International Standard Serial Number (ISSN): 2249-6807

International Journal of Institutional Pharmacy and Life Sciences 5(2): March-April 2015

INTERNATIONAL JOURNAL OF INSTITUTIONAL PHARMACY AND LIFE SCIENCES

Pharmaceutical Sciences

Research Article……!!!

Received: 12-04-2015; Revised: 18-04-2015; Accepted: 19-04-2015

THE EFFECT OF *HENNA* (*LAWSONIA INERMIS*) BASED UNANI FEMALE CONTRACEPTIVE FORMULATION: A PILOT STUDY

Tarannum*, Mohammad Idris**

* M.D. Scholar, PG Deptt. Of Ilm-us-Saidla, Ayurvedic & Unani TIbbia College & Hospital, Karol Bagh, New Delhi, India

** Professor & H.O.D., PG Deptt. Of Ilm-us-Saidla, Ayurvedic & Unani TIbbia College & Hospital, Karol Bagh, New Delhi, India

Keywords:

Unani contraceptive formulation, Henna, female local contraceptive

For Correspondence:

Dr. Tarannum

M.D. Scholar, PG Deptt. Of Ilm-us-Saidla, Ayurvedic & Unani TIbbia College & Hospital, Karol Bagh, New Delhi, India

E-mail:

dr.tarannum87@gmail.com

ABSTRACT

The Unani medicine is plentiful with several antifertility formulations. Out of these a transdermal *henna* based Unani contraceptive formulations (HUCF) was selected for study purpose. Ten volunteers, having the desire of contraception were randomly assigned after a written consent. Out of which seven participants were assessed for single menstrual cycle. Only two participants were assessed for two cycles and only one for three menstrual cycles. The HUCF was applied over the palm and sole of the volunteers from third to twentieth day of menstrual cycle. Sonographic impression was taken on the mid day of the same cycle. The size of ovum and other significant changes with menstrual cycle regularity were considered as a parameter of assessment of efficacy of HUCF. Significant changes in size of ovum with no missed period were found after HUCF administration. Hence, HUCF may be a good choice as female contraceptive formulation. The major conclusion of the study are that majority of the participants were in the age group of 26-30 years (80%).Mean was 29.7yrs S.D =4.52, SEM=1.43. For statistical assessment no follicle dominant in both ovaries was assigned 1 number and dominant follicle as 0. Mean was 0.8, S.D 0.426, SE=0.133. For the assessment of result t-test was used for seven participants with single menstrual cycle. One tailed P value was .0001 (<1) t= 6 d.f 9. One way ANOVA (Turkey-Kramer multiple comparison test) was used for assessment of result in all the ten volunteers. In one way ANOVA the P=0.0430 value is considered significant. Turkey-Kramer multiple comparison test was also applied and q > 3.76 between the columns considered significant (q=3.86). A further clinical study is needed on a large sample size.

INTRODUCTION

Constantly increasing population in the developing nations like India becomes a matter of concern. To combat the problem, family planning was propagated by the Government of India with several contraceptive measures. These contraceptive measures include oral contraceptive pills (OCP's), intra uterine devices (IUCD's), barrier methods and even surgery. But, all these measures have been reported adverse effects. Hence, a search for a safe, efficacious and convenient mode of contraception remains a challenge [1]. Unani is a non-conventional system of medicine based on plant, mineral/metal and animal origin drugs. The classical literature of Unani medicine is enriched with several contraceptive formulations. These formulations have been described as *mane'y hamal advia* (anti-fertility drugs).The antifertility Unani drugs are used topical and/or oral formulations in the form of single contraceptive agents and compound formulations for both: male and female. Further, these antifertility agents are classified in various categories, such as *mudir-e-haiz* (emmenagogue), *mane'y hamal* (contraceptive measures), *musiq-e-janeen* (abortifacient), *muzeef-e-bah* (anaphrodisiac) and *mufasid-e-mani* (anti-spermatogenic) etc [2]. A unique henna based Unani contraceptive formulation (HUCF) was designed and developed for a study on pilot basis. Some Unani antifertility agents were chosen for their contraceptive potential in HUCF. To make it attractive and user-friendly, *henna* has been added for its dyeing and carrier activity. The main objective of the study was to validate the efficacy of HUCF in 10 volunteers with 14 sonographic evidences.

MATERIALS AND METHODS

Formulation preparation:

The HUCF is based mainly on two ingredients i.e. *Henna* and *Pakhanbed* in 2/3rd and 1/3rd ratio respectively [3, 4, 5, 6, 7]. It also contains *Sibr* and *Namak Chirchita* in quantity sufficient (Q.S.)[8]

Name and weight of ingredients:

The weight of the ingredients is given below in the table:

Table 1: Ingredient of HUCF

Name of ingredients	Botanical Names	Part used	Part in formulation	Weight of ingredients
Henna	*Lawsonia inermis*	Leaves	2/3 part	14 gram
Pakhanbed	*Bergenia ciliata*	Rhizome	1/3 part	5 gram
Chirchita	*Achyranthes aspera*	*Khar* (laxiviate)	Q.S.	½ gram
Sibr	*Aloe barbadensis*	Latex	Q.S.	½ gram

Collection of material:

Henna leaves were collected from herbal garden of Ayurvedic & Unani Tibbia College Karol Bagh, New Delhi. Other three ingredients were collected from the open market. Identification was done from National Institute of Science Communication and Information (NISCAIR). All chemicals, reagents and preservatives were obtained from authentic source.

Preparation of HUCF:

Fresh leaves of *henna* were spread over the piece of cotton cloth after washing with tap water. Left it to dry in the shade. Rhizome of *Pakhnabed* was also washed with tap water.

Extraction of pakhanbed by soxhlet apparatus:

Extraction of pakhanbed was carried out according to Indian Pharmacopoeia (2010).

Preparation of *Khar-e-Chirchita:*

Khar-e-Chirchita was prepared according to the classical Unani method described in UPI (2011)[9].

Preparation of *Sibr Maghsool:*

Preparation of *Sibr maghsool* was carried out according to the classical Unani method described in UPI (2011)[10].

For the *in vivo* pilot study:

A) Sample:

The volunteers in the age group 21-40 years with majority in 26-30 years were randomly selected. The inclusion criteria were married and multiparous women in reproductive age and last childbirth was more than one year. The sample size was 10. The volunteers were selected on the basis of their desire of contraception and who had at least two children. History of intake of any other measure of contraception was taken as exclusion criteria. After taking informed consent the eligible women were given the HUCF and advised to apply on the palm and sole from the third to twentieth day of menstrual cycle. All the volunteers were advised to discard any mode of contraception before two months of starting the use of HUCF.

B) Research design:

The study was designed on the basis of information from the classical literature of Unani medicine as well as reported information about the menstrual as well as ovarian cycle. Twenty gram of formulation was applied over the sole and palm of the volunteers from third day to twentieth day of

menstrual cycle. As it was already reported that follicle start to become dominant as early as day 3-5 of menstrual cycle. Seven volunteers were assigned for single menstrual cycle. Two volunteers were assigned for two menstrual cycles consecutively. A volunteer was assigned for 3 menstrual cycles consecutively.

C) Parameter for assessment of result:

Size of ovum and menstrual cycle regularity was considered as parameter of assessment of result. Sonographic impression was taken to observe the size of ovum and other significant changes in 10 volunteers. Mid day of menstrual period was selected for sonographic evidence. Mid day of menstrual period was calculated from the menstrual history of volunteers.

D) Statistical analysis:

Statistical analysis was done by DATASET1 with SD and effect of HUCF on follicle dominance in first cycle was assessed by t-test and effect of HUCF on three cycles in all 10 volunteers was done by one way ANOVA (Turkey Kramer multiple comparison test).

OBSERVATIONS AND RESULTS:

As a pilot study, the sonographic impressions of 10 volunteers in 14 menstrual cycles showed significant result. The sonographic study had significant changes in size of ovum on mid-day of menstrual cycle with no miss period. It was already reported that a dominant follicle should be seen on the mid day of menstrual cycle but no dominant follicle as well as thin endometrial thickness was noticed in report of USG.

Result of sonographic impression in the 7 volunteers assigned for single menstrual cycle.

No dominant follicle as well as no miss period was seen in USG in all the 7 volunteers.

Result of sonographic impression in two volunteers assigned for 2 menstrual cycles consecutively:

No dominant follicle in sonographic impression as well as no miss period was observed in the first menstrual cycle in both volunteers. In the second menstrual cycle, a dominant follicle with no miss period was observed in one volunteer and no dominant follicle as well as no miss period was observed in second volunteer.

Result of sonographic impression in a volunteer assigned for 3 menstrual cycles consecutively:

The first cycles showed a dominant follicle in left ovary. But no miss period was observed. In the second and third cycle no dominant follicle as well as no of miss period was observed.

Statistical analysis of observations:

For statistical assessment no follicle dominant in both ovaries was assigned 1 no. and dominant follicle as 0. Mean was .8 S.D 0.426 SE=0.133. One tailed P value was .0001 t= 6 d.f 9. Analysis of effect of HUCF in all ten volunteers divided into two groups. Group one contains all the volunteers assigned for single menstrual cycle. Group two contains all the volunteers including those were assigned for two and three consecutive menstrual cycles.

Distribution of volunteers according to age:

Majority of the participants were in the age group of 26-30 years (80%). Mean was 29.7yrs S.D =4.52, SEM=1.43 as shown in the table or figure:

Table 2: Distribution of participants according to age

Age	Number	Percentage
21-25yrs	01	10%
26-30yrs	07	70%
31-35yrs	01	10%
36-40	01	10%

(N=10)

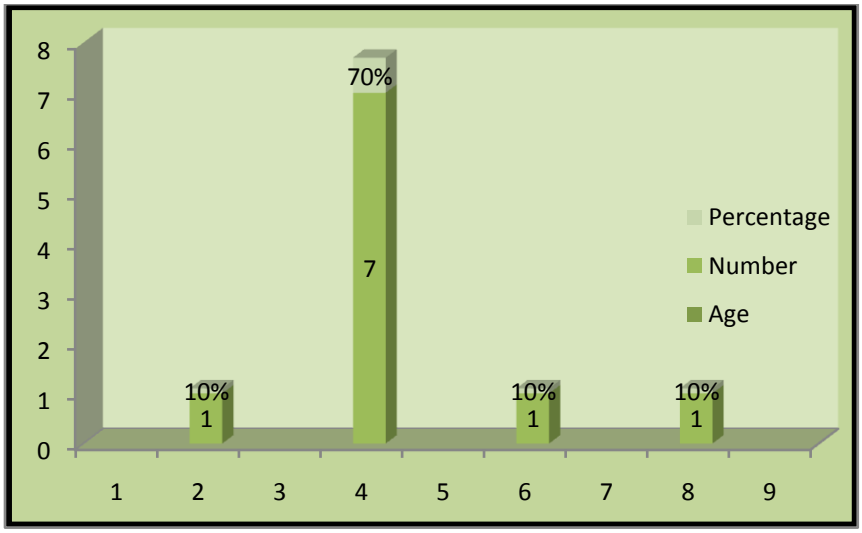

Fig 1: Distribution of participants according to age

Group one:

The analysis of 7 volunteers assigned for one menstrual cycle is given in below in the table and figure:

Table 3: Analysis of HUCF on Follicle dominance

Observations	Number	Percentage
No Follicle dominancy in both ovaries and Regular menstrual cycle	08	80%
Follicle Dominancy in one ovary and Regular Menstrual cycle	02	20%

(N=10)

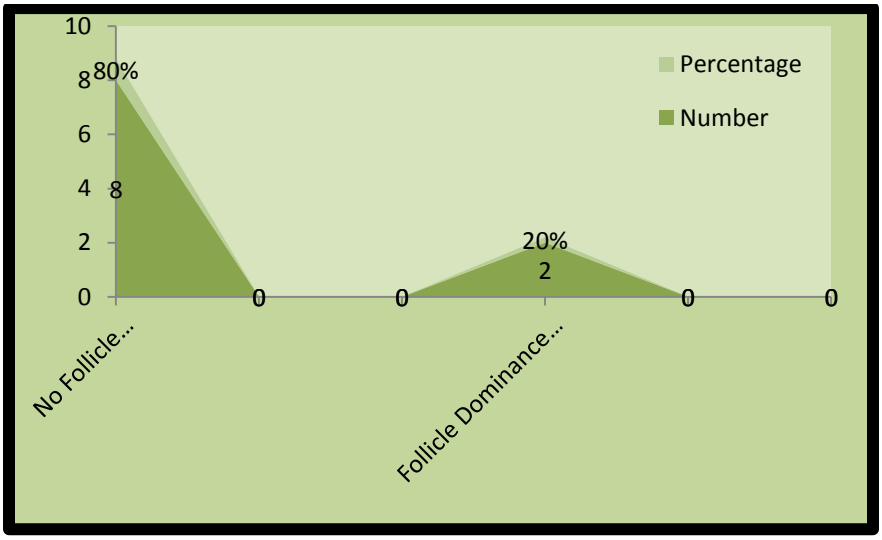

Figure 2: Analysis of HUCF on Follicle dominance after one month

Group two:

The summarized statistical analysis of all the volunteers assigned for one menstrual cycle, two menstrual cycles and three menstrual cycles are given below in the table and figure:

Table 4: Follicle dominancy in all 10 volunteers

No. of cycle	Follicle dominancy in one ovary and Regular menstrual cycle	No Follicle Dominance in both ovaries and Regular Menstrual cycle
Cycle 1	02	08
Cycle 2	00	02
Cycle 3	00	01

Applying One way ANOVA P=0.0430 value is considered significant.Turkey-Kramer multiple comparison test was also applied and q >3.76 between the columns considered significant (q=3.86).

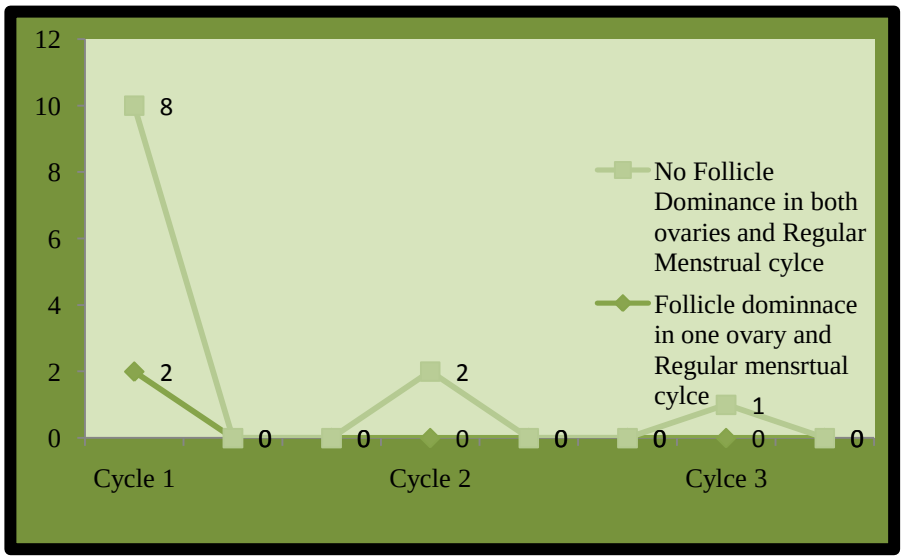

Figure 3: Analysis of HUCF in three cycles in all the volunteers.

CONCLUSION

In the present study majority of the participants were in the age group of 26-30 years (80%). Mean was 29.7yrs S.D =4.52, SEM=1.43. For statistical analysis of efficacy of HUCF no follicle dominant in both ovaries was assigned 1 number and dominant follicle as 0. Mean was .8 S.D 0.426 SE=0.133 One tailed P value was .0001 t= 6 d.f 9. Only two participants were assessed in second cycle and only one in the third cycle. Applying One way ANOVA P=0.0430 value is considered significant. Turkey-Kramer multiple comparison test was also applied and q >3.76 between the columns considered significant (q=3.86). It was concluded that HUCF may serve as an important alternate for female contraception.

RECOMMENDATION

A further clinical study is the felt-need of the hour on a large sample size for further evaluation of efficacy and safety of HUCF as a topical Unani female contraceptive measure.

REFERENCES

1. Singh, A. , Kala, S., Kapoor, N. Reversible contraceptive efficacy and safety evaluation of ethanolic extract of Tinospora Cordifolia in animal model. 2011. Archives of applied sciences research. 3 (5): 587-592.
2. Jurjani, Ismail. Zakhira-e-Khwarzam Shahi (Urdu translation by Hadi Hossain Khan), Vol 6, Chapter 20. Matba-Munshi Nawal Kishor Lucknow. 1878. Pp. 1431-1432.
3. Khan, Hakeem Sayyed Mohammad Hossain. Majmeul Jamae ba Maroof Qarabadeen-e-kabeer. 1272 Hijri, pp. 725-726.
4. Khan, Hakeem Azam. Muheet-e-Azam Part 1st Vol 2nd . Matba Nizami Kanpur. Pp. 92-93.
5. Momin, Meer Mohammad Ibn Meer Mohammad Zaman. Tohfatul Momeneen. Matba Mustafahi, Kashmiri gate Delhi. 1272 Hij. Pp. 77.
6. Hossain, Meer Mohammad Ibn Sayyed Hadi Ali Aqeeli Alwi. Makhzanul Advia. 1278 Hij. Matba Ahmadi Shahadara Delhi. Pp. 217, 253-254.
7. Nafees, Burhanuddin. Tarjuma Kulliyat Nafeesi (urdu translation by Hakeem Mohammad Kabeeruddin) part 2nd. Y.N.M. Idara-e-kitabus-shifa, Koocha chalan, Daryaganj, New Delhi
8. Bhaduri, B., Ghosh, C.R., Bose, A.N., Moza, B.K., Basu, B.P. antifertility activity of some medicinal plant. Indian j. exp. Boil., 1968 6:252-263
9. Anonymous$_a$, The Unani Pharmacopoea of India. CCRUM, Part 1st vol 1st & 4th. 2007. Pp. 26-27, 82-83.