 21-30 years. 30 patients (50%) belonged to the age group of 31-40 years. 10 patients (16.66%) belonged to the age group of 41-45years.o patients was from age group 18-20years.

Table No.2: Distribution of patients according to *ManasikaBhav*

ManasikBhav	**Group A (n)**	**Group B (n)**	**Total**	**Percentage**
Depressed	20	22	42	70
Anxiety	10	08	18	30

Out of 60 patients observed, 42 patients (70%) were depressed and 18 (30%) patients were having anxiety.

Table 3: Distribution of patients by Type of infertility

Type of infertility	**Group A (n)**	**Group B (n)**	**Total**	**Percentage**
Primary	16	18	34	56.66
Secondary	14	12	26	43.33

Out of 60 patients observed 34 (56.66%) patients were having primary infertility and 26
(43.33%) patients were of secondary infertility.

Distribution of patients by changes in menstrual cycle pattern: Out of 60 patients observed 24 (40%) patients had regular menstrual cycle and 36 (60%) having irregular menstrual cycle. During menstruation, quantity of bleeding in 27 (45%) patients was scanty, in 24 (40%) patients had moderate menstrual flow, 3 (5%) patients had heavy menstrual bleeding and 6 (10%) patients had only spotting.32 (53.33%) patients had dysmenorrhoea and 28 (46.67%) had painless menstruation. Duration of bleeding in 34 (56.66%) patients was 1-2 days, in 33 (55%) patients was 3-5 days and in 3 (5%) patients it was 6-8 days. Interval of bleeding in 21(35%) patients was 31-40 days, in 12(20%) patients 41-50 days, in 7(11.66%) patients 21-30 days, only 1(1.66%) patient had less than 20 days and remaining 19(31.67%) patients had interval of more than 50 days.

B. Clinical efficacy of therapy:

Effect of therapy on the pain during menstruation in patients of both groups: It was seen that in group A, 15 (50%) patients out of 30 patients had dysmenorrhoea, after the treatment, it was seen that, 16 patients out of 30, (53.33%), 21(70%),26 (86.66%) - had painless menstruation after 1st 2nd and 3rd cycle respectively. In group B, 17(56.67%) patients out of 30 had dysmenorrhoea, after the control group regimen, it was observed that, 11 patients (36.67%) had painless menstruation after 1st cycle, 11 (36.67%),12 (40%) had painless menstruation after 1st 2nd and 3rd cycle respectively.

Effect of therapy on regularity of menses in patients of both groups: In group A, it was observed that, 10 patients (66.66%) had regular menses. After giving the trial drug treatment, 12 patients (40%), 20 (66.66%), 26 (86.66%) out of 30 had regular menstruation after 1st 2nd and 3rd cycle respectively**.** In group B, it was seen that, 14 patients (46.66%) had regular menses. After giving the control group regimen, it was seen that, 12 (40%),14 (46.66%) and 15 patients (50%) had regular menstruation after 1st 2nd and 3rd cycle respectively.

C. Statistical analysis

(Table No.4): Statistical Analysis of effects of therapy on subjective parameters in **Group A** by Wilcoxon signed rank test

Sr. No	Symptom		Mean	SD	SE	W	n	Z	p
1	Menstrual pain	BT	1.73	0.98	0.17	378	27	4.54	<0.001 highly significant
		AT	0.63	0.71	0.13				
		DIFF	1.10	0.54	0.10				
2	Quantity of bleeding	BT	1.36	0.71	0.13	136	16	3.51	<0.001 highly significant
		AT	2.00	0.26	0.04				
		DIFF	-0.63	0.66	0.12				
3	Endo metrial thickness	BT	1.96	0.49	0.08	-15	5	2.02	<0.01 very significant
		AT	2.13	0.62	0.11				
		DIFF	-0.16	0.37	0.06				
4.	Follicle size	BT	0.40	0.49	0.09	-404	28	4.6	<0.001 highly significant
		AT	2.73	0.78	0.14				
		DIFF	-2.31	0.93	0.17				

(Table No.5) Statistical Analysis of effects of therapy on subjective parameters in **Group B** by Wilcoxon signed rank test

Sr. No	Symptom		Mean	SD	SE	W	n	Z	p
1	Menstrual pain	BT	1.83	0.71	0.14	2	3	0.5	>0.05 not significant
		AT	1.8	0.84	0.15				
		DIFF	0.03	0.31	0.05				
2	Quantity of bleeding	BT	1.83	0.79	0.14	-6	3	1.5	>0.05 not significant
		AT	1.80	0.84	0.15				
		DIFF	0.03	0.31	0.05				
3	Endo metrial thick-ness	BT	1.90	0.60	0.11	-3	2	1.34	>0.05 not significant
		AT	1.96	0.66	0.12				
		DIFF	-0.06	0.25	0.04				
4.	Follicle size	BT	0.4	0.49	0.09	378	27	4.54	<0.001 highly significant
		AT	2.53	0.89	0.16				
		DIFF	-2.13	0.93	0.17				

(Table No.6) **Comparison of Results of two Groups by Mann Whitney U Test:**

Sr. No	Symptom	$\sum R_1$	$\sum R_2$	U_1	U_2	SD	Z	P
1	Menstrual pain	1297. 5	532.5	67.5	832.5	67.63	5.67	<0.001 Highly significant
2	Quantity of bleeding	715.5	1114.5	250.5	649.5	67.73	2.9	<0.01 very significant
3	Endometrial Thickness	0.00	900	1365	465	67.63	6.65	<0.001Extremely Significant
4	Follicle size	865	965	400	500	67.63	0.73	>0.05 not significant

(Table No.7) **Efficacy of therapy during every menstrual cycle in Ovulation:**

Ovulation	Group-A		Group-B		Result
	Ovulated	Anovulated	Ovulated	Anovulated	
1st Cycle	**5**	**25**	**7**	**23**	>0.05
2nd Cycle	**12**	**18**	**10**	**20**	>0.05
3rd Cycle	**26**	**04**	**22**	**08**	>0.05

Thus from the above statistical analysis it can be seen that there is hardly any difference in both the therapies on ovulation. Thus the study drug is as effective as controlled drug, clomiphene citrate.

(Table No.8) **Efficacy of therapy during every menstrual cycle for Regularity:**

Regularity	Group-A		Group-B		Result
	Regular	Irregular	Regular	Irregular	

1st Cycle	12	12	18	18	>0.05
2nd Cycle	20	10	14	16	<0.05 significant
3rd Cycle	26	04	15	15	<0.001very significant

Thus from the above statistical analysis it can be seen that with the study drug menstrual cycle became regular after the second cycle of the treatment. Hence the result for the 2nd and 3rd menstrual cycle is significant.

Regularity of menstrual cycle: Table no 9 Percentage wise reliefs in the regularity of cycle.

Group	Cycle	BT	1st	2nd	3rd
A	Regular	33.33	40.00	66.66	86.66
	Irregular	66.67	60.00	33.33	13.33
B	Regular	46.66	40.00	46.66	50.00
	Irregular	53.33	60.00	53.33	50.00

The above table is showing % of patients with regular/irregular before and after every cycle of the treatment. Thus it can be seen that in Group A, the percentage of patients with regular menstrual cycle is increased after 2nd cycle of the treatment in Group A than in Group B.

(Table No.10) **Analysis of total effect of therapy by chi square test**

Groups	Ovulated	Conceived
Group A	20	6
Group B	12	4

2 = 0.05 (with Yates' correction) P>0.05, not significant

Mode of Action by Group-A Intervention:

a) Uttarbasti,

b) Rasona siddha taila

c) Rasona siddha kshirpaan

a)* Action of *Uttarbasti:

Action of the *uttarbasti* occurs by the synergistic action of *Rasona siddha Taila*. *Uttarbasti* is the procedure through which the drug is instilled into the uterus. Uterus is the *Mulasthana* of *Aartavavahastrotasa.* The study drug being directly instilled in the uterus gives direct access to the seat of *Strotovaigunya* and *Dosha-Dushya Sammurchana* and hence acts on the *vikrutvaayu* thereby disintegrating the *Samprapti*. Besides, Uttarbasti by the virtue of its movement causes *vatanulomana*. *Charaka* says, the uttarbasti, in the females, when given during *Aartavkaal* i.e. after the menstruation causes the shaman of *vatadosha* situated in the*garbhashaya* and *yoni*.

Uterine route as a mode of drug administration: Uterine Mucosa formed by a ciliated and secretory epithelium resting on a very cellular lamina propria. The number of ciliated cells and non-ciliated secretory cells varies along the oviduct. Secretory activity varies during the menstrual cycle.

Vascularity of endometrium in proliferative phase: Both the endometrial and subendometrial vascularization index (**VI**) and vascularization flow index (**VFI**) increased during the proliferative phase, peaking approximately 3 days prior to ovulation before decreasing to 5 days post-ovulation. Thus an oil based drug when instilled in the uterus during the proliferative phase might be getting easily absorbed in the systemic circulation. The advantages of this route might be:

i. Easiness of administration, Hepatic first pass-effect bypass.
ii. Low systemic drug exposure (namely in the case of products used for local conditions) and increased permeability for some

drugs when comparing to the oral or other routes.

iii. Low enzymatic activity and the possibility of preferential transfer of absorbed drugs to the ovary (referred as the "first-ovary-pass effect") may also benefit drug delivery.

b. Action of *Rasonataila:*

Rasa: Amlavarjit pancharas: By the virtue of this property study drug acts on the *Vaata* and *Kaphadosha*. It causes the shaman of vitiated *Vaat* and *Kapha doshas.*

Veerya: Ushna - By being *ushna veeryaatamak,* it causes shaman of *sheetaguna* of*Vaat* and *Kapaha*. When instilled in the uterus it may directly act on the *aartavavahasrotasa*, thereby splitting the '*Sanga'* caused by the *Kapha* in the pathway of *Apaanvaayu*. Thus it causes *vaataanulomana*. Besides being *ushna,* it probably results into *Agni deepana* and hence *deepana* of *rasa dhatvagni*, thereby increasing the *utpatti* of *rasa dhatu* and hence *aartava updhatu*.

Guna:

Sara*:Rasona* being *sara* stimulates all the *doshas* to perform their normal function.

***Guru* &*Snigdha*:** Being *guru* and *snigdha* pacifies the *vaatadosha* and improves the functions of *Kaphadosha*.

Tikshna: Being *tikshan* it acts on the *sangha* created by the *vikruta kaphadosha*, thereby receiving the *apaanvayu* from the *avrudhamarga.*

Picchil: by the virtue of this property, *rasona* causes *kaphavrudhi*, and exerts *sanvardhana* and *sandhana* action on the *garbhashayya.*

Karma: *Aartavajanan, Vaatanulomana, Kapha and Vaatashaamka.*

d) ***Rasona siddha kshirpan:*** It might be enhancing the effects of *uttarbasti.* It being *Rasayana***,** might be acting on the *Rasa dhatu*. Thereby improving the process of folliculogenesis and hence ovulation.

Effect of the drug formulation on the parameters:

1. Bleeding:

***Ayurvedic* view:** From the literature review it is seen that *Pitta dosha* is responsible for*Rajastraavakala. Rasonataila uttarbasti* may act on the *sthanik Pitta dosha* thereby increasing the raja *strava.*

Modern view: As seen above, *Rasona* is an emmenagogue, thereby increasing the menstrual bleeding. From the literature review it can be said that the *Rasona* is a vasodilator, hence it will cause vasodilatation of the spiral arteries in the uterus thereby increasing the endometrial proliferation and hence increases menstrual flow.

2. Painful Cycle:

***Ayurvedic* view:** *Rasonataila uttarbasti* causes *vatanuolomana* thereby reducing the pain. Besides, *Rasona* is a known *shoolaprashamak* and *vatashamak dravya* and so the formulation results in the reduced pain of the menstrual cycle.

Modern view: *Rasona* is an antispasmodic herb thereby reduces the contractions of the uterus during menstruation. Thus reduces the dysmenorrhoea.

1. Follicle size/ovulation:

Ayurvedic view: *Aartav* is *aagneya* by nature. The vitiation in the *sheetaguna* of *vata* and *kaphadosha* results into decrease *ushna* of this *aartava* leading to anovulation. By being *ushna veeryaatamak,* it causes *shaman* of *sheetaguna* of *Vaat* and *Kapaha.* When instilled in the uterus it may directly act on the *aartavavahasrotasa,* thereby splitting the '*Sanga'* caused by the *Kapha* in the pathway of *Apaanvaayu*. Thus it causes *vaataanulomana*. Besides being *ushna,* it probably results into *Agni deepana* and hence *deepana* of *rasa dhatvagni*, thereby increasing the *utpatti* of rasa *dhatu* and hence *aartavaup dhatu*.

Modern view: Being instilled in the uterus it might be getting absorbed into systemic circulation and might be affecting the hypo-

thalamo-pituitary-ovarian axis thereby regularizing the secretion of hormones.

2. Endometrial thickness:

Ayurved review: Increase in the endometrial thickness occurs during the proliferative phase which is related to the *kaphadosha*. By the virtue of its *gunas* (*snigdha and pischhila*) *kapha* increases the endometrial thickness. Inanovulation there occurs derangement of these *gunas*. *Rasona* is *snigdha* and *picchila.* Being *ushna* it acts on the derangements reduces the *sheetaguna* of *kaphadosha* and being *snigdha* and *picchila* it increases these *guna* of *kapha* thereby increasing the endomentria lthickness.

Modern view: Being a phytoestrogen, it exerts both estrogenic and antiestrogenic activity. It acts in both high estrogenic and low estrogenic condition. Thus increases the endometrial thickness.

DISCUSSION

In this study statistical analysis revealed that 50% of patients belonged to age group 31-40 years, 48.33% of patients were of *kaphavataprakruti* which suggestive of involvement of *vata and kaphadosha* in the etiopathogenesis of *vandhyatva*. Maximum numbers of patients 73.33% were found to be depressed. In the menstruation history, 60% of patients had irregular menstrual cycle, 45% of patients had scanty menses, 53% of patients had painful menstrual cycle, 56.66% of patients had menstrual cycle of duration 1-2 days followed by 55% of patients with menstrual cycle of 3-5 days. It is seen that the results of the therapy in both groups, in case of ovulation/follicle size are equally effective. In this concern, *Rasona-Taila Uttarbasti* and *Siddha Kshirpan* are as effective as Clomiphene Citrate. In case of other parameters viz. painful menstruation, menstrual flow and endometrial thickness results of Group A are better than Group B.Thus *RasonaTaila Uttarbasti and Siddha Kshirpan* is not only effective in ovulation but also reduces the dysmenorrhoea, increases menstrual flow and increases the endometrial thickness. Also it was found effective in the regularity of menstrual cycle which is not seen with Group B.

Total effect of therapy: Total effect of therapy was seen in terms of change in the follicularsize and ovulation. It was also measured in terms of conception. In Group A, at the end of the treatment it was seen that 66.67% of patients had ovulated, 20% of patients had conceived and follicle size of 6.67% of patients was increased. In Group B, it was seen that 40% of patients had ovulated, 13.33% of patients had conceived and follicle size of 20% of patients was increased. This suggests that the Group A is as effective as Group B in inducing ovulation.

CONCLUSION

Rasonataila uttarbasti and kshirpaan has significant results in all the parameters. It reduces the pain of menstrual phase and increase the menstrual flow also enhances the irregular menstrual cycles into regular mode. Trial drug also effective for inducing the timely ovulation and increases the endometrial thickness. It induces ovulation in patients which are resistant to clomiphene citrate also. This formulation proves to be an alternative, cost effective, herbal treatment for anovulatory menstrual cycles.

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