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Clinical evaluation of *Qillat tams* and its Management with Unani formulation

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Abstract

Qillat tams refers to a spectrum of conditions varying from scanty flow to menstruation occurring at interval of more than 2 months. 1-2% of non pregnant women will have absent or infrequent periods. In addition to the potential infertility problems and the concern provoked by unexplained alterations in the bleeding patterns, considerable morbidity is directly attributable to menstrual dysfunction. Aim of the study was to evaluate the efficacy of the Unani formulation as an alternate therapy in the management of Qillat tams. The trial was designed as standard controlled randomized single blind study, conducted in Dept. of Ilmul Qabalat wa Amraze Niswan, National Institute of Unani Medicine hospital, Bangalore. 45 patients were randomly assigned to test (30) and control (15) groups respectively. In test group Unani formulation was given in the form of majoon in a dose of 1 teaspoonful twice daily from 5th to 25th day of cycle for 3 consecutive cycles. In control group Tablet Douluton L once daily was given for the same duration. Subjective parameters i.e. duration of cycle, duration of flow together with objective parameters like pictorial blood loss assessment chart score and body mass index were assessed for improvement. There was a significant improvement in the subjective and objective parameters; test drug was found to be more effective than the control drug in the management of Qillat tams ($P < 0.01$); results were analyzed using Chi-square test. This study confirms the efficacy of the Unani formulation as an alternate therapy in the management of Qillat tams.

Keywords: Qillat tams-Unani formulation-pictorial blood loss assessment chart-body mass index.

Introduction

Regular, cyclic menstruation is an obvious aspect of 'normality' for women in their reproductive years[1]. Clinical situations where menstruation becomes abnormal are common sand varied; the limits of normal menstruation are not defined in any internationally agreed manner. Reduced menstrual bleeding include light bleeding, scanty bleeding, spotting, hypomenorrhoea and oligomenorrhoea. These all imply decrease in blood loss volume during menses[2], this in classical Unani literature is referred to as *Qillat tam*; i.e. a spectrum of conditions varying from scanty flow to menstruation occurring at interval of more than 2 months[3] any disturbance in its cyclicity or flow is considered abnormal[4]. Oligomenorhoea and hypomenorrhoea may be just a transitory phase before the onset of amenorrhoea[5].

At any time 1-2% of non pregnant women will have absent or infrequent periods[6]. The combined oral contraceptive pill is commonly used to regulate menses, which may exacerbate insulin resistance and since many patients are overweight and obesity is a relative contraindication, this treatment may be unsuitable[7].

In Unani system of medicine, *mudir haiz* drugs (emmenagogue) are used in the treatment of *Qillat tams*, these drugs rectify the functional defect in the uterus and the *mizaj* of such drugs should be *haar* and *lateef*. Emmenagogue means the drugs which liquefies the blood and removes the *sudda* there by it clears the passage for menstrual blood; these drugs rectify the abnormal *balgham* and metabolize it to blood[8-13].

The principle of treatment in Unani system of medicine is *Ilaj biz zid*; the temperament of the disease being *barid ratab*, the drugs having *garm wa khushk mizaj;* possessing the properties like *mudir haiz, mulattif balgham, mufatteh* are used in the management of *Qillat tams*; such drugs stimulate the flow of blood towards uterus and its blood vessels and dilate them, rectify the functional defect of the uterus[14], liquefy blood and removes *sudda.* 3 Also they transform the *akhlat* towards hot temperament, facilitating the metabolism of *balgham* to *dam*[9,11,13,15]. Unani formulation comprising of *Abhal* and *Mushktramashi* in the form of *majoon* was selected for the trial while Tab. Douluton L was given as control.

This trial was carried out to validate the Unani formulation scientifically, with the hypothesis that the research formulation is as effective as the standard drug in the management of *Qillat tams* and also aimed to confirm the mode of action of the research formulation retrospectively.

Methodology

This was a standard controlled randomized single blind study, conducted in the Dept. of Ilmul Qabalat wa Amraze Niswan, National Institute of Unani Medicine, Bangalore, over a period of 1 1/2 year. Institutional ethical committee, NIUM, Bangalore, approved the study protocol, after which the clinical study was commenced.

As shown in figure-5, 98 patients were enrolled, of whom 43 denied participation; investigations were carried out on 55 patients. 10 patients were excluded for thyroid dysfunction; 45 patients were included in the study, assigning 30 patients and 15 patients to test and control groups respectively.

Method of collection of data: i. Clinical interview. ii. Pictorial blood loss assessment chart.

Method of drug collection: Quality drugs were provided by the pharmacy of National Institute of Unani Medicine. Before preparing the formulation, all drugs were properly identified by the chief pharmacist NIUM to ascertain their originality. The preparation was dispensed in 250 gms air tight pet jars.

Method of preparation: *Majoon* of *Abhal (Juniperus communis) and Mushktramashi (Mentha Pulegium)* was prepared using sugar as base, according to the standard method of preparation[16].

Dosage and administration: 1tsf BD ½ hr before food from 5th to 25th day of cycle.

Standard control: Tab. Douluton. L 1 OD after food from 5th to 25th day of cycle.

Inclusion criteria: i. Patients with infrequent periods of more than 35 days or scanty flow both in amount and duration. ii. PBAC Score < 30, iii. Patients from menarche to 40 years of age.

Exclusion criteria: i. Patients with endocrine disorders like hypothyroidism, hyperprolactinaemia. ii. Patients with uterine synaechiae, endometrial tuberculosis, ovarian tumors & malignancy. iii. Patients with H/o systemic diseases like hypertension, diabetes mellitus etc. iv. Subjects were excluded if there was endocrine disorders like hypothyroidism, hyperprolactinaemia; uterine synaechiae, endometrial tuberculosis, ovarian tumors and malignancy.

Following thorough evaluation of history and clinical examination, patients were subjected to baseline investigations in the early follicular phase.

RBS, thyroid profile and serum prolactin were determined to exclude diabetes, hyperthyroidism or hypothyroidism and hyperprolactinaemia respectively.

USG- pelvis: TAS and TVS in unmarried and married patients respectively to exclude uterine synechiae, endometrial tuberculosis, ovarian tumors and malignancy.

Observations: The patients fulfilling the inclusion criteria were enrolled after explaining the study in detail and receiving the informed consent.

History: After recruitment, history regarding the menstrual cycle, duration and amount of flow (assessed by PBAC score), change in weight (if any) etc were noted.

Clinical Examination: A full clinical examination, including measurement of BMI and waist to hip ratio were performed.

Assessment of *mizaj* was done according to mizaj chart attached with CRF in annexure II.
Laboratory investigations: ***Routine***: Blood grouping, CBP, ESR, CUE. ***Biochemical***: Lipid profile, LFT, RFT. ***Endocrinological***: LH: FSH, ***USG- pelvis***: TAS and TVS in unmarried and married patients respectively.

Additionally RBS, thyroid profile and serum prolactin were determined to exclude diabetes, hyperthyroidism or hypothyroidism and hyperprolactinaemia respectively.

Procedure: Treatment was scheduled for 21 days, starting from the 5th day of the menstrual cycle. Test / standard formulation was given for 3 consecutive cycles, at which time an assessment of menstrual regularity, duration and amount of flow were made. Repeat biochemical estimations were carried out after the completion of trial.

Duration of treatment: 3 cycles.

Assessment and follow-up: The study was divided into three cycles of assessment during treatment and one follow up there after. All visits were made on 4th or 5th day of the menstrual cycle.

At every visit, the patients were asked about the duration of cycle, duration of flow and amount of flow which was assessed by PBAC score. They were also asked for any adverse effect observed during the treatment.

At the first follow up visit after treatment specific investigations were performed. Pre and post treatment values of symptoms were analyzed and were subjected to comparison statistically to evaluate the response and effect of the treatment. Follow up was scheduled to look for recurrence of symptoms in three cycles following completion of trial.

Subjective parameters: i. Infrequent menstruation, ii. Scanty menstrual loss both in amount and duration, iii. Altered weight.

Objective parameters: Body mass index (BMI): **BMI Inference**[18]: i. < 21 Underweight, ii. 21-25 Normal weight, iii. >25 Obesity.

Pictorial blood loss assessment chart (PBAC): **PBAC score Inference:** i. 1-10 Spotting, ii. 11-30 Hypomenorrhoea, iii. 31-100 Eumenorrhoea , iv. 100+ Menorrhagia

Improvement Criteria: Cured: i. Restoration of spontaneous menses (onset of natural menstruation without any medication with cycle duration of 28-35 days), ii. Restoration of normal menstrual flow (PBAC Score > 30 and <100) after completion of treatment and also at follow up visit. iii. Significant changes in BMI, iv. Positive changes in the USG &/or biochemical parameters. (Values should come within normal range in the post treatment evaluation.)

Relieved: i. Restoration of spontaneous menses (onset of natural menstruation without any medication with cycle duration of 28-35 days) ii. Restoration of normal menstrual flow (PBAC Score > 30 and <100) after completion of treatment and also at follow up visit. iii. Significant change in BMI, iv. No change in USG and/or biochemical parameters.

Partially relieved: i. Restoration of spontaneous menses (onset of natural menstruation without any medication with cycle duration of 28-35 days), ii. Restoration of normal menstrual flow (PBAC Score > 30 and <100) after completion of treatment and presenting with pre-treatment symptoms at follow-up visit. iii. No Significant change in BMI / USG and /or biochemical parameters.

No response: No change in pre-treatment subjective and objective parameters either during or after the treatment.

Withdrawal criteria: i. Failure to follow protocol, ii. Cases in which adverse drug reaction is noticed.

Safety assessment: Clinical assessment at every visit.

Record of adverse effects: The patients were observed for any side effects throughout the study.

Documentation: The case proforma and consent forms were submitted to the Dept of Ilmul Qabalat wa Amraze Niswan, NIUM after completion of the study.

Analysis of results: Statistical software SPSS 11.0 and Graph pad were used for analysis. Descriptive statistical analysis has been carried out in the present study. Level of significance is at 5%.

Results and Discussion

The representativeness of the study participants was checked among the test and control group. There was no significant difference in age, *mizaj*, marital status, SES, BMI, W: H etc with p >0.05 as shown in table 1.

70% in test group and 13.3% in control group were cured, 23.4% in test and 33.43% in control group were relieved and 3.3 % in test and 46.6 % in control group were partially relieved and 3.3% in the test and 6.7% in the control had no response as shown in table 2. Statistical analysis of this data, using chi-square test shows test drug was found to be more effective than compared to control drug in the management of *Qillat tams* with $p < 0.01$. Thus confirming the efficacy of a Unani formulation as an alternate therapy in the management of *Qillat tams.*

As shown in table 3, mean and SEM of duration of cycle in test group before intervention, day one of 1st, 2nd, 3rd menstruation during treatment and day one of 1st menstruation after treatment were 58.33 + 4.04, 31.86 + 1.59, 31.80 + 0.86, 31.46 + 1.27, 32.0 + 0.64 respectively. There exist a significant decrease in duration of cycle in 1st assessment and continued till 1st menstruation after treatment, $p< 0.001$; considered extremely significant. Similarly in control group, mean + SEM before intervention, day one of 1st, 2nd, 3rd menstruation during treatment and day one of 1st menstruation after treatment were 69.68 + 5.68, 31.06 + 1.0, 31.28 + 0.71, 31.70 + 0.84, 42.2 + 4.48 respectively. There exist a significant decrease in duration of cycle in the 1st assessment and continued till 3rd menstruation during traement, duration of cycle was increased during the follow up cycle, $p>0.05$; considered not significant. The inter group comparison was done showed p<0.0 01 w.r.t test group after intervention, considered extremely significant statistically.

Mean and SEM of duration of flow before intervention, day one of 1st, 2nd, 3rd menstruation during treatment and day one of 1st menstruation after treatment were 2.6 + 0.29, 3.43 +0.19, 3.80 + 0.18, 3.96 +0.25, 4.0 + 0.32 respectively in test group and 2.5 + 0.25, 3.2 + 0.24, 3.53 + 0.25, 3.53 + 0.25, 3.6 + 0.25 respectively in control group. Intra group comparison were made. In test group, duration of flow was progressively increased from the first menstruation during treatment to the first menstruation after treatment, and was statistically significant with $p<0.01$.

In control group, duration of flow was increased from the second menstruation during treatment which was significant statistically at $p <0.05$, this was further increased in the third menstruation during treatment and remained the same in the first menstruation after treatment and this was statistically significant with $p<0.01$. The inter group comparison was done and the results were significant; $P <0.01$ w.r.t test group after intervention, considered highly significant statistically.

The effect of test drug and control drug on PBAC score were assessed, with mean + SEM before intervention, day one of 1st, 2nd, 3rd menstruation during treatment and day one of 1st menstruation after treatment were 14.02 +2.01, 43.36 +4.18, 66.80 +3.39, 78.53 +4.49 and 71.53 + 2.77 respectively in test and 18.0 + 4.26, 36.1 + 9.99, 47.30 + 6.21, 51.71 + 5.03 and 42.30 + 3.98 respectively in control group.

In test group, the PBAC score was progressively increased from the first menstruation during treatment to the first menstruation after treatment and was statistically significant with $p<0.001$ at each assessment. In control group, the PBAC score was increased from the first menstruation during treatment which was significant statistically at $p<0.05$, this was further increased progressively from the second menstruation during treatment to the first menstruation after treatment and this was statistically significant with $p<0.001$. In the inter group comparison the results were significant with $p<0.01$, suggesting that the test drug possess better efficacy than the control drug in improving PBAC score.

The effect of test and control drug on BMI were assessed, with mean $\pm$ SEM before intervention, day one of 1st, 2nd, 3rd menstruation during treatment and day one of 1st menstruation after treatment were 26.15 + 1.11, 25.56 + 1.08, 25.05 + 1.06, 24.54 + 1.04, 24.10 + 1.17 respectively in test group and 25.35 + 1.40, 25.05 + 1.31, 25.01 + 1.27, 25.28 + 1.28, 25.32 + 1.28 in control group respectively.

The intra group comparisons were carried out. In test group, BMI progressively decreased from the first menstruation during treatment to the first menstruation after treatment cycle, with $p<0.05$ at the first assessment and $p<0.001$ in subsequent cycles, considered extremely significant. In the control group, change in BMI was not significant statistically with $p>0.05$. The inter group comparison was done; change in BMI in test group was not significant as compared to control group $0.1> p>0.05$.

In addition to evaluation of the objectives in the protocol, the retrospective finding was that in the test group 12 out of the 19 cases of PCO in the evaluation scan were reported to be normal in the post trial USG of pelvis. This finding was significant statistically with $p<0.01$ (table 4). It can therefore be inferred that the research formulation regulates menses through its effect on the ovaries, rectifying the ovarian function. This hypothesis may be supported by the observation that one patient in test group conceived in the 3rd cycle during treatment, merely after cycle regulation, with no additional therapeutic measures.

Table-1
Comparison of basic variables

Basic variables	Test group (n=30)	Control group (n=15)	p value
Age in years			
≤ 20	10 (33.3%)	5(33.3%)	0.78
21-30	13(43.3%)	8(53.3%)	
31-40	7(23.3%)	2(13.3%)	
Socio-economic Status			
Upper Middle	6(20.0%)	4(26.7%)	0.840
Lower middle	8(26.7%)	3(20.0%)	
Upper lower	16(53.3%)	8(53.3%)	
Marital Status			
Single	16(53.3%)	9(60.0%)	0.757
Married	14(46.7%)	6(40.0%)	
Mizaj			
Balghami	23(76.7%)	9(60.0%)	0.511
Damvi	5(16.7%)	4(26.7%)	
Soudavi	2(6.7%)	2(13.3%)	
BMI			
Under weight <21	7(23.33%)	3(20%)	0.928
Normal 21-25	3(10%)	2(13.33%)	
Obese >25	20(66.67%)	10(66.67%)	
W:H			
≤ 0.86	30(100%)	15(100%)	0.97

Table-2
Improvement Criteria

	Improvement Criteria	No. of patients (%)	
		Test group (n=30)	Control group (n=15)
01	Cured	21 (70%)	2 (13.3%)
02	Relieved	7 (23.4%)	5 (33.4%)
03	Partially relieved	1 (3.3%)	7(46.6%)
04	No response	1 (3.3%)	1(6.7%)

Cured rate was significantly high in test group than compared to control (70% vs 13.3%) with p=0.006**, **Test used**: chi-square test, **p value** - $p < 0.01$.

Majority of the patients in the present study were in the age group of 21-30 yrs, with extremes of 14 and 36. This observation is supported by Ferriman et al. who stated that great majority of the patients were between 15-35 years of age range, with extremes of 9 and 47.

32(71.1%) patients possess *balghami mizaj,* 9 (20%) were *damvi* and 4 (8.8%) were *soudavi* and none of the patients had *safravi mizaj*. The findings are allied to the theories presented by the eminent *Unani* physicians, that this disease is more frequent in individuals with dominance of *khilt balgham.*

The precipitating causes of *Qillat tams*; 24(19 + 5) patients had PCO, 29 (19 + 10) were obese and12 (8 + 4) were under weight (table 5). The underlying diagnosis was based on clinical examination and ultrasound finding. i.e. 53% patients had PCO; this observation was supported by the study of Ferriman et al., who stated that some 57% patients in their series had enlarged polycystic ovaries. It is notable that 4 out of the 6 women with PCO were underweight in the study conducted by Adams et al.; in present study 4 out of the 24 women with PCO were underweight.

Table-3
Effect of research formulation on duration of cycle, duration of flow, PBAC score and BMI

Assessment	Duration of Cycle		Duration of Flow		PBAC Score		BMI	
	Test group (Mean ± SEM)	Control group (Mean ± SEM)	Test group (Mean ± SEM)	Control group(Mean ± SEM)	Test group (Mean ± SEM)	Control group(Mean ± SEM)	Test group(Mean ± SEM)	Control group(Mean ± SEM)
Before intervention	58.33 ± 4.04	69.65 ± 5.68	2.6 ± 0.29	2.5 ± 0.25	14.02 ± 2.01	18.06 ± 4.26	26.15 ± 1.11	25.35 ± 1.40
Day 1 of 1st menstruation during treatment	31.86 ±1.59 a3	31.06 ±1.00 a3	3.43 ±0.19 a2	3.2 ± 0.24	43. 36 ± 4.18 a3	36.1 ± 9.99 a1	25.56 ± 1.08	25.05 ± 1.31
Day 1 of 2nd menstruation during treatment	31.80 ± 0.86 a3	31.26 ± 0.71 a3	3.80 ± 0.18 a3	3.46 ± 0.25 a1	66.80 ± 3.39 a3	47.30 ± 6.21 a3	25.05 ± 1.06 a3	25.01 ± 1.27
Day 1 of 3rd menstruation during treatment	31.46 ±1.27 a3	31.70 ±0.84 a3	3.96 ± 0.25 a3	3.53 ±0.25 a2	78.53 ± 4.49 a3	51.71 ± 5.03 a3	24.54 ± 1.04 a3	25.28 ± 1.28
Day 1 of 1st menstruation after treatment	32.0 ± 0.64 a3b3	42.20 ± 4.48 a3b2	4.0 ± 0.30 a3 b2	3.6 ± 0.25 a2 b1	71.53 ± 2.77 a3 b3	42.30 ± 3.98 a3b2	24.10 ± 1.17 a3b+	25.32 ± 1.28 b+

Table-4
Effect of research formulation on PCO

PCO	BT	AT
Test (No. of patients)	19	07
Control (No. of patients)	05	04

Test used: Chi square, **p value:** < 0.01

Table-5
Analysis of patients with regard to etiology

	Etiology	No. of patients (%)		
		Test group	Control group	Total
01	PCO	19(63.33%)	05 (33.33%)	24 (53.33%)
02	Obese	19 (63.33%)*	10 (66.66%)†	29 (62.22%)††
03	Underweight	08 (26.67%) **	04 (26.66%)	12 (26.66%)

*12 Obese with PCO, **4 Underweight with PCO, †4 Obese with PCO, †† 16 Obese with PCO.

Fairley et al. reported that only a third of women with PCO are obese, in the present study nearly 2/3rd (62.2%) patients with PCO were obese. This may be due to the increase in the incidence of obesity.

In present study, apart from oligomenorrhoea, hypomenorrhoea was also evaluated; since the later is least evaluated and treated; though the etiology and sequel are similar to those of oligomenorhoea or amenorrhoea in general; factors like hypothyroidism and PCO were consistent with both oligomenorrhoea and hypomenorrhoea.

Research formulation is being used as a potent emmenagogue since antiquity; present study has made the first move in its scientific validation with positive outcomes.

The main limitation of this study was loss of long term follow up and small sample size.

Further the inclusion criteria was quite stringent, which included cases with a single organic pathology, studies can also be done by including the other etiologies that were excluded in the present study.

Phase III clinical trials can be carried out to confirm the efficacy and potency of the research formulation. Research formulation being significantly effective in oligomenorrhoea and hypomenorrhoea, the same can be evaluated in secondary amenorrhoea.

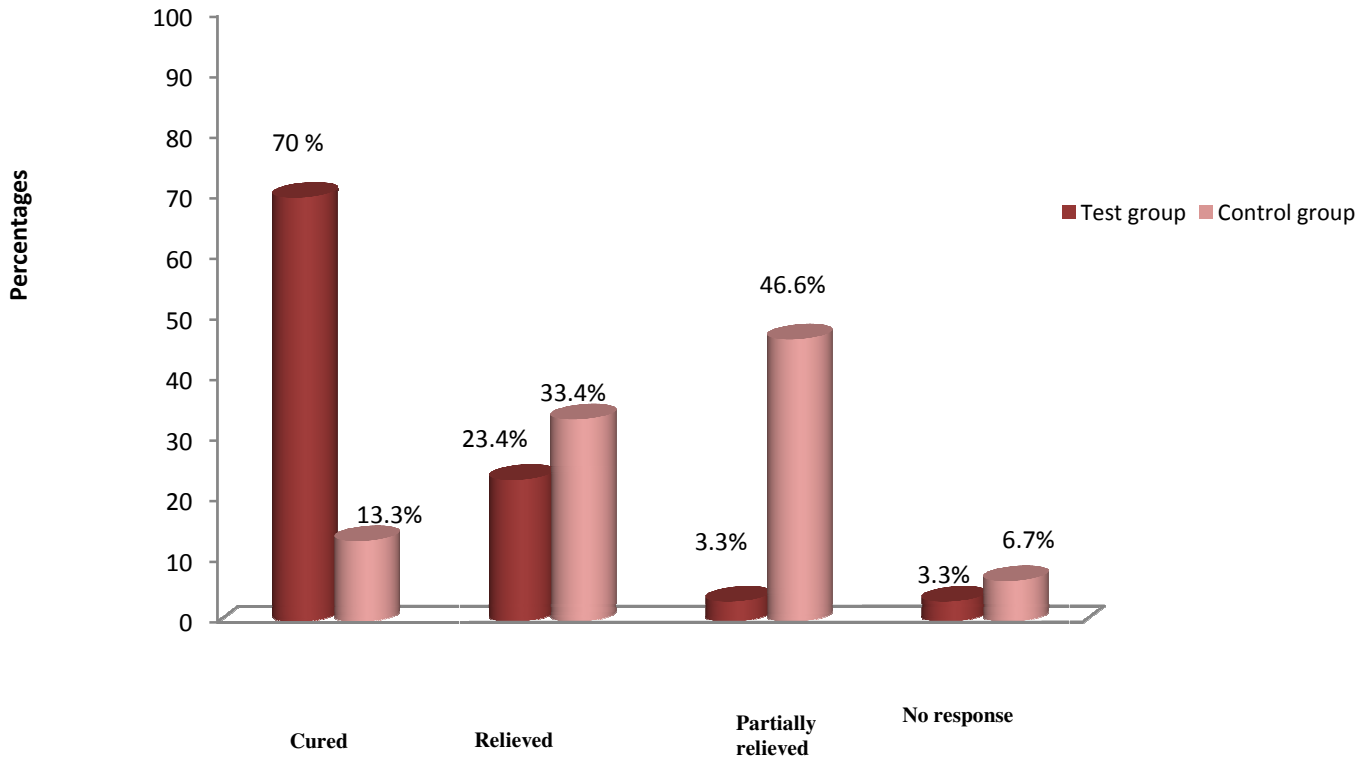

Figure-1
Improvement Criteria

70% in test and 13.3% in control group were cured; 23.4% in test and 33.4% in control group were relieved; 3.3% in test and 46.6% in control group were partially relieved; 3.3% in test and 6.7% in control group had no response. a - w.r.t control group before intervention / test group before intervention. b - w.r.t test group after intervention. 1- p <0.05, 2-p<0.01, 3-p<0.001, + - 0.05 > p<0.1. **Test used**: **Inter group** - one way ANOVA. **Intra group** – repeated measure ANOVA.

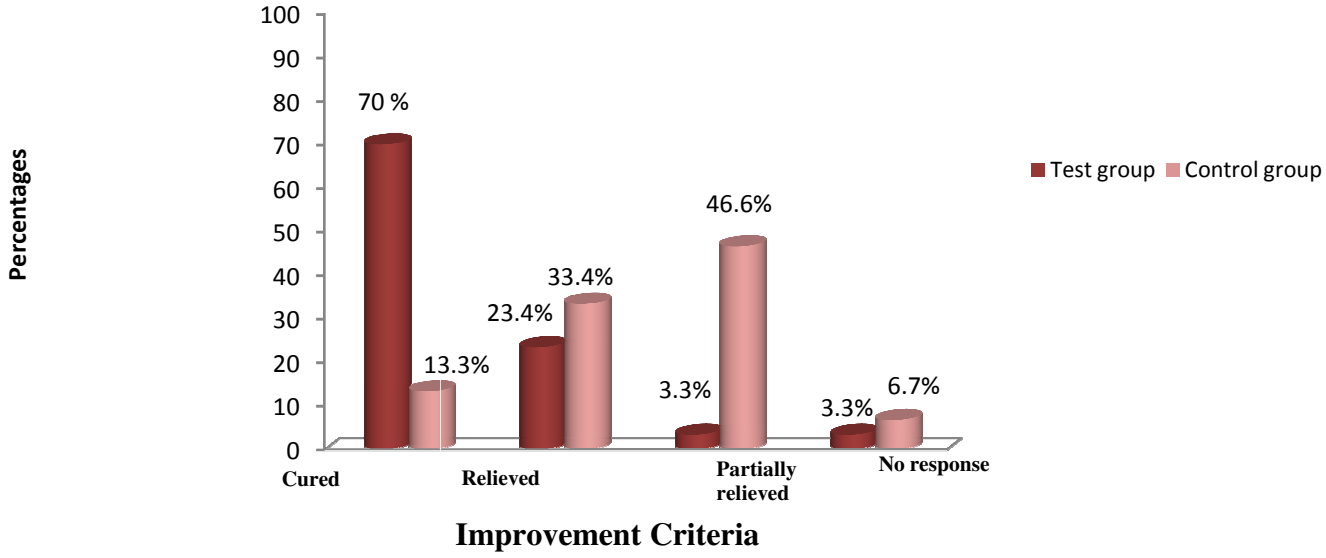

Figure-2
Improvement Criteria

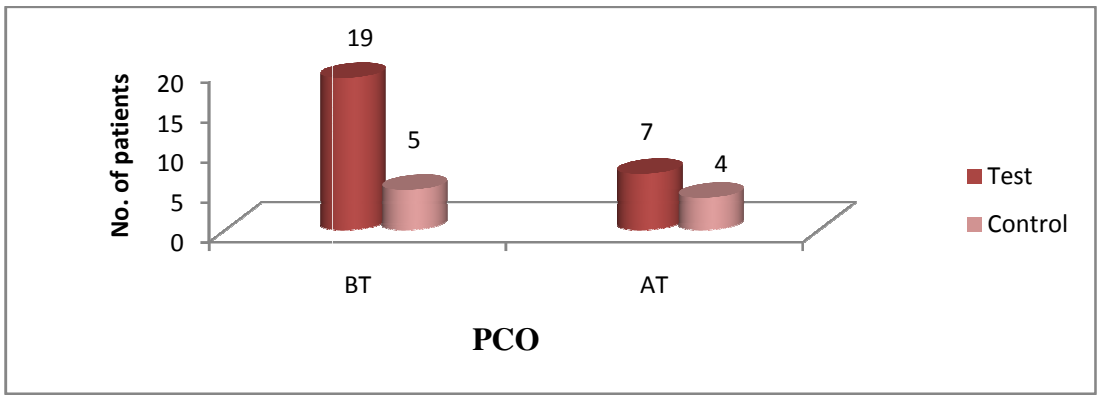

Figure-3
Effect of research formulation on PCO

PCO were relieved in 12 out of 19 patients in test group and 1 out of 5 patients in control group.

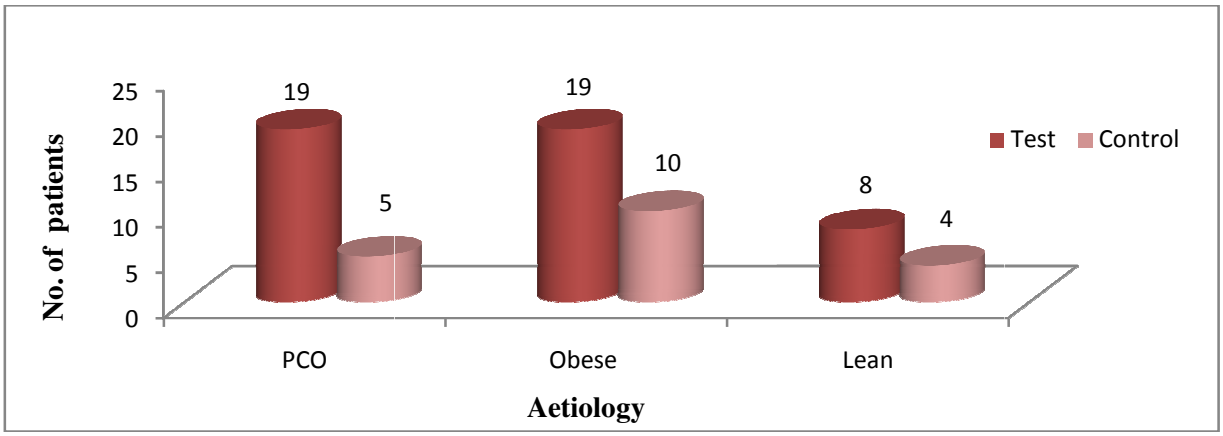

Figure-4
Analysis of patients with regard to aetiology

19 (63.33%) in test and 5(33.33%) in control group had PCO; 19(63.33%) in test and 10 (66.66%) in control group were obese; 8(26.67%) in test and 4(26.66%) in control group were underweight.

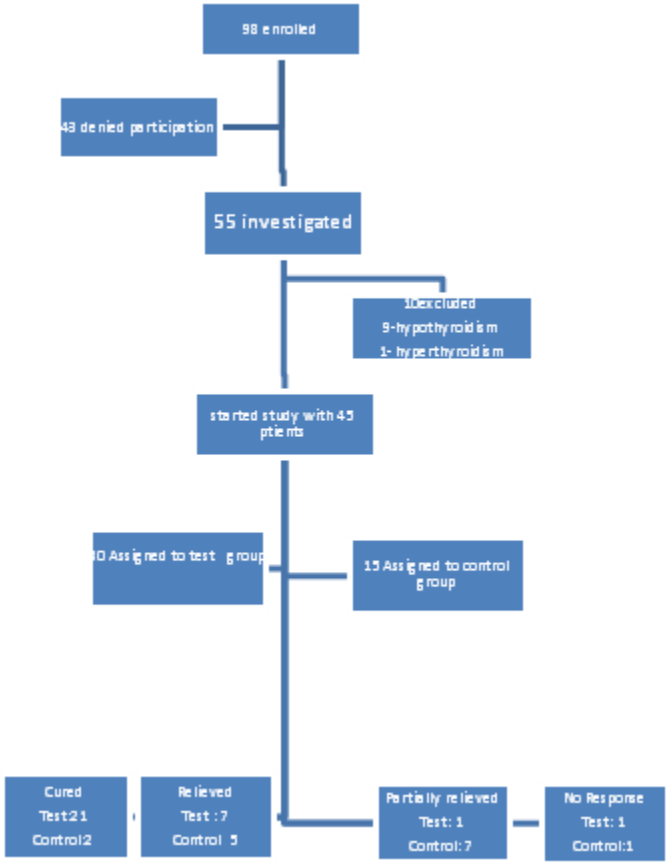

Figure-5
An Overview of the study

Conclusion

This study confirms the potency and efficacy of the research formulation as emmenagogue. 70% in test and 13.3% in control group were cured; 23.4% in test and 33.43% in control group were relieved; 3.3 % in test and 46.6 % in control group were partially relieved; 3.3% in test and 6.7% in control group had no response. Statistical analysis of this data using chi-square test shows, test drug was found to be more effective than compared to control drug in the management of *Qillat tams*, $p < 0.01$. It can be inferred through the USG findings that the research formulation regulates menstruation through its effect on the ovaries, rectifying the ovarian function.

Phase III clinical trials can be carried out to confirm the efficacy and potency of the research formulation. Studies can also be carried out by including the other etiologies that were excluded in the present study. Research formulation being significantly effective in oligomenorrhoea and hypomenorrhoea, the same can be evaluated in secondary amenorrhoea.

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