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Research Article

Efficacy of Unani Formulation (*Mentha Longifolia*) And *Ruta Graveolans* in The Management of *Ihtebas-E Hayd* (Secondary Amenorrhea): A Case Series

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ABSTRACT

Ehtbas-e-Hayd (secondary amenorrhoea) is defined as cessation of menses for 6 month in female previously irregular menstrual pattern, or the cessation of menses for 3 consecutive month. This accounts for approximately 3 to 4 % of the population. It is a commonest problem in the reproductive years. As a result, a large number of female populations rely on exogenous source of hormones to cure the imbalance. But the prolong use of hormones causes side effects and other health related complications. Methodology: In this study of case series, 5 patients irrespective of their marital status who presented with secondary amenorrhoea were randomly enrolled. After history taking, pregnancy test evaluation and systemic examination were given oral capsules containing ground test drugs (suddab & mushktramashee) thrice in a day for a week for withdrawal bleeding. The primary outcome variable was the occurrence of withdrawal bleeding after consumption of the study drug. Secondary outcome measure was to regularize the bleeding pattern during the 3month study period. Discussion & Conclusion: The management of secondary amenorrhea as per the conventional system of medicine mainly includes hormonal therapy. This treatment however, provides temporary relief to the patients. Long-term use of hormonal pills results in significant number of side effects and hence there is a need of an alternative therapy to treat the same. Hence, keeping in view the need of a non-hormonal drug with minimum side-effects, the 2 Unani drugs *suddab* and *mushktramasheeh* have been selected to study their effect on secondary amenorrhea.

INTRODUCTION

Amenorrhoea is derived from the Greek word men (month) and rein (to flow), denotes the absence or suppression of menstruation¹ It is not a diagnosis in itself but rather a most common clinical sign of

reproductive dysfunction^{2,3,4} It signifies failure to menstruate either primarily or secondarily by a certain age or over a period of time due to failure of functions in any of the organs involved in this cascade⁵

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Initiation of menstruation is an important milestone in the reproductive lives of women. It may be physiological or pathological. Its onset may be primary or secondary. Physiological amenorrhoea naturally prevails prior to the onset of puberty, during pregnancy and lactation and after menopause. Pathological amenorrhoea is the result of genetic factors, systemic diseases, endocrinopathies, disturbance of the hypothalamic–pituitary–ovarian–uterine axis, gynatresia, nutritional factors, drug usage, psychological factors and other rarer causes.⁶

It can be classified as primary and secondary amenorrhoea. primary amenorrhoea is women has never menstruated and secondary amenorrhoea is women attained menarche but no periods for 3 consecutive month in a women with previous and regular menses..secondary amenorrhoea is more common from primary amenorrhoea⁷ it may be physiological ,concealed (cryptomenorrhoea) true secondary amenorrhoea⁸ . Now a days secundary amenorrhoea has become the commonest problem of female in age between 18-35 in low and high socioeconomic status .it is found commonly in young unmarried girls, nulliparous females, poor nutritions and have general ill health. The Prevalence of secondary amenorrhoea varies depending on the age group 8.5% in women aged 13- to 18 year ,3% in women aged 25- 34 yrs⁹

Secondary amenorrhoea not including pregnancy or other normal physiologic causes affects estimated 3to 4%of women.¹⁰ Beside pregnancy ,cases of secondary amenorrhoea are likely due to pcos ,thyroid dysfunction ,hyperprolactinimia ,hypothalamic amenorrhoea and ovarian failure and anatomical abnormalities such as Asherman syndrome^{11,12} Conservative medical treatment for the management of secondary amenorrhoea is hormonal therapy may result in a substantial reduction in symptoms¹³ But these therapies have their own side effects including GIT disturbances, nausea, vomiting, obesity, etc.,due to these side effects). Such a situation invites some alternative treatment for secondary amenorrhoea.

In classical Unani literature, Ihtebas tams is defined as cessation of menstruation^{14,15} either it varies from scanty flow to complete cessation or it occurs at interval of 22 months. It can be tabayi or ghair tabayi. tabayi ihtebas tams occur prior to sine balooghat, during hamal wa razaa't, and baad sine yaas When ihtebas tams occur apart from above mentioned conditions. then it is known as ghair tabayi ihtebas tams It generally occur in women with balghami mizaj and fair complexion. Women having ihtebas tams usually suffer from usre tams.¹⁶ ihtebas tams usually occur due to zoaf quwwate dafia'h rahim secondary to sue mizaj either sada or maddi; as a result quwwat-i- masika over powers the quwwate dafia'h rehm¹⁷.

In the treatment of ihtebas tams, mudire hayd drugs are used to induce the menstruation; these drugs are hot in temperament, which dilate the blood vessels, liquefy the blood by quwwate talteef and taqtee and remove sudda; ultimately clear the passage for menstrual blood and discharge the fuzlat in the form of menstruation.. Such drugs act as musleh for rahim having aromatic property, which carries the effect of the drug to the uterus. These drugs can be used either orally or locally in the form of dhooni, humool, abzan, dimad, takmeed, huqna etc¹⁸.

In Unani medicine the line of treatment (Usul-e Ilaj) for secondary amenorrhoea is to remove the cause at first step by those drugs which possess the properties of mudire hayd and mudirr-i- bol properties . Treatment objective in secondary amenorrhoea is to improve quality of life as well as alleviating menstrual flow. Although to treat secondary amenorrhoea , hormonal drugs including oral contraceptive pills, oral progestin, and levonorgestrel releasing intrauterine devices are available as conventional treatment, side effects related to these drugs as well as contraindication in some women are the major problems . Hence despite a wide range of treatment options for the management of secondary amenorrhoea over recent years there is still an acute need to look for better option and some alternative treatment with least side effects.

The Unani compound formulation (powder of suddab and mishkatramsseh) has been envisaged to conduct the study on clinical aspect, as no clinical study has been done so far. The ingredients of the said formulation possess the medicinal properties same as mentioned by Unani scholars in their treatise i.e mudire hayd, mudirr-i- bol, muqawwi rahim .

Case description :

Diagnosis was made by taking proper menstrual history, assessment of blood loss. Patients went through for both general and systemic examination. 5 patients has visited OPD of Ajmal Khan Tibbiya College & Hospital of A.M.U, Aligarh. Follow-up is during and after every menstrual cycle during the study period and after completion of study period another next 3 months to observe the progression and regression of symptoms. Subjective Parameter is ,at every visit menstrual blood loss will assess, by reduction in amount of flow (number of pads per cycle used by the patient).Objective Parameter is at every visit PBAC score was used to assess the amount of bleeding.,and improvement of quality of life.

Methodology:

5 cases of secondary amenorrhoea were randomly selected from the patients visiting the gynecology opd of Ajmal khan Tibbiya college and hospital during .Cases were selected primarily on the basis of signs and symptoms which includes history of amenorrhoea 3 months or more than 3 months ,weight gain backache, Both married and unmarried subjects in the age group 18-40 years with complete history like marital status ,history of medical illness like history of hormonal pills ,tranquillizers and hypertensive etc. Gynoecc history ,obstetric history was taken general examination for both married and unmarried women for thyroid ,hair growth and abdominal examination .and for married women p/s and p/v had done ,routine investigation and specific investigation and ultrasound of pelvis done.

Patients having pregnancy and lactation ,malignancy, uterine fibroid ,polyp,and those who need surgical intervention are excluded from study. The treatment protocol was for 3 consecutive cycles .capsules of drugs were given to the patient for a period of 7 days thrice in a day with divided dose of 3gm orally for 7 days.

Drug preparation and Dispensing:

Pharmacopeal *Unani* formulation Dried *sudaab* (Ruta graveolans) and *mashkatramasheeh* (Mentha longifolia) were purchased from GMP certified company of Dawakhana Tibbiya College AMU Aligarh. The drug were identified and authenticated in the department of Ilmul advia (Dept. of Pharamacology) AMU Aligarh .The drugs were finely grind and filled in capsules .The patients were called for followup after a cycle to record her PBAC score .The patient was evaluated for regular menstrual cycle and overall improvement in secondary amenorrhoea and its associated symptoms .

Duration of protocol therapy: The protocol Is to be followed for 3 consecutive menstrual cycle 3gm capsule thrice in a day for 7 days is to be given to the patient: Case 1.A 30 Years old nulliparous women present with complaints of 3 month amenorrhoea .she report menarche at the age of 13 and describe her periods as having always be irregular .over the last two years they have been increasingly less frequent .she has also experienced weight gain .she denies any vaginal dryness ,hot flushes nipple discharge ,or new headache .she had no prior medical or surgical history also had no significant medical history she is not having any history of contraceptives

Physical Examination:

General appearance well nourished women in no acute distress Her temperature was afebrile pulse was 64/min blood pressure 130/90 mm hg respiratory rate14/min on her breast examination there was no nipple discharge no lump was seen



per abdomen was soft non distended there was no tenderness .laboratory investigation shows that her TSH was 1.91 Her prolactin was 5.26 ng/ml and her AMH was 0.561 ng/ml and rest of the investigation was with in normal limit on imaging usg TVS shows normal scan . After keeping all these investigation the drug was given thrice daily upto 7 days and now she had started menses within 7 days after completion of drug In the next cycle her menses occurs on regular interval of time with normal amount of flow and the PBAC score was 90 and assess upto 3 consecutive menstrual cycle . Patient regain their normal mensuration with normal amount of flow.

Case 2: A 24 Years old women came to the OPD of obstetric and gyanecology with the chief complaints of absences of menses from 4 month she reported her menarche at the age of 15 she had a history of previous normal cycle she had no family history of irregular menses she had no history of any medical or surgical history .on examination her vitals was stable and her breast and pubic hair was tanner stage 1v her prolactin was 13.1 and her TSH Level was 1.99 and her AMH level was 6.76 and rest of the blood investigation was with in normal limits on imaging her tvs ultrasound shows that normal scan except for grade 1 fatty liver keeping in mind all above investigation the drug was given thrice in a day upto 7days then she had onset of menses after 5 days of completion of drug which was scanty in amount and persist for 5 days her amount of menstrual blood was assessed by PBAC score which was 80 and assess upto 3 consecutive menstrual cycle. Now she had their normal menstrual cycle .

Case 3: A 28 years old nulliparous women came to the OPD of obstetrics and gyanecology with the chief complaints of absences of menses from 3 month she reported at her menarche at the age of 16 year she had s married life for 5 years she also having not any child she had a history of previous normal cycle she had no family history of irregular menses at the age of previous cycle she had no family history of irregular menses she had no

history of any medical or surgical history . her vitals was stable and there was no gross abnormality on per abdomen there was no oragnomegally .her normal laboratory findings was in normal limit and in specific test her TSH was 4.66 and her AMH was 0.464 and her prolactin was 10.6 on imaging her usg TVS shows grade1.fatty liver with mild hepatomegaly with no intrauterine or extrauterine uterine gestational sac seen .her urine pregnancy kit test was also negative keeping all these investigation in mind the drug was given to the patient on the same day when she came to our opd for 7 days after taking the drug menses occurs with in 10 days after completion of the drug and persist for 10 days which was heavy in flow which was assessed by her PBAC score which was 112 assesment was done upto 3 consecutive menstrual cycles .now she had their normal menstrual cycle.

Case 4. A 29 years old female came to the opd of ajmal khan tibbiya collge and hospital amu Aligarh with the chief complaints of absences of menses from 5 months she had a history of normal cycle her family history is her sister have same problem in menstruation .she had no medical or surgical history on examination she found to be stable her laboratory investigation was with in normal limits her specific investigation are as follows AMH was 0.54 ng/ml her prolactin was 31.90 ng /dl her FSH were 4.62 and LH was 2.75 her TSH was 2.160 on imaging usg tvs shows normal scan except bulky uterus the drug was given for the same duration for 7 days wait for 5 days then menses occurs with profuse bleeding her bleeding was assessed by PBAC score which was 112.asesement was done upto the 3 consecutive cycles and now she had their normal menstrual cycle.

Case 5 . A 42 years old multiparous women with P3A0 having full term delivery at hospital without any complication came to the opd of ajmal khan tibbiya college AMU Aligarh with the chief complaints of absences of menses from 6 month she had given history of previous normal regular menstrual cycle .she has no Relievant family

history and has non medical and surgical history .her laboratory investigation are within normal limit her specific test are as follows .

TSH was 5.631 and her AMH 0.34 ng/dl and her prolactin level was 11.6 and her FSH level are 31.6

On imaging usg shows normal scan except fatty liver .The drug was given for the 7 days but there was no menstruation occurs after even 10 days and follow up was done for 3 consecutive cycle. During these periods there was no menstruation.

Main therapy

As per references available in the classical Unani literature, Unani formulation sudaab and mishkatramaseh is a pharmacopoeil formulation taken from Al Qanoon fit tib , Published by Idara Kitabusshifa, New Dehli .This compound unani formulation was prescribed for 3 consecutive menstrual cycle. Thereafter, improvement was noticed in the patient's complaints. Patient was visited during and after every menstrual cycle upto 3 months to see the results of treatment during the course of treatment.

Probable mode of Action

The drugs used for secondary amenorrhoea should possess the properties of mudire haiz and mudire bol) properties . The Unani formulation of sudaab and Mishkatramashee) has all above mentioned properties. The temperament of above drugs are mostly Cold and Dry (2nd /3rd degree) and the mode of actions are Mulattif (Demulcent) ¹⁹,Muhallil(Resolvent) ,Mudire hayd wa baul (emenagogue and diuretics) ²⁰. these drugs contain ,flavonoids ,phenolic acids terpenes and Terpenoids have been suggested for the pharmacological action for secondary amenorrhoea.

Result of Intervention

This Safuf of compound Unani formulation has given to the patient for 3 consecutive menstrual cycle and in these patients with unani treatment

onset of menses occurs .Patient has visited during and after every menstrual cycle ,while full duration of treatment.

The patient kept on follow up for 3 consecutive menstrual cycle after the treatment for the normal menstrual cycle recurrence of Pervaginal bleeding during menses. . No adverse effect of Unani formulation was noted in the patient .This Unani formulation is very effective in secondary amenorrhoea That's why further studies will be recommended.

DISCUSSION:

Secondary amenorrhoea is a common complaint present in the women worldwide. Patient with absence of menses along with complication which should managed instantly to stop further complication. Unani system of medicine has number of single as well as compound formulation, useful to manage this problem. In this paper *sudaab and mashkatramaseh* was selected to treat the secondary amenorrhoea because of its mudire hayd and mudirr-i- bol properties.

CONCLUSION:

These results proved the claim of unani scholars that the Unani medicine is effective in secondary amenorrhoea. The Unani formulation was found to be safe and effective in the treatment of secondary amenorrhoea with overwhelming and an early result. This case series and the given Unani formulation may become a research epitome for the scientific community to explore the safety and efficacy of this Unani formulation using a larger sample size with prolonged follow-up of cured patients to see any recurrence.

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