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Research Article

Efficacy of *Asparagus recemosus* (Satavar) in stimulating follicular growth and ovulation in anovulatory infertility: a randomized controlled trial

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ABSTRACT

Background: Anovulation is the commonest cause of female infertility, responsible for 30% of cases and the most frequent cause of anovulation in women is polycystic ovarian syndrome. The aim of the study was to evaluate the anovulatory efficacy of *Asparagus recemosus*, commonly known as *Satavar*, in stimulating follicular growth and ovulation in an ovulatory infertility.
Methods: A randomized standard controlled study was carried out at the National institute of Unani medicine Hospital, Bangalore. Patients (n=40) were randomly allocated to test (n=20) and control (n=20) groups. Infertile women in the age group of 18-40 years with menstrual irregularities, polycystic ovarian disease & spouse normal seminogram were included in the study. Patients with primary ovarian failure, thyroid dysfunction, hyperprolactinaemia, systemic illnesses, malignancy and those on hormonal therapy in last 3 months were excluded. In test group, 6 grams of *A. recemosus* powder twice daily from day 1-14 of cycle and in control group, clomiphene citrate 50 mg once daily from day 2-6 of cycle was administered orally for 2 consecutive cycles. Primary outcome measures (follicular growth & ovulation) and secondary outcome measure (conception) were assessed for improvement. Data were analyzed using Student 't'test, chi-square and Fisher exact test.
Results: After 1st and 2nd cycles of treatment, follicular growth was 30% and 40% in test group and 60% & 50% in control group; ovulatory rate was 25% & 30% in test group and 40% & 25% in control group and conception rate was 0% in test group and 10 % and 5% in control group.
Conclusions: The effect of test drug was comparable with that of control drug in stimulating follicular growth & ovulation, though the drug was not as effective as control drug to achieve conception.

Keywords: Anovulatory infertility, *Asparagus recemosus*, Clomiphene citrate, Follicular growth, Ovulation, Conception

INTRODUCTION

Anovulation is the most common etiologic factor of infertility[1,2] which accounts for approximately 30% of all cases of female infertility.[3,4] The causes of anovulation include hypothalamic failure, hyperprolactinaemia, polycystic ovarian syndrome, premature ovarian failure, subclinical hypothyroidism, adrenal failure and obesity. Out of these disorders, polycystic ovarian syndrome is the commonest, easily diagnosed and most treatable cause of an anovulatory infertility[5] accounting for 75% of cases. In classical Unani literature, the concept of ovulation is mentioned by renowned Unani physician Al Majoosi in his treatise Kamilus Sana centuries ago. He states that an ovary produces a follicle which secretes ovum, the later reaches the uterine cavity through the fallopian tubes.[6] The description of anovulation is mentioned under the headings of infertility (uqr) which is

defined as inability to conceive either due to defect in sperm of male partner or ovum of female partner or both.[6-8] Chronic anovulation (*Tooleehtebase mani*) is mainly caused by altered temperament (*sue mizaj*) which may be either due to excess heat, cold, moist & dryness.[7] Any sort of defect in ovaries leads to faulty production of ovum, which is either due to oligo-ovulation/anovulation, dysovulation[9] or extreme cold.[10] The only treatment available in conventional medicine for follicle growth and ovulation is hormone therapy, which though effective but has its own side effects. Hence, there is a need for alternative therapy which is to be safe, effective, easily available and free from side effects. Herbal drugs are safe with lesser side effects and presence of multiple active compounds in them provide a potentiating effect such as they enhance the immunity of the body, regularize the menstrual cycle and induce the ovulation by maintaining hormonal balance.[11] In Unani system of medicine, principles of treatment includes correction of altered temperament (*sue mizaj*), maintaining body weight with regimen, diet and drugs; use of emmenagogue (*mudir haiz*) and ovulation inducing (*Mwallide mani)* drugs.[6,7] Satavar was selected as research drug due to its ovulation inducing (*Mwallide mani)* and aphrodisiac (*muqawwi bah*) propereties,[12] and is known to contain phytohormones (steroidal saponins & glycosides) which stimulates the follicular growth by maintaining the hormonal balance.[13] The aim of the study was to evaluate the effectiveness of satavar scientifically in patients of anovulatory infertility.

METHODS

Study design

A single blind standard controlled randomized study was carried out from November 2013 and March 2015 in OBG Dept. National Institute of Unani Medicine Hospital, Bangalore. Ethical clearance was obtained from the institutional ethical committee.

Participants

Total 235 patients were evaluated for the study, 115 patients didn't meet the inclusion criteria and 80 denied participation, hence were excluded (Figure 1). Sample size of 40 was estimated on the basis of previous study conducted on induction of ovulation in anovulatory infertility[14] and were randomly allocated in two equal groups by computer generated simple randomization table. All participants gave written informed consent prior to study.

Selection criteria

Married women in the age group of 18-40 years who were anxious to conceive having irregular menstrual cycle, with features of polycystic ovarian disease and no follicular growth & ovulation on TVS and spouse normal seminogram were included in the study. Patients with primary ovarian failure, thyroid dysfunction, hyperprolactinaemia, systemic illnesses, malignancy and on hormonal therapy for anovulation within last 3 months were excluded. Investigations like UPT, RBS, thyroid profile, Sr. prolactin and spouse semen analysis were done for exclusion.

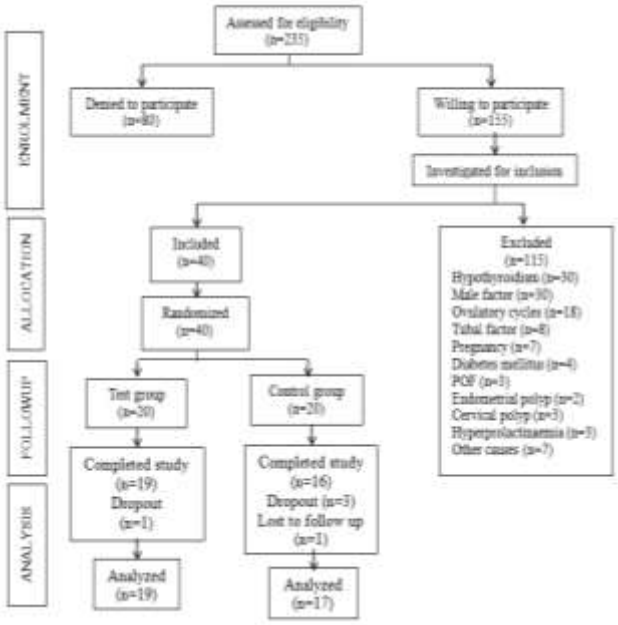

Figure 1: Consort flow chart.

Procedure

On entry into the study, detailed history were enquired from each patient regarding infertility, particularly about its duration, type, any pervious treatment received etc. Complete physical examination was performed in all patients and findings were recorded in the case record form designed for the study. In patients with oligomenorrhoea or amenorrhoea, emmenagogue drugs (*safoof or hab mudir haiz with sharbat bazoori*) were given for 1-2 weeks to induce menstruation. Once menstruation was established, patients were advised to report on D_1 of menstrual cycle for routine investigations, lipid profile, LFT and RFT.

Intervention

In test group, 12 grams of satavar powder[15,16] was administered orally, with milk in two divided doses daily from $D_{1\text{-}14}$ of cycle and in control group, clomiphene citrate 50 mg once daily[17-19] was administered orally from $D_{2\text{-}6}$ of cycle for two consecutive cycles. Patients of both groups were unaware of treatment provided as medicine was dispensed to one patient at a time. Compliance was assessed at every follow up visit by examining the packets in which medicine was dispensed.

Follow up

Patients were followed on 1st day of every cycle to start the therapy and were instructed to come for follicular study from D_{12}-D_{16} on every alternate day and again on D_{21} of cycle for serum progesterone. Timed intercourse was advised to the patients at the time of ovulation. If the patient had missed period, then urine for pregnancy test was done to detect the pregnancy. If UPT was negative, no medicine was prescribed for withdrawal bleeding; rather, the patient was asked to wait for spontaneous menstruation and simultaneously pattern of menstrual cycle were also noted. Patients were also enquired for any adverse effect of test drug during the trial. After treatment, patients were followed once in a month for one month to look for spontaneous follicular growth and ovulation on TVS.

Subjective parameter

Menstrual irregularity was assessed by menstrual cycle pattern which includes nature of cycle, duration of cycle, duration of flow and amount of flow.

Objective parameters

TVS for follicular study was performed to detect ovulation (follicular growth & rupture, endometrial thickness, presence of fluid in POD) and Serum progesterone was done to confirm ovulation.

Outcome measures

Primary outcome measures were follicular growth & ovulation. Follicular growth was confirmed by the presence of total no. of growing follicles on TVS, no. of follicle >10 mm, no. of follicle >14 mm, no. of follicle >17 mm.[20] Secondary outcome measure was conception which was confirmed either by UPT or ultrasonography.

Statistical analysis

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, Med Calc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used to analyze the data and Microsoft word and Excel have been used to generate graphs and tables. Significance was assessed at 5 % level. Student t test, chi-square/Fisher exact test were used to analyze the data.

RESULTS

Baseline characteristics

Mean age of patients in test & control group were 22.85±2.35 and 24.85±4.11 respectively (p=0.102). Majority of patients 26 (65%) had primary infertility, mean±SD of duration of infertility were 3.40±2.36 & 3.83±2.72 respectively in test and control group. Maximum patients 22 (55%) were from upper lower class; and majority of the patients 31 (77.5%) had predominance of *balghami mizaj* (Table 1).

Table 1: Comparison of baseline characteristics in two groups.

Baseline characteristics	Test Group (n=20)	Control Group (n=20)	p value
Age (years)	22.85±2.35	24.85±4.11	0.102
Age at marriage	18.55±2.56	20.10±3.23	0.101
Married life	4.43±3.02	4.78±2.98	0.714
Type of infertility Primary Secondary	 14 (70.0%) 6 (30.0%)	 12 (60.0%) 8 (40.0%)	0.507
Duration of infertility	3.40±2.36	3.83±2.72	0.601
Socioeconomic status Lower middle Upper lower Upper Middle	 8 (40.0%) 10 (50.0%) 2 (10.0%)	 6 (30.0%) 12 (60.0%) 2 (10.0%)	1.000
Mizaj *Balghami* *Damvi* *Safravi*	 16 (80.0%) 3 (15.0%) 1 (5.0%)	 15 (75.0%) 3 (15.0%) 2 (10.0%)	1.000

Subjective parameters

In test group, 75% patients had irregular cycle at base line which becomes regular in 65% after 1st cycle, 73.7% after 2nd cycle and 63.2% patients on post treatment follow up with a % change of 38.2; while in control group, 70% patients had irregular cycle at base line which becomes regular in 45% after 1st cycle, 73.3% after 2nd cycle and 76.9% patients on post treatment follow up with a % change of 46.9 (Table 2).

The mean ± SD duration of cycle before treatment, after 1st & 2nd cycle of treatment and on post treatment follow up were 70.40±32.28, 38.35±13.52, 35.11±18.01, 38.58±21.87 respectively in test group and 57.90±26.41, 46.50±20.83, 36.50±17.38, 40.77±28.91 respectively in control group. The difference was strongly significant (p<0.001) in test group as compare to control group (Table 3).

Objective parameters

After 1st & 2nd cycle of treatment number of follicle >10 mm were 0.20±0.41, 0.32±0.48 respectively in test group and 1.05±1.28, 1.20±1.21 respectively in control group. The difference in follicle growth was strongly significant in control group (inter group comparison) (p=0.007 & 0.006). The difference in follicle growth was suggestive significant after 1st cycle of treatment (p=0.095) and even on post treatment follow up (p=0.082) in control group (intra group comparison). Number of follicle >14 mm after 1st & 2nd cycle of treatment were 0.26±0.45,

0.29±0.47, respectively in test group and 0.75±1.13, 0.85±0.99 respectively in control group. The difference in follicle growth was suggestively significant in control group (inter group comparison) (p=0.093 & 0.052). The difference in follicle growth was suggestive significant in test group (p=0.083) after 1st cycle of treatment and even in control group (p=0.017) on post treatment follow up (intra group comparison). Number of follicle >17 mm after 1st & 2nd cycle of treatment were 0.00±0.00, 0.08±0.28, respectively in test group and 0.53±0.99, 0.50±0.85 respectively in control group. The difference in follicle growth was moderately significant (p=0.046) in control group after 1st cycle of treatment (inter group comparison) and suggestive significant (p=0.056) in test group on post treatment follow up (intra group comparison) (Table 4).

Table 2: Comparison of nature of menstrual cycle in two groups.

Nature of menstrual cycle	Before treatment	After I cycle treatment	After II cycle treatment	Follow up after treatment	% change
Test group					
Irregular	15 (75%)	7 (35%)	5 (26.3%)	7 (36.8%)	-38.2%
Regular	5 (25%)	13 (65%)	14 (73.7%)	12 (63.2%)	38.2%
Control group					
Irregular	14 (70%)	11 (55%)	4 (26.7%)	3 (23.1%)	-46.9%
Regular	6 (30%)	9 (45%)	11 (73.3%)	10 (76.9%)	46.9%
p value	0.723	0.204	0.929	0.409	-

Table 3: Comparison of menstrual cycle pattern in two groups.

Duration of cycle (Days)	Before treatment	After I cycle treatment	After II cycle treatment	Follow up after treatment
Test group	70.40±32.28	38.35±13.52 (p<0.001**)	35.11±18.01 (p<0.001**)	38.58±21.87 (p=0.001**)
Control group	57.90±26.41	46.50±20.83 (p=0.083+)	36.50±17.38 (p=0.033*)	40.77±28.91 (p=0.173)
p value	0.188	0.150	0.818	0.809
Duration of flow (Days)				
Test group	4.90±3.11	5.05±2.98	4.68±1.95	4.68±1.95
Control group	4.45±2.35	4.35±2.25	4.44±2.22	4.36±2.50
p value	0.609	0.408	0.728	0.675
Amount of flow (Pads/cycle)				
Test group	9.26±6.60	9.30±6.63	8.61±4.39	8.61±4.39
Control group	7.15±5.06	6.85±5.17	7.13±4.84	7.46±5.03
p value	0.268	0.200	0.355	0.504

Table 4: Comparison of follicle growth on TVS in two groups.

Follicle growth	Before treatment	After I cycle treatment	After II cycle treatment	Follow up after treatment
No. of follicle >10mm				
Test group	0.50±1.00	0.20±0.41	0.32±0.48	0.21±0.54
Control group	0.60±0.60	1.05±1.28	1.20±1.21	0.15±0.38
p value	0.703	0.007**	0.006**	0.744
No. of Follicle >14mm				
Test group	0.35±0.67	0.26±0.45 (p=0.429)	0.29±0.47 (p=0.431)	0.05±0.23 (p=0.083+)
Control group	0.30±0.47	0.75±1.13 (p=0.088+)	0.85±0.99 (p=0.111)	0.00±0.00 (p=0.017*)
p value	0.786	0.093+	0.052+	0.436
No. of Follicle >17mm				
Test group	0.25±0.55	0.00±0.00 (p=0.164)	0.08±0.28 (p=0.337)	0.00±0.00 (p=0.056+)
Control group	0.20±0.41	0.53±0.99 (p=0.136)	0.50±0.85 (p=0.193)	0.00±0.00 (p=0.167)
p value	0.746	0.046*	0.105	-

After 1st & 2nd cycle of treatment, 25% and 21% patients had fluid in POD in test group with a percentage change of 5.3%, while in control group it was 20% & 40% and the difference (p=1); ovulation was detected in 25% and 31.6 % patients in test group and 20% and 0% patients in control group; serum progesterone was 1.43±3.46 & 3.12±5.83 respectively in test group and 4.51±7.53, 4.15±7.38 respectively in control group (p>0.05) (Table 5).

Primary outcome measures

After 1st & 2nd cycles of treatment, follicular growth was 30% & 40% in test group and 60% & 50% in control group. The difference was suggestive significant (p=0.057) in control group after 1st cycle of treatment although the difference was not significant after 2nd cycle of treatment (p>0.05). After 1st & 2nd cycles of treatment, ovulatory rate was 25% & 30% in test group and 40% & 25% in control group and the difference was not significant statistically (p>0.05).

Secondary outcome measure

After 1st & 2nd cycles of treatment, conception rate was 0% in test group and 10 % & 5% in control group (Table 6).

Table 5: Comparison of fluid in POD & ovulation on TVS; Serum progesterone in two groups.

Fluid in POD	Before treatment	After I cycle treatment	After II cycle treatment	Follow up after treatment	% change
Test group					
No	20 (100%)	15 (75%)	15 (78.9%)	18 (94.7%)	-5.3%
Yes	0 (0%)	5 (25%)	4 (21.1%)	1 (5.3%)	5.3%
Control group					
No	20 (100%)	16 (80%)	9 (60%)	13 (100%)	0.0%
Yes	0 (0%)	4 (20%)	6 (40%)	0 (0%)	0.0%
p value	1.000	1.000	0.465	1.000	-
Ovulation					
Test group					
No	20 (100%)	15 (75%)	13 (68.4%)	18 (94.7%)	-5.3%
Yes	0 (0%)	5 (25%)	6 (31.6%)	1 (5.3%)	5.3%
Control group					
No	20 (100%)	16 (80%)	15 (60%)	13 (100%)	0.0%
Yes	0 (0%)	4 (20%)	0 (0%)	0 (0%)	0.0%
p value	1.000	1.000	0.723	1.000	-

Serum progesterone	**After I Cycle Treatment**	**After II Cycle Treatment**	**p value**
Test group	1.43±3.46	3.12±5.83	0.113
Control group	4.51±7.53	4.15±7.38	0.657

Table 6: Comparison of outcome measures in two groups.

Outcome Measures	Test group (n=20)	Control group (n=20)	p value
Follicular growth			
Before treatment	2(10.0%)	2(10.0%)	1.000
After I cycle treatment	6(30.0%)	12(60.0%)	0.057+
After II cycle treatment	8(40.0%)	10(50.0%)	0.525
Follow up after treatment	3(15.0%)	2(10.0%)	0.633
Ovulation			
Before treatment	0(0.0%)	0(0.0%)	-
After I cycle treatment	5(25.0%)	8(40.0%)	0.311
After II cycle treatment	6(30.0%)	5(25.0%)	0.723
Follow up after treatment	1(5.0%)	2(10.0%)	1.000
Conception			
Before treatment	0(0.0%)	0(0.0%)	1.000
After I cycle treatment	0(0.0%)	2(10.0%)	0.487
After II cycle treatment	0(0.0%)	1(5.0%)	1.000
Follow up after treatment	0(0.0%)	0(0.0)	1.000

DISCUSSION

Baseline characteristics were statistically similar in both groups (p>0.05). Mean age of patients were 22.85±2.35 and 24.85±4.11 respectively in test & control group; majority of the patients were belonged to upper lower SES, had primary infertility within 1-5 years of duration, possessed *balghami mizaj* and had PCOD on ultrasonography (Table 1).

Subjective parameters

In test group, 63.2% patients achieved regular menstrual cycles and 36.8% had persistent irregular cycles with a %change of 38.2%; while in control group, 76.9% patients achieved regular menstrual cycles and 23.1% had persistent irregular cycles with a % change of 46.9% after treatment. Qayyum B et al[21] reported 73% patients achieved regular menstrual cycles and 26% had persistent irregular cycles after treatment which is in accordance with the present study (Table 2). Strongly significant reduction in duration of cycle (p<0.001), was observed after every cycle of treatment in test group as compared to control group on intra group comparison, although the difference was not significant on inter group comparison. No significant difference in amount of flow & duration of flow was observed in both groups (Table 3).

Objective parameters

After 1st & 2nd cycle of treatment, strongly significant difference in follicle growth (>10 mm) was observed in control group (p=0.007 & 0.006); the difference in follicle growth (>14 mm) was suggestively significant (p=0.093 & 0.052) in control group and the difference in follicle growth (>17mm) was moderately significant (p=0.046) in control group after 1st cycle of treatment on inter group comparison (Table 4). Ovulation was detected in 25% and 31.6% patients in test group and 20% and 0% patients in control group. No significant differences in endometrial thickness, fluid in POD & Sr. progesterone were observed between two groups with p>0.05 (Table 5).

Outcome measures

After 1st and 2nd cycles of treatment, follicular growth was 30% & 40% in test group and 60% & 50% in control group; ovulatory rate was 25% & 30% in test group and 40% & 25% in control group. Kafeel G et al[22] reported ovulatory rate of 40%, & 35.3% which is in conformance with the present study. Conception rate was 0% in test group and 10% & 5% in control group. Kafeel G et al[22] reported conception rate of 10%, & 18.8% on 1st and 3rd cycles of treatment respectively; which was not in accordance with the present study. Test drug was well tolerated with no adverse effect reported as safety profile was within normal limits. Limitations of study were small sample size, use of single drug for short duration of intervention, loss of long term follow up for efficacy and serial follicular monitoring was not performed by the same observer. Further trials with variable dose regimen with long term follow up are required to confirm the efficacy of test drug; moreover, compound formulation could be preferable than single drugs for ovulation induction (Table 6).

CONCLUSIONS

Satavar was effective in stimulating follicular growth and ovulation, as it possesses the properties like ovulation inducing (*mwallide mani*) and aphrodisiac (*muqawwi bah*), and is known to contain phytohormones (steroidal saponins & glycosides). The effect of test drug was comparable with that of control drug in stimulating follicular growth & ovulation, though the drug was not effective to achieve conception.

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