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A clinical study to evaluate the efficacy of Kashmarya Kutaja Kwatha Sidha Gritha Uttarabasti in Vandhyatwa w.s.r. to Anovulation

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ABSTRACT

The topic of infertility is still utterly taboo and that's why so many women with infertility suffer silence. Infertility is defined as a failure to conceive within one or more years of regular unprotected coitus.^[1] The WHO performed a large multinational study and found that in 37% of infertility couples, female infertility was the cause and Ovulatory disorders accounts 25%. [2] Our Acharya's has mentioned that Love, Strength, Happiness, Fame, Pleasure are the attributes, which are acquired by children.[3] Our Acharya's has explained Infertility under Vandhyatwa, where in, Acharya Charaka has not explained Vandhyatwa as independent Yoni Vyapat, but while explaining Asruja Yoni Vyapat, Arajaska Yoni Vyapat, Putraghni Yoni Vyapat, it all has the outcome of Vandhyatwa, for which he has also explained the treatment with Kashmarya Kutaja Kwatha Sidha Uttara Basti and Acharya Kashyapa has explained Shatapushpa having Rtu Pravartana effect. As there are many side effects by using modern (contemporary) medicines for induction of ovulation. This study was intended to evaluate the efficacy of Kashmarya Kutaja Kwatha Siddha Ghrita Uttarabasti in the management of Vandhyatwa w.s.r. to Anovulation. 30 subjects fulfilling the criteria were randomly selected from OPD & IPD of SSCASR & H and were assessed before and after treatment.

Key words: Infertility, Vandhyatwa, Uttarabasti, Kashmarya Kutaja Kwatha Sidha Gritha, Shatapushpa Taila.

INTRODUCTION

Infertility is a medical condition that can cause psychological, physical, mental, spiritual, and medical detriments to the patient. Procuring the progeny depends on the fertility potential of both male and female partner. Male is directly responsible in about 30-40%, female in about 40-55%, both in about 10% of

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cases and remaining 10% is unexplained. Similarly infertility also depends on both male and female partners. Therefore, Infertility is defined as a failure to conceive within one or more years of regular unprotected coitus.[4] About one-tenth of the world's population suffer from infertility, and infertility trend has been increasing in recent years in most parts of the world. [5] There are many causes for female infertility such as Ovarian factors, Tubal factors, Uterine factors, Cervical factors, Pelvic endometriosis, among which 30-40% are due to ovarian factors. In Ayurveda many explanations have been given for Vandhyatwa among which Acharya Sushruta has explained, destruction of Artava a Vandhya in turn causing Vandhyatwa. [6] Acharya Charaka has not explained Vandhyatwa as independent Yoni Vyapat, but while explaining Asruja Yoni Vyapat, Arajaska Yoni Vyapat, Putraghni Yoni Vyapat, [7] it all has the outcome of Vandhyatwa, for which he has also explained the treatment protocol. Acharya Kashyapa, while explaining the treatment of

Vandhyatwa (Alpa Pushpa, Nasta Pushpa, Nasta Artava), he has mentioned Basti as the ideal treatment. Basti is considered as the main treatment protocol in all Vataja disorders as per Acharya Charaka, whereas Acharya Sushruta opines that Basti is useful in management of diseases occurred due to Vata, Pitta, Kapha and Rakta Dosha. Uttarabasti being one among the Basti procedure, which is of different types based on the route of administration, among which Garbhashayagata Uttarabasti is mainly

AIMS

 To evaluate if Kashmarya Kutaja Kwatha Siddha Gritha Uttarabasti has better effect in the management of Vandhyatwa with special reference to anovulation.

concerned with Yoni, Beeja, Artava Dusti.

2. To reevaluate *Shatapushpa Taila Uttarabasti* in the management of *Vandhyatwa* with special reference to anovulation.

Ethical Clearance

Ethical clearance for conduction of the clinical trial involving human subjects was taken from the IEC before the commencement of trial.

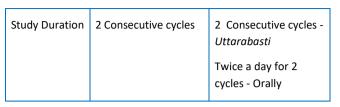
Clinical Study Design

Table 1: Showing the Study Design

Study Design	Group A	Group B
Procedure	Uttarabasti with Kashmarya Kutaja Kwatha Siddha Ghrita	Uttarabasti with Shatapushpa Taila and Shatapushpa Oral administration
Time of administration of <i>Uttarabasti</i>	In Rutukala that is after the menstrual flow stops for 2 Consecutive cycles, in each cycle for 3 days (Total 6 times).	In Rutukala that is after the menstrual flow stops for 2 Consecutive cycles, in each cycle for 3 days (Total 6 times).
Dosage	3 - 5ml : <i>Uttarabasti</i>	3 - 5ml : <i>Uttarabasti</i> 500mg : Oral administration

ORIGINAL ARTICLE

September 2023



Criteria for selection of patient

Inclusion Criteria

- 1. Married women of age between 20-35 years.
- 2. Subject of Primary or Secondary Infertility.
- 3. Subject with the history of Anovulation.
- 4. Subject with the history of PCOD, Oligo menorrhea, Menorrhagia.
- 5. Subject with the history of Habitual or Spontaneous abortion.

Exclusion Criteria

- 1. Subjects with history of PID, Tuberculosis, Pelvic Endometriosis.
- Subjects with any known cases of Systemic disorders.
- 3. Subjects with any known case of Benign and Malignant tumors.
- 4. Subjects with any known case of Polymenorrhea, Metrorrhagia, Menometrorrhagia.

Assessment Criteria

- 1. Follicular study performed before and after *Uttarabasti*.
- 2. Efficacy of medicine and procedure assessed on the basis of the size of follicles.
- 3. Efficacy of medicine and procedure assessed on the objective parameter.

Subjective Parameter

 Mid cycle discomfort in Hypogastric region or in Iliac region. (Mittelschmerz pain).

0 = Absent

1 = Present

Mid cycle pain and tenderness in breast.

0 = Absent

ORIGINAL ARTICLE

September 2023

1 = Present

- Mid cycle P/V slight loss of blood or of mucus tinged with blood (Mittelblut).
- 0 = Absent
- 1 = Present

1) Objective Parameter

- Assessment for folliculogenesis Scoring pattern of follicle.
- 0 = < 12 mm
- 1 = 12-20 mm
- 2 = > 20 mm
- 3 = Ovulate
- Fluid in POD
- 0 = Absent
- 1 = Present
- Overall Assessment
- 0 = Unchanged: No change in the growth of follicles
- 1 = Improved: Ovulation not occurred but there is significant growth in the follicles
- 2 = Ovulated: Ovulation occurred
- 3 = Conceived

OBSERVATIONS AND RESULTS

Table 2: Showing the distribution of Patients based on Mittelschmerz Pain

Group A	ВТ	%	АТ	%
Grade 0 (Absent)	12	80%	6	40%
Grade 1 (Present)	3	20%	9	60%
Group B	вт	%	АТ	%
Grade 0 (Absent)	11	73.3%	11	73.3%
Grade 1 (Present)	4	26.6%	4	26.6%

Table 3: Showing the distribution of Patients based on Breast Tenderness & Pain

Group A	ВТ	%	AT	%
Grade 0 (Absent)	10	66.6%	4	26.6%
Grade 1 (Present)	5	33.3%	11	73.3%
Group B	вт	%	AT	%
Grade 0 (Absent)	13	86.6%	8	53.3%

Table 4: Showing the distribution of Patients based on Mittel blut

Group A	ВТ	%	АТ	%
Grade 0 (Absent)	9	60%	6	40%
Grade 1 (Present)	6	40%	9	60%
Group B	ВТ	%	AT	%
Grade 0 (Absent)	15	100%	13	86.6%
Grade 1 (Present)	0	0%	2	13.3%

Table 5: Showing the distribution of Patients based on Folliculogenesis

Group A	ВТ	%	АТ	%
Grade 0 (<12MM)	11	73.3%	3	20%
Grade 1 (12- 20MM)	3	20%	2	13.3%
Grade 2 (>20MM)	1	6.6%	2	13.3%
Grade 3 (Ovulated)	0	0%	8	53.3%
Group B	ВТ	%	AT	%
Grade 0 (<12MM)	9	60%	6	40%
Grade 1 (12- 20MM)	6	40%	5	33.3%

ORIGINAL ARTICLE

September 2023

Grade 2 (>20MM)	0	0%	1	6.6%
Grade 3 (Ovulated)	0	0%	3	20%

Table 6: Showing the distribution of Patients based on Fluid in Pouch of Douglas

Group A	ВТ	%	AT	%
Grade 0 (Absent)	15	100%	5	33.3%
Grade 1 (Present)	0	0%	10	66.6%
Group B	ВТ	%	AT	%
Group B Grade 0 (Absent)	BT 15	% 100%	AT 8	% 53.3%

Table 7: Showing the distribution of Patients based on Over All Assessment

Group A	Assessment	%
Grade 0 (Unchanged)	3	20%
Grade 1 (Improved)	2	13.3%
Grade 2 (Ovulated)	3	20%
Grade 3 (Conceived)	7	46.6%
Group B	Assessment	%
Grade 0 (Unchanged)	2	13.3%
Grade 1 (Improved)	7	46.6%
Grade 2 (Ovulated)	4	26.6%
Grade 3 (Conceived)	2	13.3%

RESULTS

Table 8: Showing the Wilcoxon Signed Rank Test & Mann-Whitney Rank Sum Test based on Mittelschmerz Pain

Mittelschmerz Pain (Data: Median, 25th & 75th percentile)			
Group	Day 0	After 2 Months	
Group A	0.00(0.00 - 0.00)	1.00 (0.00 – 1.00)@	
Group B	0.00 (0.00 – 1.00)	0.00 (0.00 – 1.00)@	

Table 9: Showing the Wilcoxon Signed Rank Test & Mann-Whitney Rank Sum Test based on mid cycle Breast Tenderness and Pain

BTP (Data: Median, 25 th & 75 th percentile)			
Group	Day 0	After 2 Months	
Group A	0.00(0.00 – 1.00)	1.00 (0.00 – 1.00)@	
Group B	0.00(0.00 - 0.00)	0.00 (0.00 – 1.00)	

Table 10: Showing the Wilcoxon Signed Rank Test & Mann-Whitney Rank Sum Test based on Mittel Blut

Mittel Blut (Data: Median, 25 th & 75 th percentile)			
Group	Day 0	After 2 Months	
Group A	0.00(0.00 - 1.00)	1.00 (0.00 – 1.00)	
Group B	0.00(0.00 – 0.00)*	0.00 (0.00 – 0.00)*	

Table 11: Showing the Wilcoxon Signed Rank Test & Mann-Whitney Rank Sum Test based on Folliculogenesis

Folliculogenesis (Data: Median, 25 th & 75 th percentile)			
Group	Day 0	After 2 Months	
Group A	0.00(0.00 – 1.00)	3.00 (1.00 – 3.00)@	
Group B	0.00(0.00 – 1.00)	1.00 (0.00 – 2.00)@	

Table 12: Showing the Wilcoxon Signed Rank Test & Mann-Whitney Rank Sum Test based on Fluid in POD

Fluid In POD (Data: Median, 25 th & 75 th percentile)		
Group	Day 0	After 2 Months
Group A	0.00(0.00 – 0.00)	1.00 (0.00 – 1.00)@
Group B	0.00(0.00 – 0.00)	0.00 (0.00 – 1.00)@

ORIGINAL ARTICLE

September 2023

Over All Result

Among 15 patients in group A, 3(20%) had unchanged result, 2(13.3%) had improved in follicle size, 3(20%) ovulated and 7 (46.6%) conceived after the treatment & Among 15 patients in group B, 2(13.3%) had unchanged result, 7(46.6%) had improved in follicle size, 4(26.6%) ovulated and 2 (13.3%) conceived after the treatment.

DISCUSSION

Probable mode of action

1. Uttarabasti

- In *Uttarabasti*, the drug is administered into the uterine cavity.
- The epithelial tissues present in the endometrial layer has the function of Absorption and diffusion.^[9]
- Due to this action, the medicine administered based on its *Guna*, *Karma*, acts locally by the simple diffusion and systemically by the absorption.
- Thus, it helps in providing the proper feed mechanism, by governing the H-P-O axis, which is necessary for the regulation of Follicular phase which in turn promote the growth of follicle by correcting the hormone imbalance, which is the main cause for Anovulatory cycle leading to Vandhyatwa.

2. Kashmarya Kutaja Sidha Ghrita

- Kashmarya having Guru Guna has the action of Brimhana which helps in the growth of Follicles and Usna Veerya along with Rechana Karma helps for the follicles to rupture which is the essential factor for ovulation to occur. [10]
- Kutaja having Laghu Ruksha Guna along with Lekhana Karma helps the ovum which is surrounded by corona radiate to escape out of Graafian follicle hence the process of rupture takes place.[11]
- Due to Dhatavagni Mandhyata, there will be formation of Ama and the Karma like Deepana Pachana helps in Ama Nirharana and does the

- Samprapti Vighatana by correcting Dhatavagni along with Tridosha Hara Karma of the drug.
- As the drug is given in the form of Ghrita, which has the properties like Madhura Snigdha Guna and Brimhana karma further helps in the growth of follicle, also corrects the Vata which is mainly involved in Samprapti of Vandhyatwa by its Sneha Guna.

3. Shatapushpa Taila

- Shatapushpa having Teekshna Guna^[12] helps in quick absorption and also does the stimulation which is necessary for the ovarian function and Lekhana Guna helps in rupture of the dominant follicle which is needed for ovulation.
- Based on its Vata Hara property it helps in Samprapti Vighatana as Vata is the main Dosha involved in Vandhyatwa.
- Shatapushpa also has the karma of Rutupravartana^[13] which indicates both Artavajanana and Beejotsarga and can be inferred as ovulatory cycles.
- As the drug is given in the form of Taila, which has the properties like Snigdha Usna Guna and Yoni Vishodhana Karma helps in treating the Vigunata of Apana Vayu which is mainly involved in Samprapti of Vandhyatwa.

CONCLUSION

The action of Kashmarya Kutaja Kwatha Siddha Ghrita and Shatapushpa Taila is similar to the drugs which induce ovulation, without any side effects. In the overall assessment it is seen that there is increase in conception when associated with anovulatory cycles with this protocol. Thus, it can be concluded that Uttara Basti with Kashmarya and Kutaja in the form of Gritha and Shatapushpa Taila has a better effect in Vandhyatwa.

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ORIGINAL ARTICLE

September 2023

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