

Efficacy of a combination of Unani drugs in patients of Trichomonal vaginitis

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A controlled, randomized single blind clinical trial was conducted in women suffering from Trichomonal vaginitis. After confirming the clinical and microbiological diagnosis, the patients were divided into two groups. The patients in control group were administered Metronidazole in a dose of 200 mg three times a day, for seven days by oral route. While the patients in the test group were treated with a combination of Unani drugs, i.e. pills made of *Afsanteen* (*Artemisia absinthium* Linn.), *Kabab Chini* (*Piper cubeba* Linn.) and *Bahroza* (*Pinus longifolia* Roxb.) and capsule of *Mazu* (Gall of *Quercus infectoria* Oliv.), twice a day, for 10 days, by oral route. They were also treated with intravaginal tampon made of *Barge Neem* (Leaf of *Azadirachta indica* A. Juss.), *Haldi* (Rhizome of *Curcuma longa* Linn.) and *Phitkiree* (*Alum*), at bed time, for 10 days. The findings suggest that test drugs have been proved effective and safe in treatment of Trichomonal vaginitis.

Keywords: Trichomoniasis, Unani medicine

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Trichomonal vaginitis (*Sh'ari Sa'alitee Ittehab Mahbal*) is the most common non-viral sexually transmitted infection of the genitourinary tract with approximately 120 million women worldwide diagnosed with this infection every year¹. The disease is caused by a pear shaped, actively motile, flagellated parasite, i.e. *Trichomonas vaginalis*²⁻⁴. In spite of the prevalence of this disease at mass level, the choice of treatment available in modern system of medicine is comparatively few. Even the drugs available for the purpose are not devoid of side effects and often fail to cure the disease completely. The disease is usually treated with Metronidazole, a 5-nitroimidazole drug derived from the antibiotic azomycin. Common adverse reactions of Metronidazole are usually mild, although some patients do have reactions severe enough to necessitate halting Metronidazole therapy⁵. Such a situation warrants some alternative arrangement for the treatment of a common ailment having potential of leading to diverse complications. As per the Unani literature the diseases occurs due to changes in the quality and quantity of Phlegm (*Balgham*). It is usually synthesized in the liver and used by the organs. When it becomes abnormal

Quwate Jaziba does not absorb and *Quwate Dafea* excretes it. Unani system of medicine claims to possess a number of effective and safe drugs that can be used in the treatment of Trichomonal vaginitis. However, the major lacuna with the drugs of Unani medicine lies in the fact that the drugs are neither standardized nor scientifically evaluated on specific parameters for their efficacy and safety raising an element of doubt in the mind of modern medicine practitioners and the scientific community. Therefore, it is substantial to subjects this clinically very important group of drugs for scientific evaluation. If Unani medicine could offer more effective or even less effective but safer agent, a big need of western medicine would be fulfilled. A combination of Unani drugs, i.e. Pills made of *Afsanteen* (*Artemisia absinthium* Linn.), *Kabab Chini* (*Piper cubeba* Linn.) and *Bahroza* (*Pinus longifolia* Roxb.), capsule of *Mazu* (Gall of *Quercus infectoria* Oliv.) and intravaginal tampon of *Barge Neem* (Leaf of *Azadirachta indica* A. Juss.), *Haldi* (Rhizome of *Curcuma longa* Linn.) and *Phitkiree* (*Alum*), are also commonly being used in the management of Trichomonal vaginitis at Mohammadia Tibbia College and Assayer Hospital, Mansoor, Malegaon that is well supported by long legacy of Unani

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physicians who are treating such patients successfully since a long without the report of any serious side effect. But despite being extensively used in the therapy, have not been so far, scientifically studied for their desired effect. Therefore, scientific evaluation of these drugs is quite necessary.

Methodology

Afsanteen (*Artemisia absinthium* Linn.), *Kabab Chini* (*Piper cubeba* Linn.), *Bahroza* (*Pinus longifolia* Roxb.), *Mazu* (Gall of *Quercus infectoria* Oliv.), *Barge Neem* (Leaf of *Azadirachta indica* A. Juss.), *Haldi* (Rhizome of *Curcuma longa* Linn.) and *Phitkiree* (*Alum*) were procured from local market of Malegaon and dried at room temperature. The drugs in their suitable dosage form were prepared after getting their identity and purity confirmed by a pharmacognocist. *Afsanteen* (*Artemisia absinthium* Linn.), *Kabab Chini* (*Piper cubeba* Linn.) and *Bahroza* (*Pinus longifolia* Roxb.) were taken in an equal quantity and powdered finely in an electric grinder. A semi-solid paste was made by addition of water in the powdered drug to make pills of pea size. The pills were made so that after drying each pill weighs 600 mg. The *Mazu* (Gall of *Quercus infectoria* Oliv.) was also powdered finely in an electric grinder and 500 mg of the powder was filled in an empty capsule. *Barge Neem* (Leaf of *Azadirachta indica* A. Juss.), *Haldi* (Rhizome of *Curcuma longa* Linn.) and *Phitkiree* (*Alum*) were taken in equal quantity and finely powdered in an electric grinder. The powdered drugs were mixed together and 3 gm drug was kept in a gauze piece to make tampon for local use.

The permission of Institutional Ethics Committee (IEC) was taken prior to the initiation of the clinical trial. The patients visiting the OPD of Department of Ilmul Qabalat wa Amraze Niswan, Mohammadia Tibbia College and Assayer Hospital, Mansoor, Malegaon during 2007-08, were screened for the presence of *Trichomonas vaginalis* on the basis of clinical signs and symptoms compatible with the classical description of the disease. The diagnosis of screened patients was however confirmed after pathological investigations. Sixty diagnosed patients of 18-45 yrs of age group were included in the study after taking the informed consent from them. They were informed about the disease, examination performed and type of treatment given. The patients suffering from candidiasis, chlamydial vaginitis, diphtheritic vaginitis, granular vaginitis, bacterial vaginitis, senile vaginitis, emphysematous

vaginitis, vaginitis adhaesiva, neoplasm of cervix or vagina or any other systemic disease were excluded from the study.

The patients were divided into two groups of 30 patients each with the help of computer randomized tables/ numbers. The patients in group I were administered 5 pills and 2 capsules, twice a day, by oral route and also treated with intravaginal tampon at bed time for 10 days. While the patients in group II serving as standard control were treated with Metronidazole in a dose of 200 mg, three times a day for 7 days, per oral. Abstinence was advised and no concomitant therapy was allowed during the period of treatment.

At each visit the patients were carefully interviewed and their statement about the vaginal discharge, pruritus, burning micturition and dysuria, backache and inflammation of vagina were recorded. After general and systemic examination each patient underwent per vaginal examination in lithotomy position. Tenderness of vaginal wall and straw berry appearance of vagina and cervix was recorded by per speculum examination. Saline wet mount examination of vaginal discharge was done to confirm the diagnosis, before and after the treatment. Finally, recorded findings were statistically analyzed using chi square test.

Results and discussion

The test drugs were studied in the management of Trichomonal vaginitis by observing clinical sign and symptom and laboratory investigation. The findings were tabulated, analyzed and compared with the standard drug (Table 1). On the day of registration abnormal vaginal discharge was found in 100% of the patients, while after treatment it remained only in 13.33% and 6.66% of the cases in group I and II, respectively. Tenderness and congestion of vaginal wall on day zero, was found in 100% and 83.33% of the cases in group I and II, respectively, whereas after treatment it had reduced to 6.66% in group I and totally disappeared in group II. Backache on day zero was found in 83.33% and 66.66% of the patients in group I and II, respectively, while after treatment it was decreased and found in 13.33% of the cases in each group. On day zero burning micturition and dysuria was found in 76.66% and 70% of the cases in group I and II, respectively, while after treatment it remained only in 3.33% of the cases in group I and totally disappeared in group II. Prior to the treatment dyspareunia was found in 43.33% and 30% of the cases in group I and II, respectively, while after

Table 1—Effect of test and standard drug in trichomonal vaginitis

Clinical features	Group I				Group II			
	Baseline		Post treatment		Baseline		Post treatment	
	No.	%	No.	%	No.	%	No.	%
Abnormal vaginal discharge	30	100	4	13.33	30	100	2	6.66
Tenderness of vaginal wall	30	100	2	6.66	25	83.33	Nil	0
Backache	25	83.33	4	13.33	20	66.66	4	13.33
Burning micturition, dysuria	23	76.66	1	3.33	21	70	Nil	0
Dyspareunia	13	43.33	Nil	0	9	30	Nil	0
Pruritus	23	76.66	Nil	0	22	73.33	Nil	0
Strawberry appearance	18	60	Nil	0	9	30	Nil	0
Trichomonas in slide	30	100	2	6.66	30	100	2	6.66

treatment, it totally disappeared in each group. Pruritus on day zero was found in 76.66% and 73.33% of the cases in group I and II, respectively, whereas after treatment, it totally disappeared in each group. Prior to the treatment strawberry spot was found in 60% and 30% of the cases in group I and II, respectively, while after treatment, it totally disappeared in each group. Prior to the treatment trichomonas in slide was present in 100% of patients in each group, while after treatment it remained only 6.66% in both groups. Relief in clinical symptoms along with reduction in microbiological count was considered as the criteria of efficacy. The cases having relief from abnormal vaginal discharge along with absence of trichomonas in slide after treatment were rated as cured. While the patients having no relief in abnormal vaginal discharge and trichomonas were found in slide after treatment, were rated as not cured. Complete cure was observed in 86.66% patients in group I and 13.33% cases were not cured. While 93.33% cases were cured in group II and 6.66% patients have not cured (Table 2).

As per the Unani literature the diseases occur due to irregular and disproportional distribution of the *Akhlat* (Humours). The *Akhlat* are classified in to four categories with four primary qualities. According to this *Dam* (Blood) is hot and moist, *Balgham* (Phlegm) is cold and moist, and *Safra* (Yellow Bile) is hot and dry, while *Sauda* (Black Bile) is cold and dry. The mucous fluid secreted from the vagina is a kind of *Balghami Khilt*⁶. This disease also occurs due to change in the quality and quantity of *Balgham*⁷. Thus, either the temperament (*Kaifiyat*) of *Balgham* is itself altered or some other normal or abnormal *khilt* is mixed with *Balgham* to the extent of altering its temperament and making it abnormal, or its quantity is altered. These abnormalities could be identified with various signs and symptoms produced by the abnormal *Balgham* due to alteration in its *kaifiyat*

Table 2—Response to treatment

Response	Group I		Group II	
	No.	%	No.	%
Cured	26	86.66	28	93.33
Not cured	4	13.33	2	6.66

(quality composition) or *kamiyat* (quantity); or the abnormal forms could be identified by the chemical and physical examination of various samples of *Balgham*⁶. It is usually synthesized in the liver and used by the organs⁸. When it becomes abnormal, *Quwate Maska* (retentive power) does not absorb and *Quwate Dafea* (expulsive power) excretes it. Thus the retention of morbid matters leads to the causation of vaginitis, and also invites various organisms to grow. It is one of the facts that wherever there is focus of infection in the body, the culture media is provided by Phlegm. In the other words *Balgham* is the first to catch infection⁶. As it has been earlier discussed that the temperament of *Balgham* is *barid ratab* (cold, moist) because signs and symptoms manifested in most of the *Balghami* diseases are those which are attributed to *burudat* and *rutubat* (cold and moisture). The Trichomonal vaginitis is also a disease of *khilt Balgham*. It is obvious to treat the disease by the drugs whose temperament is hot and dry. Therefore, most of the drugs used to treat the disease having hot and dry temperament. The drugs selected for the present study, i.e. *Afsanteen* (*Artemisia absinthium* Linn.), *Kabab Chini* (*Piper cubeba* Linn.), *Bahroza* (*Pinus longifolia* Roxb.), *Mazu* (Gall of *Quercus infectoria* Oliv.), *Barge Neem* (Leaf of *Azadirachta indica* A. Juss.), *Haldi* (Rhizome of *Curcuma longa* Linn.) and *Phitkiree* (*Alum*), were also reported in classical and ethnopharmacological literature as anthelmintic, antiprotozoal, antiseptic and described to be effective in vaginal discharge⁹⁻³³. The drugs in form of pills and capsule were administered by oral route for systemic action while the tampon was used

intravaginally for local action. Because the vagina not only secretes; it absorbs water, electrolytes and the substances of low molecular weight. Absorption and re-absorption are believed to occur mainly in the lateral recesses of the lower vagina³⁴.

The study clearly showed that the test drug is very effective in Trichomonal vaginitis, which is evidenced by decrease in amount of abnormal vaginal discharge, tenderness and congestion of vaginal wall, backache, burning micturition and dysuria, dyspareunia, pruritus, strawberry appearance and trichomonas in slide. The efficacy of the test drugs may be attributed to their antiprotozoal activity which was almost equal to that of Metronidazole. Thus, the study validated the therapeutic regimen proposed by Unani physicians and their age old practice with the test combination in the management of Trichomonal vaginitis.

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