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Hippocratic Journal of Unani Medicine

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**Instructions to Contributors**
Editorial

Unani system of medicine, although originated in Greece, is one of the recognized systems of medicine of the country. Although, the Unani medicine have been in use for centuries and are known for their therapeutic efficacies, there is a need to scientifically establish their efficacy and safety in order to achieve global acceptance. Organized research work in this system was, therefore, a need of the hour. In post independent era, Central Council for Research in Unani Medicine, through its clinical, drug research, literary research, survey & cultivation of medicinal plants programme is contributing significantly for last three decades. Vitiligo, Sinusitis, Filariasis, Eczema, Malaria, Infective Hepatitis, Asthma, are some of the conditions where Unani therapies have earned recognition after scientific validation.

With the availability of new scientific tools in recent years, a large number of traditional drugs, mainly herbals, have been further subjected to clinical, pharmacological, phytochemical and pharmaceutical studies in an effort to validate them and prove their medical efficacy and safety. All these investigations have yielded extensive and valuable findings and insights, and there is a need for wide exchange of this information among scientists engaged in the development of new drugs of natural origin.

The Council has been publishing the peer reviewed Hippocratic Journal of Unani Medicine (HJUM), mainly to bring out fundamental and applied aspects of Unani Medicine. The journal also publishes recent advances in other related sciences and traditional medicines as well as different streams of medical sciences, which have bearing on validation and scientific interpretation of various concepts and strengths of Unani medicine.

In view of an overwhelming response, the journal earlier published twice a year, its periodicity has now been changed to quarterly w.e.f. January 2008 to accommodate more articles for quick dissemination of research data among scientific community. The journal has sufficient room for invited articles from luminaries of modern medicine and sciences as well as scholars of Unani medicine. The broad areas being covered include clinical research on single and compound Unani drugs, validation of regimental therapy, Clinical and experimental pharmacological studies, standardization of single and compound drugs, development of standard operating procedures, ethnobotanical studies, experimental studies on medicinal plants and development of agro-techniques thereof, and literary research on classics of Unani medicine. The journal is also open for studies on safety evaluation of Unani and other herbo-mineral drugs, nutraceuticals, cosmotherapeutics, aromatics, oral health, life style disorders, sports medicine etc. and such other newer areas which are the outcome of modern day living.

The current issue of this journal provides 13 original and review papers in the areas of clinical research, drug standardization, pharmacology, ethnobotanical surveys and allied disciplines contributed by eminent scholars in their respective fields. It is hoped that data presented will contribute significantly in R&D sector of traditional drugs and prove to be an excellent exposition of current research efforts of scientists in this direction. Council acknowledges the authors for their contributions included in this issue and hope for their continued support in this endeavor. We wish to ensure the readers to bring out the future issues of the journal on time.

We at the CCRUM have been constantly striving to reach to higher standards and make HJUM the leading journal of Unani Medicine and related sciences. In this context, we thank our learned reviewers for their invaluable inputs in improving the manuscripts. We sincerely hope and trust that the mission can be accomplished with active partnership of quality-conscious individuals and institutions. Through these lines we seek your cooperation and support in materializing our dreams about the HJUM. In this regard, we request you for your as well as your colleagues’ contributions for publication in and subscription to the journal. Further, we will appreciate if the journal is introduced far and wide. We would also welcome esteemed suggestions for achieving the highest standards of quality for the journal.

(Prof. S. Shakir Jamil)
Editor-in-Chief
Study of Diuretic Activity of Tukhm Karafs (Seeds of Apium graveolens L.) in Albino Rats

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Abstract

Hydroalcoholic extract of Tukhm Karafs (seeds of Apium graveolens Linn) was studied for diuretic effect on Wistar albino rats divided into 4 groups of 6 animals each. Animals were treated with 1 ml of distilled water (Group I), 4 mg/kg of Furosemide (Group II) and 150 mg/kg and 300 mg/kg of the test drug (Group II & IV, respectively) by oral route with the help of a gastric cannula. The animals were placed singly in metabolic cages and urine sample of each animal was collected after 12 hours to determine the diuretic activity. The volume of the urine and the concentration of sodium and chloride in it were found increased significantly showing diuretic activity. An increase in sum total of sodium and chloride and the sodium and potassium ratio demonstrated saluretic and natriuretic activity, respectively. The study demonstrated that Tukhm Karafs possesses diuretic, saluretic and natriuretic activity.

Key words: Diuretics, Apium graveolens Linn., Furosemide, Unani Medicine

Introduction

Tukhm Karafs (seeds of Apium graveolens Linn. f., Apiaceae) known as celery in English, is an important drug of Tibbe Unani. It is used therapeutically as a single drug and as an important ingredient in many formulations/preparations such as Banadequl Bozoor and Jawarish Zarooni etc. It has been described to possess mudir baul (diuretic), muhallil (antiinflammatory), mufattit hisat (lithotryptic), mufatteh sudad (deobstruent), etc activities (Hussain, 1884; Dioscorides, d. 72 AD) and is used in the diseases of heart, kidney and liver etc where diuresis is an important part of therapeutic regimen. It is an erect, annual or biennial herbaceous plant native to Europe and now naturalized and occurring wild in the foot hills of North-Western Himalayas and the outlying hills of Punjab, Himachal Pradesh and Uttar Pradesh (Anonymous, 2003). Seeds and roots of this plant are equally popular for their medicinal values but the diuretic effect has been mainly attributed to the seeds. Its seed is light brown in color having a characteristic aroma with a warm bitter taste. The decoction prepared from it is frequently used as diuretic, emmenagouge and lithotriptic. A number of phytochemicals have been isolated from the seeds (Anonymous, 1997) and few of them have been reported to possess significant diuretic effect (Chandra et al., 2008). Synthetic diuretics although are very useful in the treatment of many diseases, yet serious side effects like hyperuricemia, acidosis, gastric irritation and high level of blood sugars associated with them
have revived the interest in natural diuretics (Shahid et al., 1999). A number of medicinal plants are being investigated for their diuretic and related activities (Serhat and Bora, 2006) and many of them have shown very promising results (Caceres et al., 1987; Karim et al., 2011). Therefore the age-old practice of Unani physicians to use Tukhm Karafs (TK) as a diuretic agent in a number of diseases without any report of major side effect makes it a promising candidate to be studied scientifically for diuretic activity.

Materials and Methods

The study was undertaken in the Dept. of Ilmul Advia, National Institute of Unani Medicine (NIUM), Bangalore. The Institutional Animal Ethics Committee of National NIUM approved the protocol vide Reg. No. IAEC/ IV/IA.

Experimental animals

The experiment was carried out on 24 healthy albino rats of Wistar strain weighing 150-200 gm of either sex. The animals were procured from Central Animal Research Facility (CARF) of National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore. Prior to the experiment, the animals were allowed to get acclimatized for at least one week. They were housed in clean polypropylene cages in an ambience maintained at a temperature of 25-30°C and humidity of 45-55% with 12 hr light and 12 hr dark cycles and had free access to standard diet and water ad libitum. The animal care procedure and experimental protocol were adhered to, in accordance with the guidelines of CPCSEA.

Preparation of extract

The test drug Tukhm Karafs was procured from local market of Bangalore. The sample was authenticated by Dr Siddamallaya at Regional Research Institute (Ay), Govt. Central Pharmacy, Bangalore. A voucher specimen has been stored vide no RRCBI/MCW/8 at the institute for future reference. The air dried seeds were put in drying chamber at 40°C for about 30 min to remove the moisture if any, and were ground in an electric grinder to get the powder of the crude drug. The powdered drug was subjected to Soxhlet extraction with a mixture of water and alcohol (50% each) for about 6 hours to prepare the hydroalcoholic extract. The liquid extract was filtered using a filter paper (Whatman No. 40) and the filtrate was concentrated over a water bath at 80°C. The resulting brownish-black residue was collected and stored for use. The yield percentage of the extract with respect to crude drug was found to be 23.64%.
Dose

The dose of the crude drug for albino rats was calculated by multiplying its human dose by the conversion factor of 7 (Freidrich et al., 1966) and was found to be 600 mg/kg. Another dose of 1200 mg/kg was also used to study the dose dependant effect if any. Since the drug was used in extract form therefore the dose of extract corresponding to 600 mg/kg and 1200 mg/kg of crude drug was calculated on the basis of yield percentage and was found to be 151.84 mg/kg and 303.68 mg/kg, respectively. The two doses however were rounded off to 150 mg and 300 mg, respectively. The doses appear to be appropriate as the LD$_{50}$ of 50% ethanolic extract of Tukhm Karafs has been reported to be 1000 mg/kg in rats (Tandon and Gupta, 2004).

Drugs and chemicals

Ethanol (95%) of analytical grade (S.D. Fine chemicals), distilled water and Furosemide (Aventis) were used for the study. Elyte 3 kit of Crest Biosystems (Coral) laboratory reagent was used for the analysis of electrolytes.

Test for diuretic activity

The method described by Taylor and Toplis (1962) and Afzal et al. (2004) was employed to study the diuretic activity. The animals were divided into four groups of six animals each. The animals in plain control group (Group I) received 1 ml of distilled water. The standard control group (Group II) received Furosemide in the dose of 4 mg/kg. Whereas the two test groups i.e., Group III and Group IV were treated with 50% hydroalcoholic extract of Tukhm Karafs at the dose of 150 mg/kg and 300 mg/kg, respectively. The drugs were suspended in distilled water and administered once, orally with the help of a gastric cannula. On the day of experimentation food and water was withdrawn 6 hours before the treatment. At 8.00 p.m., immediately after dosing, all the animals were placed singly in metabolic cages and the urine passed overnight was collected next morning at 8.00 a.m. in a measuring jar. The total urine output was measured for the assessment of diuretic activity. The Na$^+$, K$^+$ and Cl$^-$ excretion were measured using Star 21 plus Auto analyzer (Aspen). The sum of Na$^+$ and Cl$^-$ excretion was calculated as a parameter of saluretic activity. The ratio Na$^+$/K$^+$ was calculated to determine the natriuretic activity. The ratio Cl$^-$/Na$^+$ + K$^+$ was calculated to estimate carbonic anhydrase inhibition (Nirupama et al., 2005).
Statistical Analysis

The data was analyzed using graph pad software. The results were analysed using ANOVA one way with post hoc Tukey Kramer comparison test. \( P<0.05 \) was considered significant.

Results

Total urine output

Furosemide treated rats (GP II) showed significant increase in the volume of urine \((p<0.01)\) as compared to the plain control group, as it increased from 1.51ml in plain control to 3.65 ml in standard control. The rats in group III and IV treated with the test drug also produced a significant increase in the urinary volume of urine \((p<0.01)\). It was measured to be 2.91 ml and 3.78 ml respectively. The urine output of rats in GP II and GP IV was found almost similar and did not show any significant difference (Table 1).

Urinary Sodium

The concentration of sodium was measured as 41.82 mmol in plain control group which increased to 211.08 mmol/l, 121.81 mmol/l and 185.18 mmol/l in Group II, III, and IV, respectively showing a significant increase as compared to the plain control \((p<0.01)\). A significant dose dependent effect \((p<0.01)\) was also observed in the concentration of sodium of urine passed by rats in Group III and IV (Table 1).

Urinary Potassium

No significant increase in the excretion of potassium in the urine of rats in standard or any of the test groups was observed. However, there was a significant decrease \((p<0.05)\) in the excretion of potassium in the urine of rats in group IV as compared to the standard drug treated rats in (Table 1).

Urinary Chloride

The three test groups II, III and IV showed increase in the excretion of chloride in the urine samples \((p<0.01)\) as compared to the plain control group. The concentration determined as 41. 30 mmol/l in plain control group increased to 78.61 mmol/l, 55.20 mmol/l and 84. 92 mmol/l in Group II, III and IV, respectively. A dose dependent effect was also observed in the concentration of chloride in the urine of rats in group III and IV \((p<0.01)\) (Table 1).
**Table-1:** Diuretic activity of 50% hydroalcoholic extract of Tukhm Karafs.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>GP-I Distilled water (1 ml)</th>
<th>GP-II Furosemide (4 mg/kg)</th>
<th>GP-III Tukhm Karafs (150 mg/kg)</th>
<th>GP-IV Tukhm Karafs (300 mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume ml (mean ± SEM)</td>
<td>1.51±0.24</td>
<td>3.65±0.27&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.91±0.20&lt;sup&gt;a&lt;/sup&gt;</td>
<td>3.78±0.24&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sodium mmol/l (mean ± SEM)</td>
<td>41.82±3.37</td>
<td>211.08±9.42&lt;sup&gt;a&lt;/sup&gt;</td>
<td>121.81±4.80&lt;sup&gt;a,c&lt;/sup&gt;</td>
<td>185.18±11.23&lt;sup&gt;a,d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Potassium mmol/l (mean ± SEM)</td>
<td>32.09±1.53</td>
<td>34.60±0.46</td>
<td>28.73±0.08</td>
<td>25.99±3.29&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Chloride mmol/l (mean ± SEM)</td>
<td>41.30±2.69</td>
<td>78.61±3.26&lt;sup&gt;a&lt;/sup&gt;</td>
<td>55.20±3.17&lt;sup&gt;a,c&lt;/sup&gt;</td>
<td>84.92±1.41&lt;sup&gt;a,d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Na&lt;sup&gt;+&lt;/sup&gt; + Cl&lt;sup&gt;-&lt;/sup&gt; (mean ± SEM)</td>
<td>83.13±4.39</td>
<td>289.70±11.83&lt;sup&gt;a&lt;/sup&gt;</td>
<td>177.02±6.92&lt;sup&gt;a,c&lt;/sup&gt;</td>
<td>270.11±10.25&lt;sup&gt;a,d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Na+/K+ (mean ± SEM)</td>
<td>1.31±0.12</td>
<td>6.09±0.24&lt;sup&gt;a&lt;/sup&gt;</td>
<td>4.23±0.16&lt;sup&gt;e&lt;/sup&gt;</td>
<td>7.91±1.42&lt;sup&gt;a,d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Cl&lt;sup&gt;-&lt;/sup&gt;/Na&lt;sup&gt;+&lt;/sup&gt; + K&lt;sup&gt;+&lt;/sup&gt; (mean ± SEM)</td>
<td>0.56±0.05</td>
<td>0.29±0.02&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.36±0.01&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.40±0.02&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

N=6 in each group, Test used: ANOVA one way with Tukey Kramer multiple comparison test

a- p<0.01 with respect to GP-I, b- p<0.05 with respect to GP-II, c- p<0.01 with respect to GP-II, d- p<0.01 with respect to GP-III, e- p<0.05 with respect to GP I.

**Discussion**

Tukhm Karafs produced significant diuretic effect as it increased the urine output significantly. The significant increase in the concentration of sodium and chloride in the urine collected after the treatment further demonstrated diuresis inducing ability of the test drug. Since the excretion of electrolytes is as important as the water excretion for many pathological conditions therefore the excretion of the two electrolytes along with the fluid content makes Tukhm Karafs a good diuretic agent. Diuretics relieve pulmonary congestion and peripheral oedema and are useful in reducing the syndrome.
of volume overload, including orthopnoea and paroxysmal nocturnal dyspnoea. They also decrease plasma volume and subsequent venous return to the heart (Jain et al., 2002). 50% hydroalcoholic extract of Tukhm Karafs by demonstrating significant diuretic effect has emerged as a promising candidate for the treatment of peripheral oedema, ascites, congestive cardiac failure and hypertension etc (Vogel, 2002). The control of plasma sodium is important in the regulation of blood volume and pressure (Guyton and Hall, 1998) therefore saluretic drugs and potassium sparing diuretics have been developed to deal with the situations of volume overload. In the present study it can be observed that the sum of Na\(^+\) and Cl\(^-\) increased significantly indicating saluretic effect possessed by test drug. Further, despite changes in Na\(^+\) and Cl\(^-\) value no alteration occurred in the level of potassium (Table 1). This phenomenon is also important therapeutically and renders an edge over the diuretics that induce hypokalemia. The control of plasma potassium is required to maintain proper function of cardiac and skeletal muscles (Guyton and Hall, 1998). The loss of K\(^+\) that occurs with many diuretics lead to hypokalemia giving rise the chances of derangement in cardiac and skeletal muscles functioning (Stuart, 2008). By demonstrating significant saluretic effect without inducing any alteration in potassium concentration the test drug indicated its potential as an effective and safe diuretic agent (Table 1). The mechanism of this effect may be assumed to be due to the aldosterone antagonistic action as well as the Na\(^+\) channel blockage in collecting ducts (Jayashree et al., 2011) however, this requires further elucidation. The regulation of Na\(^+\)/K\(^+\) balance is also intimately related to renal control of acid-base balance. For this reason generally potassium sparing diuretics are recommended (Stuart, 2008). Values greater than 2.0 indicate a favorable natriuretic effect whereas the ratio of greater than 10.0 indicates potassium-sparing effect. In the present study Na\(^+\)/K\(^+\) ratio of 6.09, 4.23, 7.91 was found with respect to group II, III and IV, respectively (Table 1) showing highly significant natriuretic effect, but the values are little short of being categorized to possess the potassium-sparing diuretic effect therefore the findings warrant further investigation at higher doses. Na\(^+\) + Cl\(^-\) and Na\(^+\)/K\(^+\) ratio showed dose dependent effect which suggested that the diuretic effect is intrinsic and causal and possibly receptor mediated (Jayakody et al., 2011). Though the receptors for many clinically important diuretics are yet unknown (Odlind, 1984) but Carbonic anhydrase inhibition can be excluded at ratios between 1.0 and 0.8. With decreasing ratios, slight to strong carbonic anhydrase inhibition can be assumed (Vogel, 2002). The present study however does not have evidence in favour or otherwise of such a mechanism. On the other hand, in addition to the above features, the diuretic action of the test drug appears to be identical with the standard drug.
Furosemide, a high ceiling diuretic which acts by inhibiting the Na⁺/K⁺/2Cl⁻ co-transporter in the thick region of ascending limb of loop of Henle (Lahloo et al., 2007; Rang, et al., 2003). However no conclusion can be arrived at with regard to the mechanism of action of Tukhm Karafs. In such an equivocal situation multiple mode of diuretic action reported with some of herbal medications (Chandra et al., 2008; Wright, et al., 2007) cannot be ruled out. The seeds of Tukhme Karafs have been reported to contain glycosides, steroids, phenols, flavonoids, saponins etc (Anonymous, 1997). These active phytochemicals may be responsible for its diuretic activity as some of the phytochemicals such as flavonoids, saponins, volatile oils, sterols and triterpenes etc are known diuretic agents (Chandra et al., 2008) but the cumulative effect is more likely. The findings also suggested that both doses of Tukhm Karafs are effective but the higher dose is more efficacious than the lower dose. Thus, the study demonstrated that the two doses of ‘Tukhm Karafs’ possess dose dependant diuretic effect and that the effect of higher dose is comparable with that of the standard drug.

**Conclusion**

In view of the above findings it can be concluded that 50% hydroalcoholic extract of Tukhm Karafs possesses significant diuretic effect. The study thus validated the age-old practice of this plant drug as a diuretic agent by the physicians of Unani medicine.

**References**


Clinical Study on Efficacy and Safety of Hijāmat- bil-shart (Wet Cupping) in the Management of Waja-ul-mafāsil

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Abstract

Ilaq- bil- Hijāmat (cupping therapy) is one of the commonest classical modes of treatment in Unani System of Medicine and is widely used to manage and prevent various illnesses and ailments supposed to be caused by the predominance of humors, including Waja-ul-mafāsil (arthritis and sciatica). A randomized open controlled clinical trial was conducted to evaluate the efficacy and safety of Hijāmat- bil- shart (wet cupping). The study was conducted on 40 human subjects equally allocated in test and control groups (20 in each). The test group was subjected to the Hijāmat- bil- shart along with pharmacopoeial Unani drugs over a period of 6 weeks while the control group received the drugs only over the same period. The laboratory and radiological investigations were carried out before and after the treatment. Significant improvements were observed in disease specific symptoms e.g. joint pain, joint swelling, joint stiffness, restriction of movement and muscular weakness. In test group the pain level decreased by 62.50%, stiffness by 64.16%, swelling by 52.50%, restriction of movement by 77.50% and muscular weakness by 31.16%. Control group showed decrease in pain by 28.75%, stiffness by 38.33%, swelling by 22.50%, restriction of movement by 24.16% and muscular weakness by 22.50%. No significant difference was observed in laboratory and radiological findings in different groups. The study demonstrated that Hijāmat- bil- shart induced significant reduction in the cardinal symptoms of Waja-ul-mafāsil.

Keywords: Cupping therapy, Wet cupping, Arthritis, Sciatica, Unani Medicine

Introduction

Waja-ul-mafāsil is a broad and comprehensive term which encompasses most of the inflammatory disorders of joints such as osteoarthritis, rheumatoid arthritis and sciatica e.t.c. The commonest form of Waja-ul-mafāsil is, however, osteoarthritis. It is a common pathophysiological condition among geriatric populations across the globe. Though having a wide distribution, it is more prevalent in temperate regions. The peak age of onset is 30 to 50 years. Females are more commonly affected with it than males. Routine complains are joint pain, morning stiffness, restriction of movement, tenderness and muscular weakness (Wall and Melzack, 1994). Constitutional symptoms like general malaise and anorexia may also be felt by patients.

Rheumatoid arthritis is a chronic systemic inflammatory disease of unknown cause, chiefly affecting synovial membrane of multiple joints. The disease has
wide clinical spectrum with considerable variability in joints and extra-articular manifestations. The prevalence in the general population is 1-2%; female patients outnumber males almost by 3:1. The usual age at onset is 20-40 years, although rheumatoid arthritis may begin at any age (Lawrence et al., 2004). Diagnosis of RA is made with four or more of the following:

Morning stiffness (>1 hour), arthritis of three or more joints, arthritis of hand joints, symmetrical arthritis, rheumatoid nodules, rheumatoid factor, radiological changes and duration of six weeks or more (Nicholas et al., 2006).

In developed counties low back pain ('lumbago') is the most common medical cause of inability to work. In the great majority of patients it is due to abnormalities of joints and ligaments in the lumbar spine. Pain in the distribution of lumbar or sacral roots ('sciatica') is often due to disc protrusion, but can be a feature of other rare but important disorders including spinal tumour, malignant disease in the pelvis and tuberculosis of the vertebral bodies (Nicholas et al., 2006).

These inflammatory conditions and few other diseases of the joint have been discussed in Unani medicine as Waja-ul-mafāsil.

Non-steroidal anti-inflammatory drugs (NSAIDs) and steroids are commonly used for treatment of Waja-ul-mafāsil in modern system of medicine. The adverse effects and long-term toxicities of NSAIDs and steroids, however, motivate some of the patients to look for alternative treatment, particularly in the traditional systems of medicine. Unani system of medicine has been found at this occasion to provide effective and safe treatment of a number of diseases and therefore is being appreciated as suitable alternative for the diseases for which modern medicine does not possess effective treatment. In this system of medicine the method of treatment is divided basically into three major categories based on the therapeutic agents used. These are Ilāj-bil-Tadbeer (Regimenal therapy), Ilāj bil-Dawā (Pharmacotherapy) and Ilāj bil-Yad (Surgery) (Ajmal, YNM; Ibn Nafees., 1908; Ibn Sina., YNM; Nafees, 1313 A.H.).

The first mode of treatment is safer than the other two modes as it interferes only with six essential factors and in a large number of regimens nothing is introduced into the body and thus, normal metabolic processes are not affected. Hijāmat is an important regimen, which is practiced for treating many bodily disorders since long past. In medieval period it gained much popularity during the time of Prophet Mohammad (pbuh). He opted for this therapy frequently to prevention & to treat many bodily disorders and described its utility and effectiveness to the people also (Azeemabadi, 1415 A.H.; Bukhari, 1987; Anas, YNM.; Hajar, 1996; Abdullah, YNM; Abdullah, 1985).
The word “Hijāmat” has been derived from the Arabic verb ‘Hajama’; literally, it means to suck something and to minimize the size of a thing or to restore its previous basic size (Husaini, 2003; Ibn Manzoor, YNM). Technically it refers to a process that is carried out by creating a partial vacuum in the cupping glasses, placed on the body surface, by mean of heat or suction, in order to evacuate the morbid materials, to divert the material from the diseased part, to return a displaced organ to its normal position or to encourage the blood flow to the site of Hijāmat.

Types of Hijāmat

Hijāmat is classified on the two basis, first is the bloodletting and non letting, and second is the method of cup application.

On the basis of bloodletting and non letting it has two types:

1. Hijāmat- bil-Shart (wet cupping/cupping with scarification) and
2. Hijāmat- bilā-Shart (dry cupping/cupping without scarification),

On the basis of method of cup application also it is of two types:

1. Hijāmat-e-Nāriyah (cupping with fire)

The Mihjamah (cup) used prior to the twentieth century was made of horn, bamboo and pottery (Jafar, 2005). Nowadays very sophisticated and well-modified cups of glass are available.

The equipments needed to perform the whole procedure of Hijāmat are as follows:

Glass cups, medical antiseptics, lamp or candle, inflammable small cones of paper, sterilized gloves, sterilized medical scalpel, pack of cotton and sterilized medical gauze, micro pore tape and razor to remove the hair of the site, if needed.

Hijāmat is frequently used in many countries especially in Syria, India, China, United Arab Emirates, Saudi Arabia, Egypt, Iran, England, America, Thailand, Korea, Malaysia and Singapore etc (Anonymous, 2003, 2004). Common indications for this traditional method are muscular pain, arthritis, lumbago, hypertension, cardiac infarction, cardiomyopathy, angina pectoris, arteriosclerosis, chronic bronchitis, asthma, gastrointestinal disorders, migraine, headache, diabetes, paralysis, excessive iron level in the morbid body, hemophilia, leukemia and cancer etc (Ameen, 1999).
The present study has been designed to investigate the efficacy and safety of Hijāmat- bil-Shart in the patients of Waja-ul-mafāsīl.

**Methodology**

This is a prospective, single-centered, randomized controlled trial. All the patients underwent a treatment period of 6 weeks. The protocol was approved by the Institutional Ethics Committee of Jamia Hamdard University, New Delhi. The trial was conducted under the Good Clinical Practice (GCP) guidelines. All the patients gave written informed consent. Patients aged between 10-60 years who visited the Unani OPD in Majeedia Hospital, New Delhi, were screened. The patients having the obvious symptoms of Waja-ul-mafāsīl, irrespective of radiological and laboratory findings were included in the study. Out of total 40 subjects selected for the study, 28 were diagnosed as the patient of osteoarthritis of knee, 4 of rheumatoid arthritis and 8 of sciatica. The patients were randomly allocated into two groups (test and control) of 20 patients each. After randomization 15 cases of osteoarthritis, 2 cases of rheumatoid arthritis and 3 cases of sciatica were possessed by test group while 13 cases of osteoarthritis, 2 cases of rheumatoid arthritis and 5 cases of sciatica were possessed by control group. The test group was treated with Hijāmat and a combination of 3 pharmacopeial Unani formulations, while the control group received the pharmacopeial Unani formulations only in same dose. Since the intervention was invasive, hence it could not be blinded. On day 0 (visit 1), patients were asked to stop the use of NSAIDs and other drugs and were subjected to the regimen of Hijāmat (Ibn Sina, YNM; Jurjani, YNM; Kabeeruddin, YNM; Khan, YNM; Majoosi., 1889; Razi, 1962) along with the 3 Unani formulation. 6 sittings of Hijāmat were given with an interval of one week. Two cups were applied on and around each knee joint in case of osteoarthritis and rheumatoid arthritis as the knee joint was chiefly affected. In case of sciatica 4 cups were applied on each sides of LS spine. In single sitting around 5 ml blood was drawn in a single cup however the exact quantity was not measured. The clinical evaluation (joint pain, joint swelling, joint stiffness, restriction of movement and muscular weakness) of both groups was carried out after every 14 days. The severity of these symptoms was evaluated by using the grading system (from 0 to 4). In case of joint pain, nil, barely perceptible, mild (can carry out daily activities with some trouble), moderate (cannot carry out daily activities easily) and sever (bed ridden) were graded as 0, 1, 2, 3 & 4 respectively. In case of morning stiffness, no stiffness, up to 15 minutes, 15 to 30 minutes, 30 to 45 minutes and more than 45 minutes were graded as 0, 1, 2, 3 & 4 respectively. In case of swelling no swelling/
effusion, barely perceptible, mild, moderate, severe were graded as 0, 1, 2, 3 & 4 respectively. In case of movement, active range of motion (Full voluntary movement), active range of motion (Partial voluntary movement), passive range of motion (Full movement, when the joint is moved by the examiner), passive range of motion (Partial movement, when the joint is moved by the examiner) and no movement at all were graded as 0, 1, 2, 3 & 4 respectively. In case of muscular weakness, Full strength, strength against gravity and added resistance, strength only against gravity, not added resistance, muscular contraction occurs, but not sufficient to overcome gravity and muscular contraction with little or no movement were graded as 0, 1, 2, 3 & 4 respectively.

LFT (Bilirubin, AST, ALT, Alk. phosphatase), KFT (Blood Urea, Serum Creatinine), CBC, Arthritis Profile (RA Factor, C-RP, Uric Acid and ESR) and radiological investigations (x-ray of the affected joints) were carried out on the first day and at final visit. Test for BT, CT, Blood Sugar (F & PP) were carried out only on first visit to rule out the bleeding disorder and diabetes, as wet cupping is contra indicated in these disorders. The reading of all these investigations was recorded on case record form (CRF). The basal clinical findings (day 0) were compared with the findings recorded on days 14, 28 and 42. The basal findings of investigations were compared with that of the post treatment findings. The data of clinical findings was analyzed by Wilcoxon Signed Rank Test. The analysis of data of investigations was executed by using Paired ‘t’ test.

Inclusion criteria

Patients aged between 10-60 years, of either sex with clinical and/or radiographic evidence of Waja-ul-mafāsil (arthritis, sciatica), were included in the study.

Exclusion Criteria

Patients having anemia (Hb % < 12 g % in male <10 % in female), diabetes mellitus, obesity and past history of blood disorders were excluded from the trial.

Unani formulation

The pharmacopoeial Unani formulations given to both groups in same dose are as follows:
Capsule *Aujai* (2 cap. once a day at morning) (Anonymous, 1968), *Majoon-e-Sooranjan* (7 gm once a day at bed time) (Kabeeruddin, Y.N.M.) and *Roghane-Sooranjan* (applied/massaged locally twice a day) (Anonymous, 1968).

**Procedure adopted for Hijāmat**

To perform the Hijāmat, the patient was allowed to be in comfortable and correct position for Hijāmat. The area to be cupped was exposed (and the hairs were removed) and sponged with warm water so as to increase the blood flow to the site and Hijāmat-*bilā-Shart* (dry cupping) was applied to further increase the circulation of the blood. The area was cleaned with antiseptic lotions (e.g. Betadine lotion and Savlon), skin was lacerated with the help of surgical blade and the cups were applied for five to ten minutes to withdraw the blood. After removing the cups, the area was again cleaned with Betadine lotion and sterile dressing was applied.

**Results**

In joint pain, the improvement was statistically significant in both groups on 14th, 28th and 42nd days (P<0.01) (Table 3). In morning stiffness improvement was not significant in control group on 14th and 28th days, it however improved significantly towards the end of therapy (P<0.05). In test group on 14th, 28th and 42nd days a significant improvement was observed (P<0.01) (Table 4). In joint swelling, no significant improvement was found in control group on 14th, 28th and 42nd days (P≥0.05), whereas in test group a significant reduction in swelling was observed on 14th, 28th and 42nd days (P<0.01) (Table 5). In the movement of joint no significant improvement was found in control group on 14th, 28th and 42nd days, whereas in test group significant improvement was found on 14th, 28th and 42nd days (P≥0.01) (Table 6). No changes in muscular weakness was recorded in control group, whereas a significant improvement was recorded on 28th and 42nd days (P<0.01) in test group (Table 7). Change in laboratory parameters were assessed by using Paired ‘t’ test, however no significant change was observed in any group.

**Table 1: Distribution of the patients according to type of arthritis**

<table>
<thead>
<tr>
<th>Arthritis</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoarthritis</td>
<td>28</td>
<td>70%</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>Sciatica</td>
<td>8</td>
<td>20%</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100%</td>
</tr>
</tbody>
</table>
Table 2: Baseline characteristics of study patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>Test Group (n = 20)</th>
<th>Control Group (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joint Pain</td>
<td>3.20±0.09</td>
<td>3.00±0.07</td>
</tr>
<tr>
<td>Morning Stiffness</td>
<td>2.10±0.19</td>
<td>1.65±0.18</td>
</tr>
<tr>
<td>Joint Swelling</td>
<td>1.55±0.26</td>
<td>1.50±0.25</td>
</tr>
<tr>
<td>Restriction of Movement</td>
<td>1.50±0.15</td>
<td>1.10±0.16</td>
</tr>
<tr>
<td>Muscular Weakness</td>
<td>1.10±0.17</td>
<td>0.95±0.11</td>
</tr>
</tbody>
</table>

Table 3: Effect on joint pain

<table>
<thead>
<tr>
<th>Joint pain</th>
<th>Control Group (N = 20)</th>
<th>Test Group (N = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT 14th Day 28th Day AT</td>
<td>BT 14th Day 28th Day AT</td>
</tr>
<tr>
<td>Mean ± S.E.M.</td>
<td>3.00 ± 0.07</td>
<td>2.40 ± 0.13**</td>
</tr>
<tr>
<td>% of variation</td>
<td>20.41%</td>
<td>31.66%</td>
</tr>
</tbody>
</table>

**P<0.01 (Basal vs 14th day, 28th day and 42nd day in both groups) (Wilcoxon Signed Rank Test)

Table 4: Effect on morning stiffness

<table>
<thead>
<tr>
<th>Morning Stiffness</th>
<th>Control Group (N = 20)</th>
<th>Test Group (N = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT 14th Day 28th Day AT</td>
<td>BT 14th Day 28th Day AT</td>
</tr>
<tr>
<td>Mean ± S.E.M.</td>
<td>1.65 ± 0.18</td>
<td>1.40 ± 0.8NS</td>
</tr>
<tr>
<td>% of variation</td>
<td>14.16%</td>
<td>33.33%</td>
</tr>
</tbody>
</table>

NS P≥0.05 (Basal vs. 14th day and 28th day in control group) * P<0.05 (Basal vs. 42nd day in control group) **P<0.01 (Basal vs 14th day, 28th day and 42nd day in test group) (Wilcoxon Signed Rank Test)
Table 5: Effect on joint swelling

<table>
<thead>
<tr>
<th>Joint Swelling</th>
<th>Control Group (N = 20)</th>
<th>Test Group (N = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>14th Day</td>
</tr>
<tr>
<td>Mean ± S.E.M.</td>
<td>1.50 ± 0.25</td>
<td>1.30± 0.23 NS</td>
</tr>
<tr>
<td>% of variation</td>
<td>8.33%</td>
<td>15.00%</td>
</tr>
</tbody>
</table>

NS P≥0.05 (Basal vs 14th day, 28th, and 42nd day in control group)
**P<0.01 (Basal vs 14th day, 28th day and 42nd day in test group)
(Wilcoxon Signed Rank Test)

Table 6: Effect on restriction of movements

<table>
<thead>
<tr>
<th>Restriction of Movement</th>
<th>Control Group (N = 20)</th>
<th>Test Group (N = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>14th Day</td>
</tr>
<tr>
<td>Mean ± S.E.M.</td>
<td>1.10 ± 0.16</td>
<td>0.90± 0.16 NS</td>
</tr>
<tr>
<td>% of variation</td>
<td>15.00%</td>
<td>24.16%</td>
</tr>
</tbody>
</table>

NS P≥0.05 (Basal vs 14th, 28th, and 42nd day in control group)
**P<0.01 (Basal vs 14th day, 28th day and 42nd day in test group)
(Wilcoxon Signed Rank Test)

Table 7: Effect on muscular weakness

<table>
<thead>
<tr>
<th>Muscular weakness</th>
<th>Control Group (N = 20)</th>
<th>Test Group (N = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>14th Day</td>
</tr>
<tr>
<td>Mean ± S.E.M.</td>
<td>0.95 ± 0.11</td>
<td>0.85 ± 0.10 NS</td>
</tr>
<tr>
<td>% of variation</td>
<td>7.50%</td>
<td>17.50%</td>
</tr>
</tbody>
</table>

NS P≥0.05 (Basal vs 14th day, 28th day, and 42nd day in control group and Basal vs. 14th day in test group)
*P<0.01 (Basal vs 28th day and 42nd day in test group)
(Wilcoxon Signed Rank Test)
Discussion

The finding of the study demonstrated that the wet Cupping significantly improved pain, stiffness, swelling, restriction of movement and muscular weakness over 6 weeks. Although it is a preliminary study but provides a significant evidence in favour of the efficacy and safety of Hijāmat and indicates its wide therapeutic potential.

Pain of inflammatory origin is produced in a variety of ways. Change in local pH and concentration of certain ions play a role in stimulation of nerve endings. The release of chemicals like Histamine, 5-HT, K+ ions and plasma kinins can stimulate the local sensory nerves. In addition, the physical effect of inflammatory swelling causes an increased pressure resulting in mechanical pain. The effectiveness of wet cupping in reducing joint pain is likely to involve the inhibitory interference in the above mentioned inflammatory process. The technique of wet cupping has been quoted in literature to involve the sucking out of morbid materials (Istifrāgh) (Kabeeruddin, Y.N.M.) and reducing the local plethora which contribute to the swelling. It appears that wet cupping relieves pain by eliminating the morbid materials and by draining excessive blood along with the pro-inflammatory chemical mediators. Many a times, wet cupping diverts morbid materials from an area of high vitality or depth towards periphery and surface from where they are removed easily (like in the depth of the joints) (Imālah) (Kabeeruddin, Y.N.M.). The diversion also dislodges morbid materials from the site of actual pathology and also contributes to reduce physical cause of pain i.e. swelling. Morning stiffness originates from spasm of the synovial membrane and related tendons due to lack of oxygen and tissue nourishment. Immobilization of the joint for over night makes the area deficient of blood and relatively cool. Swelling also contributes in ischemia by exerting mechanical pressure over microvasculature. It is this coolness in turn causes spasm in synovial membrane. As the movement of a particular area is restored, circulation automatically gets improved and making the area warmer. It explains why Waja-ul- mafāsil gets aggravated in winter and it is why common in the subject of cold. Once the local temperature is maintained the spastic condition gets rectified and pain is relieved gradually. Thus in case of morning stiffness, wet cupping does what is expected from massage or physiotherapy.

Local swelling and effusion take place due to the extravasations of fluid and cells from the blood stream to the intercellular spaces. This abnormal accumulation of fluid in joint is responsible for the visible swelling, pain and also for the restriction of movement. Two main principles i.e. evacuation (Istifrāgh) and diversion (Imālah) on which wet cupping is based have direct...
effect on joint swelling by allowing fluids to come out and thereby reducing the swelling. Restriction of movement is directly related with pain and swelling. Anything that relieves the pain and swelling will reduce the restriction of movement. Muscular weakness is basically caused by poor vascularity of the area and immobilization of joint. The reason for immobilization is pain and swelling. By *Hijāmat* pain and swelling get reduced which in turn helps improve the mobility of the joint. Once the mobilization is restored, the affected part gets some strength and this strength increases gradually with frequent movement. As far as the question of poor vascularity is concerned, wet cupping helps in increasing the vascularity by vasodilatation as well as by elimination of morbid materials providing space for fresh blood.

There was no change in RA Factor, C-reactive protein, Uric Acid, ESR, Hemoglobin, TLC, DLC, LFT & KFT and in the radiological findings indicating that the normal physiological and biological process of the body have not been affected. Therefore the changes of inducing any side effect are minimal.

There was no change in C-reactive protein in both groups, suggesting that Unani formulations and wet cupping had no effect on these acute phase proteins. Further the apprehension that wet cupping leads to anemia due to blood loss was removed as the therapy was not found to alter the hemoglobin level.

In view of the above observation and discussion it can be concluded that *Hijāmat- bil-shart* is able to induce significant improvement in physiopathology and the sign & symptoms of *Waja- ul-mafāsil* specially the commonly prevalent condition such as osteoarthritis, Rheumatoid arthritis and Sciatica. The regimen can be used effectively and safely in the management of joint diseases.

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Effect of Unani Formulation in the Management of Menorrhagia (Kasrat-e-tams), Clinical Study

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Abstract

Menorrhagia is a common complaint of reproductive age group, denotes cyclic regular bleeding which is excessive in amount and duration or both. This leads to weakness, pallor, giddiness, discomfort and inconvenience in routine life. The incidence is reported to be 12.6-23.17% for gynecological admission in India. The present study was planned to evaluate the clinical efficacy and safety of ‘Gulnar’ capsules in the management of menorrhagia in reproductive age group. This study was carried out in OPD and IPD of Department of Qabalat wa Amraze Niswan, Faculty of Unani medicine A.K. Tibbya College, A.M.U Aligarh, during the period 2009-2010. Patients of menorrhagia above the 12 years of age & below 45 years (reproductive age group), during the period with complaints of increase in amount or duration of menstrual flow included in the study. Patients were interviewed and detailed history, clinical examination and laboratory diagnosis, Ultrasonography were done to exclude systemic and other diseases. Two ‘Gulnar’ capsules were given twice daily to patients from first day of menstruation for 5 days up to three consecutive cycles, and patients were called for follow-up for next three menstrual cycles. On the basis of result it was concluded that this unani formulation is effective in menorrhagia.

Key words: Menorrhagia, Humor, Temperament, Gulnar capsule.

Introduction

Menorrhagia is an abnormally heavy and prolonged menstrual flow at regular intervals. Clinically menorrhagia is defined as total blood loss exceeding 80 ml/per cycle or menses lasting longer than 7 days. Menstrual disturbances in the form of menorrhagia are a common problem during reproductive age group ( Hallberg, 1984) Normal menstruation in women of reproductive age is an indicator of health. During the active reproductive era menstruation occurs at approximately 28 days intervals (Naaz, 2009). Menorrhagia is a common debilitating condition, it affects approximately 20% of healthy women (i.e., it adversely affects life styles). The World Health Organization reports that 18 million women aged 30-55 year perceive their menstrual bleeding to be exorbitant (Goldrath, 1995). Report shows that only 10 % of women experiences blood loss severe enough to cause anemia or to be clinically defined as menorrhagia (Hallberg, 1964; Fraser, 2001; Warner, 2004). An appropriate assessment of blood loss can be made from pads and tampon count (Higham, 1990). In practice, measuring menstrual blood loss

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is difficult. Thus, the diagnosis is usually based upon the patient’s history. A normal menstrual cycle is 21-35 days in duration, with bleeding lasting an average of 7 days and flow measuring 25-80 ml (Lentz, 2007) Patients who lose more than 80 ml of blood, especially repetitively, are at risk for serious medical sequel. These women are likely to develop iron-deficiency anemia as a result of their blood loss. Menorrhagia is the most common cause of anemia in premenopausal women. (Noorhasan, 2010). According to Ibn-e-Sina (980-1037). Normal menstruation is that ‘Which is average in quantity (Miqdar) and normal in quality (kafiyat) and is discharged at the time which is normal for nature and health of women & cleans her body by removing harmful constituents of her body. Normal blood is that in which all humors (akhlat) are in normal proportion with respect to their quality and quantity. Normal menstrual cycle is 30 days including days of menstrual flow (Ibn-e –Sina, 980-1037).

Menorrhagia at pubertal age according to Unani can be described on the basis of gradual change of the temperament of ages as well as of concerned organ i.e. uterus, ovaries and arteries and mucous membrane, The Basics of unani tibb is laid on the concept of akhlat (Humors)and there respective mizaj (temperament). So according to the principal, Ilaj –biz-zid such therapy should be given which should help the tabiyat to bring the temperament to normal as well as have Habis (astringent) Qabiz (haemostatic) effect (Naaz, 1996).

According to Tibb-e-Unani, the human body is considered to be composed of following seven natural principals of body known as Al-Umur-al-tabiya. These factors are responsible for maintenance of health. Disturbances in any one of these can lead to disease. (Zaman, 2002; Ahmad, 1980)

Umur-al tabiya

1. Al arkan or anasir (Element)
2. Al mizaj (Temperament)
3. Al akhlat (Humors/body fluids)
4. Al aaza (Organ and membranes)
5. Al arwah (Pneuma or vital sprit)
6. Alquwah (Faculties or powers)
7. Al af-‘al (Functions)
In addition to above seven Umur e tabiya the following Asbabe sitta zaroorya (six essential causes) are also considered, which influence the human body to preservation of health or causation of disease. They are; (Jerjani, 1902)

1. Al-hawa al- muheet (Atmospheric air)
2. Al -makool wal- mashroob (Food and Drink)
3. Al- harkat wa sukoon e- badaniya (Physical and body movement and repose)
4. Al- harkat wa sukoon e- nafsaniya (Mental or physical movement and repose)
5. Al- naum wal- yaqza (Sleep and wakefulness)
6. Al-istefragh wal- ihtebas (Evacuation and retention)

Etiopathology of menorrhagia according to Unani concept

Unani physicians have described the etiopathology of kasrate tams under the following categories; (Majoosi, 1899; Husain, 2007; Jarjani, 1903)

1. *Ghalbae khoon (excessive congestion of blood)*: The increase in volume of blood (plethora) is either due to increased production of blood or decrease utilization of blood by body tissues, thereby increasing its volume in blood vessels. Tabiyat (The body defensive mechanism) plays its part by eliminating the excess blood from the body, either via nose, gums, and piles or in females by menorrhagia (kasrat-e tams).

2. *Ghalbae safra (dominance in bile)*: (Riqqat wa hiddate khoon) Sometimes the dominance of khilte safra alters the temperament of blood to hot. Blood becomes more liquefied by increasing the heat, making the blood vessels of uterus more fragile, resulting excessive uterine bleeding.

3. *Ghalbae balgham (dominance of phlegm)*: When there is a dominance of khilte balgham in blood, it weakens the uterine musculature and blood vessels. Khilte balgham (phlegm) by its virtues of mizaj “barid ratab” (cold and wet) increase the fluidity of blood, hence result in excessive flow of menstrual bleeding.

4. *Ghalbae soda (dominance of black bile)*: Emotional disturbances, worry, fright, anxiety, depression etc, are due to elevation of one’s temperament to soudavi (Black bile), these change cause disturbances in menstrual cycle.
5. **Zof-e- reham (uterine debility):** Frequent pregnancies, abortions and excessive intercourse weakens the uterine musculature, this alters the constricting power of uterine blood vessels and relax uterine muscles. There by resulting in excessive pain less menstrual bleeding.

6. **Soo–e- mizaj –e- reham:** The various pathological conditions in the genital tract such as polyps, ulcers or surgery alter the temperament of uterus which weakens the muscles and vessels of uterus result in excessive menstrual flow.

According to Jarjani (1903) following are causes of menorrhagia:

Uterine diseases: Weakness of uterus &uterine vasculature. Ulcers in uterus, polyp or uterine fibroid uterus, change in uterine temperament, uterine rupture, and rupture of uterine vessels

Change in blood; Increase in quantity of blood, Increase in fluidity of blood.

According to Al-majoosi (1899); Razi (2001); Tabri (1994) and Khan (1940) causes of menorrhagia are:

Weakness of retaining power (Quwwate maseka) of the uterus. Increase in the amount of blood or any humor (Khilt) and decrease in its weight. Increase in fluidity of blood. Rupture of uterine vessels. Quantity of body fluid increases leading to weakness in power of retention leads to menorrhagia. Dominant humors i.e. khilte safra, khilte balgham, khilte sauda, Uterine fibroid & polyps.

According to Akber Arzani, 1956 menorrhagia occur when,Quantity of blood increases (Imtela-ud-dam) in body & tabiyat want to get rid of it.

**Causes of Menorrhagia According to modern concept**

The etiology of menorrhagia includes hormonal, mechanical, and clotting abnormalities. Hormonal causes include: an ovulation, hypothyroidism, Mechanical causes include: Uterine Polyps, Uterine Fibroids, Intrauterine devices, cancer, Atopic pregnancy, endometriosis, and endometritis. Clotting abnormalities include: vitamin K deficiency, and circulating inhibitors of coagulation (Hawkins & Bourne, 2008). It is important to evaluate younger patients for vonWillebrand’s Disease (vWD), a bleeding disorder in which heavy menstrual bleeding is a common clinical manifestation (Rakel, 2005)

**Methodology**

The present study was conducted (2009-2010) on 80 clinically diagnosed patients of Menorrhagia, from IPD and OPD of Department of Qabalat wa
Amraze Niswan, Ajmal Khan Tibbiya College, A.M.U., Aligarh, (After obtaining their consent to participate in the study) to evaluate the clinical efficacy and safety of unani compound formulation (Gulnar capsule) in the management of menorrhagia in reproductive age group. The drugs chosen in the study have haemostatic, styptic and astringent effects which increases the constructive power of the uterine vessels by virtue of their cold and dry temperament.

Formulation composition

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Unani name</th>
<th>Botanical/Scientific name</th>
<th>Part used</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Gulnar</td>
<td>Punica granatum</td>
<td>Flower</td>
</tr>
<tr>
<td>2.</td>
<td>Gil-e- aramanee</td>
<td>Bole aramnaic</td>
<td>Clay</td>
</tr>
<tr>
<td>3.</td>
<td>Samaghe arbi</td>
<td>Acacia arabica</td>
<td>Gum</td>
</tr>
<tr>
<td>4.</td>
<td>Gul-e- surkh</td>
<td>Rosa damascena</td>
<td>Flower</td>
</tr>
<tr>
<td>5.</td>
<td>Aqaqia</td>
<td>Acacia arabica</td>
<td>Leaves Extract</td>
</tr>
<tr>
<td>6.</td>
<td>Kateera</td>
<td>Sterculia urens</td>
<td>Gum</td>
</tr>
</tbody>
</table>

All of the above giving Advia-e-mufreda, powdered and prepared as a capsule of 250 mg.

1. **Gulnar** *(Punica granatum)* (Nadkarni, 1989; Hakeem, 2002; Chopra, 1956)

   *Family: Punicaceae;*

   It is the male abortive flower of *Punica granatum* collected and used as an effective unani drug. This shrub much valued for its fruit and for the healing properties of its root, leaves, bark, flowers, and fruit rind.

   *Temperament; Cold*¹° & dry in °²*(Nadkarni, 1989)*

   *Cold &Wet*(Safiuddin, 1999)

   *Part used: - fruit, rind of fruit, root seed, flowers .fruit juice.*

   *Part under study: - flower*

   *Action and uses: - Flowers of gulnar farsi, Punica granatum Linn are 3.8-5cm long and as much across, mostly solitary, sometimes 2-4 together, reported for astringent and styptic properties and are also beneficial in the treatment of diarrhoea and dysentery. Bark of the tree and rind of fruit are astringent and stomachic. This is used as a desiccative cicatrizing, highly astringent used in prolapse of rectum, menorrhagia, and wounds healing ulcers of mouth, prolapse of uterus. Flower buds powdered, and given as best astringent in nasal hemorrhage.*
Gulnar with other styptic is recommended in excessive menstrual flow. It is locally used in the form of zemaad, farzja, Humool, Aabzan, & Huqna in kasrate tams. Gulnar is one of the effective ingredients in oral formulation used in kasrate tams (Husain, 2007).

Chemical constituents: Iron, Calcium, Phosphorus, Protein & Minerals.


It is a calcareous mineral, often made into small cakes and stamped with certain compression. It is usually prepared by mixing pipe clay or common chalk with oxide of iron or red ochre. Temperament: Cold 1° and dry 2°

Action and uses: It is an astringent, styptic, absorbent, and antiseptic, cicatrizing, haemostatic, and refrigerant. It is used as a powdered and paste.


It is a dried gum obtains from the stem and branches of *Acacia arabica*, and other parts of Acacia. It is found throughout the greater part of India, Ceylon, Baluchistan, Waziristan, Arabia Egypt and Tropical Africa.

Parts used: Bark, Gum, Leaves, Seeds and pods.

Temperament: Cold and dry in grade 2nd.

Action and uses: It acts as a general stabilizer in emulsion, lozenges, demulcent properties. aphrodisiac, nutritive and expectorant. Bark is a powerful astringent, pods are expectorant. It is highly astringent to bowel, cough, sore throat, mouth ulcers, hemorrhoids”, prolapse of rectum, conjunctivitis, gonorrhea, for stopping the bleeding, white discharge and menorrhagia.

Chemical constituents: Gum contains Arabic acid combined with calcium, magnesium, and potassium; also small quantity of malic acid, sugar, moisture 14 per cent, ash 3-4 percent. Pods contain about 22.44 per cent tannin. Bark contains large quantity of tannin.


It is found throughout India, also called Karaya gum. Indian tree, native to the mountain regions of central and eastern India.

Temperament: cold and dry.
Action and uses: It acts as glutinous demulcent and as a musakkin. It is effective in the treatment of hemoptesis, epistaxis, cough, sore throat, ulcerative colitis. Also used as a haemostatic substance, prolapse of rectum and in hemorrhagic conditions.

Chemical constituents: gum contains music acid and ash 4 %. It is cooling and used for making sweet meats; mucilage has no adhesive power. It is partially acetylated polysaccharide containing about 37% uronic acid, 8% acetyl group.

5. Aqaqia (Acacia arabica) (Nadkarni, 1989; Hakeem, 2002; Safiuddin, 1999).

It is the extract of the leaves, and gum of Acacia arabica.

Temperament: Cold & wet 2⁰

Action and uses: Demulcent, styptic, tonic, aphrodisiac, nutritive, and expectorant.

It is highly astringent for bowel, cure bronchitis, heals fractures, also used in healing old ulcer.


Rosa damascene with its red flower is the most important and cultivated in several places in Bengal, Kashmir, Punjab, Patna and Ghazipur. Several species and forms are cultivated in India.

Temperament: Cold and dry in grade 2nd. Some Unani physicians says Murakkabul quwah.

Parts used: flower, flower buds, petals, stamens, and volatile oil.

Action and uses: mildly astringent, aperients, carminative and refrigerant, cardiac tonic. It is cooling and astringent and used to relieve uterine hemorrhage.

Chemical constituents: volatile essential oil, fat, resin malic, tartaric and tannic acid. quercitanin glucoside, gallic acid, quercitannic acid, volatile oil and red colorings matter.
Fig. 1: Gulnar (*Punica granatum*)

Fig. 2: Gile armani (*Bole aramnaic*)

Fig. 3: Kateera (*Sterculia urens*)

Fig. 4: Samagh-e-arbi (*Acacia arabica*)

Fig. 5: Aqaqia (*Acacia arabica*)

Fig. 6: Gul-e-surkh (*Rosa damascena*)
Materials and Methods

Patients of menorrhagia were selected from OPD & IPD of department of Qabalat-wa-Amraze Niswan, Ajmal Khan Tibbia Collage, A.M.U., Aligarh.

Inclusive criteria: Patients of menorrhagia above the 12 years of age & below 45 years (reproductive age group). Case clinically diagnosed of menorrhagia; Patients agree to follow the protocol of the study.

Exclusion criteria: Patients of menorrhagia with fibroid uterus, ovarian cyst, with other uterine or ovarian pathology and systemic diseases.

Drug dose and their mode of administration

Two capsules (250 mg each) of Gulnar were given orally twice a day. Treatment was giving (from first day of menstrual period up to five days) for three consecutive menstrual cycles and patients were call for follow up for three menstrual cycles, and no side effects were noted.

Observations

Assessment of 80 patients was done according to the subjective parameters such as amount of blood flow, duration of blood flow, amount of pads used per day & clots pass during menses. Headache, backache, white discharge.

Results and Discussion

80 patients suffering from menorrhagia were treated with Gulnar capsule from first day of menstrual period for five days, up to three menstrual cycles and again for three cycles as follow up. The response of the drug was assessed on the basis of signs and symptoms. The drug was found effective in the treatment of menorrhagia. It has been observed that maximum numbers of patients were in the age group of 33-43 year (table 1). Maximum no of patient were married 50 and unmarried 30. Out of 50 married patient 29 patients having parity p4 to p5, 18 patients had p1-p3. Two patients had more than 6 children. Only one patient was with no issue. This study shows that patients having mutiparity were much prone to developed menorrhagia in all married patients (Table 2). It has been observed out of 80 patients, 35 were assessed Safravi, 11 patients Damvi, 28 Balgami and 6 of Saudavi temperament. This study shows that patients having bilious &phlegmatic temperament were much prone to developed menorrhagia in all age groups (table 3). There is some increment in hemoglobin percent of patients after treatment (table 4). Out of 80 patients, 17 patients complained pain in lower abdomen during
menses and 47 patients complained pain in lower abdomen during menses at the end of treatment only 7 left with pain before menses & 15 left with pain during menses. Out of 80 patients, 25 patients had low backache. At the end of treatment only 5 patients were left with back pain. Out of 80 patients 12 patient feel giddiness, completely relived this symptom at the end of treatment. Out of 80 patients 17 had loss of appetite and at the end of treatment only 5 left with this problem. It has been observed out of 80 patients 25 were found to have white discharge at base line phase, in which at the end of treatment only 7 patients left with this complain. 18 patients were found palpitation; at the end of treatment only 7 were left with this problem. Out of 80 patients 50 patients had clots passes during menstrual blood flow, at the end of treatment only 15 patient left with this complain and 75 had profuse menstrual discharge, at the end of treatment only 29 patient left with this complain. Out of 80 patient 55 have duration of menstrual blood flow 8-12 days. At the end of treatment phase only 14 patients with prolonged menstrual flow were left. 9 (Table 5)

Table 1: Distribution of patients according to the age.

<table>
<thead>
<tr>
<th>Age in year</th>
<th>No of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>13-23</td>
<td>30</td>
<td>37%</td>
</tr>
<tr>
<td>24-33</td>
<td>19</td>
<td>24%</td>
</tr>
<tr>
<td>34-43</td>
<td>31</td>
<td>39%</td>
</tr>
</tbody>
</table>

Table 2: Classification of patients according to their parity.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Parity</th>
<th>No of patient</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>P1-p3</td>
<td>18</td>
<td>22.5%</td>
</tr>
<tr>
<td>2</td>
<td>P4-p5</td>
<td>29</td>
<td>36.2%</td>
</tr>
<tr>
<td>3</td>
<td>More then 6</td>
<td>2</td>
<td>2.5%</td>
</tr>
<tr>
<td>4</td>
<td>No issue</td>
<td>1</td>
<td>1.25%</td>
</tr>
<tr>
<td>5</td>
<td>Total no</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 3: Showing classification according to temperament.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Temperament</th>
<th>No of cases</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Phlegmatic (Balghami)</td>
<td>28</td>
<td>35%</td>
</tr>
<tr>
<td>2</td>
<td>Chloeretic (Safravi)</td>
<td>35</td>
<td>44%</td>
</tr>
<tr>
<td>3</td>
<td>Sangunarine (Damvi)</td>
<td>11</td>
<td>13%</td>
</tr>
<tr>
<td>4</td>
<td>Melancholic (Saudavi)</td>
<td>6</td>
<td>7.5%</td>
</tr>
</tbody>
</table>
Table 4: Response of drug on Hb% of menorrhagic patients.

<table>
<thead>
<tr>
<th>Hb%</th>
<th>11-9</th>
<th>9-8</th>
<th>Below 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Hb% Base line</td>
<td>4</td>
<td>25</td>
<td>51</td>
</tr>
<tr>
<td>1.</td>
<td>5</td>
<td>26</td>
<td>49</td>
</tr>
<tr>
<td>2.</td>
<td>5</td>
<td>28</td>
<td>47</td>
</tr>
<tr>
<td>3. Pt, Hb% after three Tt cycle</td>
<td>10</td>
<td>30</td>
<td>40</td>
</tr>
<tr>
<td>4.</td>
<td>13</td>
<td>37</td>
<td>30</td>
</tr>
<tr>
<td>5.</td>
<td>15</td>
<td>42</td>
<td>23</td>
</tr>
<tr>
<td>6. Pt, Hb% after follow up</td>
<td>22</td>
<td>38</td>
<td>20</td>
</tr>
</tbody>
</table>

Table 5: Showing response of Gulnar capsules on sign & symptom.

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Pain before menses</th>
<th>Pain during menses</th>
<th>Profuse bleeding</th>
<th>Low backache</th>
<th>White discharge</th>
<th>Palpitation</th>
<th>Giddiness</th>
<th>Loss of Appetite</th>
<th>clots passes</th>
<th>duration of flow 8-12 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base line patient</td>
<td>17</td>
<td>47</td>
<td>75</td>
<td>25</td>
<td>25</td>
<td>18</td>
<td>12</td>
<td>17</td>
<td>50</td>
<td>67</td>
</tr>
<tr>
<td>1</td>
<td>15</td>
<td>42</td>
<td>70</td>
<td>22</td>
<td>20</td>
<td>16</td>
<td>12</td>
<td>16</td>
<td>47</td>
<td>60</td>
</tr>
<tr>
<td>2</td>
<td>15</td>
<td>30</td>
<td>67</td>
<td>15</td>
<td>17</td>
<td>14</td>
<td>10</td>
<td>11</td>
<td>41</td>
<td>57</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>25</td>
<td>55</td>
<td>11</td>
<td>13</td>
<td>14</td>
<td>8</td>
<td>10</td>
<td>38</td>
<td>45</td>
</tr>
<tr>
<td>4</td>
<td>10</td>
<td>21</td>
<td>49</td>
<td>8</td>
<td>13</td>
<td>8</td>
<td>5</td>
<td>8</td>
<td>31</td>
<td>37</td>
</tr>
<tr>
<td>5</td>
<td>8</td>
<td>19</td>
<td>40</td>
<td>6</td>
<td>10</td>
<td>9</td>
<td>5</td>
<td>7</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>15</td>
<td>29</td>
<td>4</td>
<td>8</td>
<td>7</td>
<td>3</td>
<td>5</td>
<td>15</td>
<td>14</td>
</tr>
</tbody>
</table>
Results

<table>
<thead>
<tr>
<th>S. No</th>
<th>Drug</th>
<th>Complete remission</th>
<th>Partial remission</th>
<th>No response</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Gulnar</td>
<td>39</td>
<td>25</td>
<td>16</td>
<td>80</td>
</tr>
<tr>
<td>2.</td>
<td>Percentage</td>
<td>48.75%</td>
<td>31.25%</td>
<td>20%</td>
<td>100%</td>
</tr>
</tbody>
</table>

The result showed out of 80 patients treated with Gulnar capsule 39 showed complete remission, 25 were showed partial remission, and 16 patients showed no response.

Conclusion

This study shows that maximum number of patients were anemic at base line, most probably due to excessive loss of blood during menses, poor nutrition. There is gradual increase in patients Hb% during treatment, this may be due to decrease blood flow, proper nourishment (advice) & also iron constituents present in ingredients of ‘Gulnar’ capsules.

During the study patients did not report any adverse effect like gastritis, irritation, vomiting, headache, body ache, vertigo, and excessive thirst, no change in blood pressure and pulse during and final visit of the study. The clinical study concluded that the unani compound formulation (Gulnar capsule) is effective and safe in menorrhagia in reproductive age group.

Acknowledgement

The authors are thankful to the Director General, Central Council for Research in Unani Medicine, New Delhi for encouragement and providing facilities for carrying out this study. We also wish to express our gratitude to the officials and other staff members of Department, of Qabalat-wa-Amraze Niswan, Faculty of Unani medicine, Ajmal Khan Tibbia College, A.M.U., Aligarh, for their help and cooperation during the clinical trial.

References


Non-Alcoholic Fatty Liver Disease (NAFLD) and the Clinical Evaluation of Luk Maghsool (Coccus lacca Kerr.), Sandroos (Callitris rhomboidea R.Br. ex Rich.), Ispaghol (Plantago ovata Forssk.) and Afsaneen (Artemisia absinthium Linn.) in its Management- A Pilot Study

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Abstract

Non-Alcoholic Fatty Liver Disease (NAFLD) is increasing in proportion to rise in obesity. Now it has become the most common cause of chronic liver disease after hepatitis B, hepatitis C and alcohol. It can be classified into simple fatty liver disease (or Non Alcoholic Fatty Liver, NAFL) and Non Alcoholic Steatohepatitis (NASH). The former has a benign prognosis but latter is associated with fibrosis and progression to cirrhosis. In early stage, fat accumulates within hepatocytes whereas at the same time the process of lipids removal by oxidation or export can’t keep pace with its biosynthesis.

The symptoms of both the settings are identical. They occur at any age and in children usually after 10 years. The most common symptoms are fatigue and discomfort in abdomen while patients who are obese with BMI > 25 about 1/3 have metabolic syndromes. Hepatomegaly may be present, although the signs of chronic liver disease are uncommon. Although its incidence is about 3% of population but it has come to our clinical observation that apart from obese patients, normal patients also have fatty liver on USG.

Keeping above facts in mind the present pilot study was conducted on the outdoor patients who attended the Moalejat and Modern Medicine OPD of Ajmal Khan Tibbiya College Hospital, Aligarh Muslim University, Aligarh. As there is no drug, so far, unequivocally proved to be effective in the prevention or regression of fatty liver, therefore, we opted the non pharmacopoeial preparation of Unani drugs to see its effect on established cases of NAFLD and only one type i.e NAFL was studied. There was no significant USG improvement by our drug formulation, yet clinical improvement was seen and was found to be significant to a great extent.

Key Words: Fatty Liver, Luk Maghsool (Coccus lacca Kerr.), Sandroos (Callitris rhomboidea R.Br. ex Rich. & A.Rich.), Ispaghol (Plantago ovata Forssk.) and Afsanteen (Artemisia absinthium Linn.), Non Alcoholic Fatty Liver Disease (NAFLD).

Introduction

Non-Alcoholic Fatty Liver Disease (NAFLD) is a disease of affluent societies and its prevalence is increasing in proportion to the rise in obesity. It has become the most common cause of chronic liver disease after hepatitis B, C and alcohol (Boon et al., 2006). It was first described in the 1950s when fatty liver was characterised in a group of obese patients. In 1980, Ludwig at the
Mayo clinic described to obese, diabetes, non alcoholic patients who had similar finding on liver biopsy to the patients with alcoholic liver disease, and the term non alcoholic steatohepatitis (NASH) was introduced. The prevalence of NAFLD in the United States and Europe ranges from 14-20% whereas that of NASH is around 3% of the general population, with fibrosis being seen in > 40% of significantly obese patients. The spectrum of NAFLD includes simple hepatic steatosis, which overtime can progress to NASH with the subsequent development of fibrosis and cirrhosis (Fausi et al., 2008).

NAFLD is usually asymptomatic although fatigue and discomfort in right upper quadrant may be reported (Schmotz et al., 2008). Clinically most patients are symptomatic with abnormal liver function test (LFT) particularly elevation of transaminases. Usually the condition presents with abdominal discomfort, flatulence, dyspepsia and complication of cirrhosis like gastrointestinal bleeding. In many cases there is accidental discovery of fatty liver when the patients are subjected to ultrasonography (USG) for some other reasons. Imaging technique like ultrasonography, CT and MRI scanning are reliable for detecting moderate to severe fatty changes in the liver. However the liver biopsy remains the “Gold standard” for diagnosing NAFLD especially to exclude alcoholic liver disease. Its management basically depends on weight loss and pharmacotherapy. The aim of treatment is to slow down the progression of NAFLD and to prevent liver related illness and death (Panda et al., 1991).

As far as Unani concept is concerned the disease by this name is not found in any of the classical text books and literature. However, most of the Unani scholars have described certain diseases like Sua-e-Mizaj kabid which roughly matches with non alcoholic fatty liver disease. The first description of Sua-e-Mizaj kabid barid has been found in Hippocrates’s treaties, thereafter Galen, Akbar Arzani, Mohammad Sharif Khan, Mohammad Azam Khan and Ghulam Jilani have also discussed this disease in the light of their predecessors. In Western medicine also no specific treatment of this disease has been evolved so far. However the attainment of ideal body weight, physical exercise and use of lipid lowering agents like statins is being advocated.

The present study has been carried out firstly because to the best of our knowledge no such clinical trial has been done so far in the field of Unani Medicine and secondly to evaluate the efficacy of our drug formulation which includes Luk Maghsool (Coccus lacca Kerr.), Sandroos (Callitris rhomboidea R.Br. ex Rich.), Ispaghool (Plantago ovata Forssk.) and Afsanteen (Artemisia absinthium Linn.).
Material and Method

A pilot study was carried out on the patients attending the outdoor of Moalejat and Modern Medicine (OPD) of Ajmal Khan Tibbiya College Hospital, Aligarh Muslim University, Aligarh, with any of the following symptoms like anorexia, fatigue, malaise, upper abdominal discomfort, nausea, vomiting and obesity as presenting features. Those suffering from Thyroid Disorder, Chronic Renal Failure, Diabetes Mellitus, Ishaemic Heart Disease, Nephrotic Syndrome, consuming oral contraceptives, alcoholics and primary gout were excluded from the study. Similarly those suffering from cirrhosis of liver or who had taken any type of lipid lowering agents of any system of medicine for at least one year before the clinical trial were also excluded. The results at the end of study were compared to the findings of first day i.e. on the day of commencement of therapy. Therefore, each patient acted as his own control.

The trial was carried out after approval of departmental ethics committee and informed written consent from the patients between from February 2007 to September 2009. Each case was studied on following manner that is history taking, physical examination, biochemical tests and USG abdomen. The liver biopsy was not done because of the lack of the facility of stand by operation theatre. Apart from personal interrogation and dietary habits including food cooking medium, detail of presenting complaints like anorexia, fatigue, malaise, nausea and vomiting were recorded with specific note of the abdominal discomfort in the right hypochondrium. Relevant past illness and history regarding similar attack of symptoms was also noted. The weight of the patients and BMI was also recorded. In systemic examination all the systems were examined in detail with special emphasis on gastrointestinal system like tenderness, organomegaly, ascites, lump, hernial orifices and per rectal examination.

The drugs afsanteen, luk maghsool and sandroos were taken in the ratio of 8:2:2 by weight in gram and grinded to fine powder and the patients were advised to take 6 grams with plain water preferably on empty stomach in the morning and evening. Simultaneously saboos-e-ispaghhol, telephone marked was also administered orally 5 grams at bed time for four months.

The routine investigations like haemogram, urine examination, stool examination and X- Ray Chest (PA View) were carried out. The special biochemical tests included Serum Bilirubin, AST, ALT, Alkaline Phosphotase, HBsAg, Serum cholesterol and Triglycerides. All the patients were subjected to USG abdomen before starting the treatment and at the termination of the trial. As and when require opinion of radiologist was also sought.
As there is no single criterion to diagnose non alcoholic fatty liver disease therefore the following criteria laid down by Davidson's Text book of Medicine was adopted. However the presence of atleast four or more parameters along with the bright liver on Ultrasonography was taken as diagnostic.

1. Nausea or Vomiting or both
2. Abdominal discomfort
3. Right upper quadrant (RUQ) discomfort
4. Raised ALT and AST (Greater than twice the upper limit of normal)
5. Raised Alkaline Phosphatase
6. Hypertryglyceridaemia
7. BMI (More than 25)
8. Truncal obesity
9. Bright liver on Utrasonography of Abdomen

The patients were initially followed up for every fifteen days for two successive occasions then at monthly interval for four months. The initial 15 days visit was to know any side effect of drugs. The clinical examination and necessary biochemical investigations were carried out at monthly interval where as USG abdomen as already mentioned was done before and at the termination of therapy i.e. four months. All the results were statistically evaluated using paired 't' test.

**Observations, Results and Discussion**

Keeping in view the limitation of space the results are being depicted in tabular form.

**Table 1:** Distribution of Patients According to Age and Sex

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Male</th>
<th></th>
<th>Female</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Patients</td>
<td>Percentage</td>
<td>No. of Patients</td>
<td>Percentage</td>
</tr>
<tr>
<td>25-35</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>35-45</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>45-55</td>
<td>3</td>
<td>12</td>
<td>3</td>
<td>16</td>
</tr>
<tr>
<td>55-65</td>
<td>3</td>
<td>12</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>&gt;65</td>
<td>2</td>
<td>8</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>10</td>
<td>40</td>
<td>15</td>
<td>60</td>
</tr>
</tbody>
</table>
As depicted from the above table the maximum incidence of non alcoholic fatty liver was found to be present in both sexes between the age group of 45-55 years and above 65 years of age. These findings confirm with the standard description.

**Table 2:** Distribution of Patients According to their Occupation

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Number of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Service</td>
<td>6</td>
<td>24</td>
</tr>
<tr>
<td>Labour</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Business</td>
<td>12</td>
<td>48</td>
</tr>
<tr>
<td>House Wife</td>
<td>7</td>
<td>28</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>25</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

It was observed that 24% cases were from service class, 48% were from business class and 28% were housewives but no patient was found from students as well as from labour class. These data clearly depict that physical exertion and low fat diet has protective effect for NAFLD as seen in the student and labour class. As the prosperity increase and physical exertion decrease there is a marked rise in the incidence of NAFLD and this seems to be the reason of fatty liver in remaining group.

**Table 3:** Distribution of Patients According to Dietary Habits

<table>
<thead>
<tr>
<th>Dietary Habit</th>
<th>No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetarian</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td>Non-Vegetarian</td>
<td>10</td>
<td>80</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>15</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

It was observed that the maximum number of cases were non-vegetarian i.e. 80%. This marked difference is beyond doubt that non vegetarian diets contain saturated fat which is more likely to give rise to NAFLD.
Table 4: Distribution of Patients According to Temperament

Total No. of Patients - 25

<table>
<thead>
<tr>
<th>Temperament</th>
<th>Male</th>
<th>%</th>
<th>Female</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanguinous (Damwi)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bilious (Safravi)</td>
<td>2</td>
<td>8</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Phlegmatic (Bhalghami)</td>
<td>8</td>
<td>32</td>
<td>12</td>
<td>48</td>
</tr>
<tr>
<td>Melancholic (Saudavi)</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>40</td>
<td>15</td>
<td>60</td>
</tr>
</tbody>
</table>

The maximum number of cases belonged to phlegmatic temperament while no patient was found in sanguinous temperament. As our study shows that maximum patients were of phlegmatic temperament (balghami mizaj) who were also obese with BMI > 25 which is itself a very strong risk factor for the development of NAFLD.

Table 5: Prevalence of Symptoms

Total No. of Patients - 25

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Number of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaise</td>
<td>20</td>
<td>80</td>
</tr>
<tr>
<td>Weakness</td>
<td>10</td>
<td>40</td>
</tr>
<tr>
<td>Nausea</td>
<td>25</td>
<td>100</td>
</tr>
<tr>
<td>Vomiting</td>
<td>13</td>
<td>52</td>
</tr>
<tr>
<td>Anorexia</td>
<td>20</td>
<td>80</td>
</tr>
<tr>
<td>Insomnia</td>
<td>20</td>
<td>80</td>
</tr>
<tr>
<td>Jaundice</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>RUQ discomfort</td>
<td>25</td>
<td>100</td>
</tr>
<tr>
<td>Hepatomegaly</td>
<td>15</td>
<td>60</td>
</tr>
<tr>
<td>Tender liver</td>
<td>15</td>
<td>60</td>
</tr>
<tr>
<td>Obesity</td>
<td>17</td>
<td>68</td>
</tr>
<tr>
<td>Mean BMI (&gt;27)</td>
<td>22</td>
<td>88</td>
</tr>
<tr>
<td>Non obese</td>
<td>8</td>
<td>32</td>
</tr>
</tbody>
</table>

From the above observations, it is evident that the symptoms which disturbed the patient maximum were malaise, nausea and upper abdominal discomfort followed by pain which was seen in almost all patients. Our findings are in tune with the classical presentation of this disease (Boon et al., 2006; Fausi et al., 2008; Schmotz et al., 2008).
Table 6: Effect of Drugs on Symptoms

Total No. of Patients - 25

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Follow up (in days)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 Day</td>
<td>15th Day</td>
<td>30th Day</td>
<td>60th Day</td>
<td>90th Day</td>
<td>120th Day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total No. of Patients</td>
<td>Improved %</td>
<td>Improved %</td>
<td>Improved %</td>
<td>Improved %</td>
<td>Improved %</td>
<td></td>
</tr>
<tr>
<td>Malaise</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>60</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Weakness</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>50</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>25</td>
<td>0</td>
<td>4</td>
<td>12</td>
<td>20</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>13</td>
<td>0</td>
<td>15.38</td>
<td>15.38</td>
<td>23</td>
<td>38.4</td>
<td></td>
</tr>
<tr>
<td>Anorexia</td>
<td>20</td>
<td>0</td>
<td>15</td>
<td>20</td>
<td>45</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td>Insomnia</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>14.28</td>
<td>28.57</td>
<td>71.4</td>
<td></td>
</tr>
<tr>
<td>Jaundice (O/E)</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>RUQ Discomfort</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Hepatomegaly</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>13.33</td>
<td></td>
</tr>
<tr>
<td>Tender Liver</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6.7</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Obesity</td>
<td>17</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Mean BMI (&gt;27)</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Non Obese</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

The effects of drug with respect to time have been shown in the table. The maximum improvement 80% was observed in malaise and weakness followed by improvement in anorexia 65% of cases and improvement in tender hepatomegaly in 13.33% of the cases. Whereas there was decrease in nausea and right upper quadrant discomfort by 28% and 8% respectively. There was no loss of weight in either obese or non obese patients; hence no significant improvement was seen in BMI. As far as the improvement in malaise and nausea is concerned the effect may be due to the improvement in liver function which may be the general tonic effect of afsantin on liver and stomach and antipyretic effect imparting the general well being (Khan, ynm; Karim, 1185; Nadkarni, 1982).

Improvement in anorexia may be due to the muhazzil (fat dissolution effect of sandroos (Nadkarni, 1982; Husain, 1914; Hakim, 1924) as well as luk maghsool (Chopra, 1958) and hepatotonic effect of sandroos ( Hakim, 1924), similar mechanism might be responsible for improvement in nausea and vomiting which may be due to additional carminative and appetizer
effect of afsantin (Rhazi, 1991; Lubhaya, 1982). As far as the regression in hepatomegaly and decrease in right upper quadrant discomfort is concerned the possible astringent, diuretics, antiseptic effect of afsantin and anti inflammatory effect of luk maghsool are likely to play a significant role (Khan, ynm; Karim, 1185; Israili, 1907).

It is also possible that the afsantin and luk maghsool might have lipolytic action in the hepatocytes due to its hot temperament. Over and above saboose-ispaghol might have acted as a barrier for absorption of fat from gastrointestinal tract. Therefore, it can be inferred that our drug combination which has several divergent properties which is the characteristic of a herbal drug might have acted as pivotal role in amelioration of signs and symptoms.

Table 7: Effect of Drugs on AST

Total No. of Patients - 25

<table>
<thead>
<tr>
<th>Follow up (in days)</th>
<th>0 Day</th>
<th>30th Day</th>
<th>60th Day</th>
<th>90th Day</th>
<th>120th Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean + S.D. (U/L)</td>
<td>35.08 + 3.28</td>
<td>35.98 + 1.94</td>
<td>35.48 + 2.65</td>
<td>35.44 + 2.64</td>
<td>35.2 + 2.32</td>
</tr>
</tbody>
</table>

N = 25; t = 1.26

The above table shows no significant change in AST level which implies that our drug combination has no hepatotoxic effect.

Table 8: Effect of Drugs on ALT

Total No. of Patients - 25

<table>
<thead>
<tr>
<th>Follow up (in days)</th>
<th>0 Day</th>
<th>30th Day</th>
<th>60th Day</th>
<th>90th Day</th>
<th>120th Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean + S.D. (u/ml)</td>
<td>88.4 + 4.736</td>
<td>87.32 + 4.73</td>
<td>86.32 + 4.99</td>
<td>85.12 + 5.24</td>
<td>86.8 + 4.432</td>
</tr>
</tbody>
</table>

N = 25; t = 8.77; p<0.001

Taking the face value there was no significant improvement. However paired test shows that these results are significant. The decreasing trend is indicating that either by altering the drug composition or by prolonging duration of treatment significant improvement may be expected.
Table 9: Effect of Drugs on Serum Alkaline Phosphatase

Total No. of Patients - 10

<table>
<thead>
<tr>
<th>Follow up (in days)</th>
<th>0 Day</th>
<th>30th Day</th>
<th>60th Day</th>
<th>90th Day</th>
<th>120th Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean + S.D. (u/dl)</td>
<td>33.6 + 6.4</td>
<td>32.6 + 6.6</td>
<td>31.5 + 5.7</td>
<td>30.2 + 5.4</td>
<td>20.6 + 9.68</td>
</tr>
</tbody>
</table>

N = 10; t = 6.7; p<0.001

Out of 25 patients 15 had normal serum alkaline phosphatase level. While in the remaining 10 patients the mean alkaline phosphatase was 33.6 + 6.4 u/dl, which fell to 20.6 + 9.68 u/dl, after 4 months of treatment and this fall was statistically highly significant.

The significant fall in patients with abnormal alkaline phosphatase may be attributed to the anti inflammatory effect of luk maghsool, which might have acted especially on the kupffer’s cell reducing their inflammation and thereby facilitating the flow of bile. Other possible mechanisms involved may be due to the diuretic (mudir) and Naf-e-Zuafe Kabid (Hepatotonic) effect of Sandroos (Karim, 1185; Husain, 1914; Hakim, 1924; Chopra, 1958).

Table 10: Effect of Drugs on Serum Bilirubin

Total No. of Patients - 8

<table>
<thead>
<tr>
<th>Follow up (in days)</th>
<th>0 Day</th>
<th>30th Day</th>
<th>60th Day</th>
<th>90th Day</th>
<th>120th Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean + S.D. (mg/dl)</td>
<td>2.81 + 0.43</td>
<td>2.5 + 0.37</td>
<td>2.37 + 0.37</td>
<td>2.43 + 0.32</td>
<td>1.82 + 0.31</td>
</tr>
</tbody>
</table>

N = 8; t = 8.4; p<0.001

Out of 25 patients 17 had normal serum bilirubin throughout the study. In remaining 8 mean serum bilirubin before treatment was marginally high and was 2.81 + 0.43 mg/dl which reduce to 1.82 + 0.31 mg/dl after the completion of the therapy.

The fall in the mean serum bilirubin in test group may be due to the diuretic (mudir) effect of afsantin and muhalil (anti inflammatory), muqqawi jigar (hepato protective) effect of luk maghsool. This effect may also be attributed to
NAFE ZUAFE KABID (HEPATO TONIC) OF SANDROOS (KHAN, YNM; HAKIM, 1924; ISRAILI, 1907).

**Table 11: Effect of Drugs on Total Cholesterol**

Total No. of Patients - 8

<table>
<thead>
<tr>
<th>Follow up (in days)</th>
<th>0 Day</th>
<th>30th Day</th>
<th>60th Day</th>
<th>90th Day</th>
<th>120th Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean + S.D. (mg/dl)</td>
<td>279.25 + 9.43</td>
<td>279 + 9.43</td>
<td>278.75 + 9.25</td>
<td>277.7 + 10.81</td>
<td>276.62 + 10.46</td>
</tr>
</tbody>
</table>

N = 8; t = 2.9; p<0.05

17 patients had normal total cholesterol level. Whereas in 8 remaining patients mean cholesterol level before onset of treatment was 279.25 ± 9.43 mg/dl showing a marginal fall to 276.62 ± 10.46 which have no clinical significance. The marginal fall although insignificant but may be due to the Qabiz (Astringent), Mugharri (Mucilaginous) and Mullayan (Laxative) effect of Ispaghol which causes hindrance in absorption of fat from gastro intestinal tract (Rhazi, 1991; Lubhaya, 1982). Muhazzil (Fat dissolvent) effect of Luk Maghsool, Muhazzil and Mujjajif-e-Ratubat-e-Badan (absorbent) effect of Sandroos might be the other factors for lowering the serum cholesterol (Karim, 1185; Hakim, 1924).

**Table 12: Effect of Drugs on Tryglycerides**

Total No. of Patients - 25

<table>
<thead>
<tr>
<th>Follow up (in days)</th>
<th>0 Day</th>
<th>30th Day</th>
<th>60th Day</th>
<th>90th Day</th>
<th>120th Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean + S.D. (mg/dl)</td>
<td>124.9 + 24.44</td>
<td>124.8 + 24.32</td>
<td>124.8 + 24.32</td>
<td>123.4 + 24.4</td>
<td>123.2 + 25.47</td>
</tr>
</tbody>
</table>

N = 25; t = 2.6; p<0.05

The mean serum fasting triglycerides level before treatment was 124.9 ± 24.44 mg/dl, and it fell only by 1.7 mg/dl after 4 months of treatment which has no significant value. These observations show that our drugs have no significant effects on serum fasting triglycerides reason of which remains to be explained by employing advance pharmacological studies.
**Table 13:** Effect of Drugs on Brightness of Liver

Total No. of Patients - 25

<table>
<thead>
<tr>
<th>USG Impression</th>
<th>Follow up (in days)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before Treatment</td>
<td>After Treatment</td>
</tr>
<tr>
<td></td>
<td>0 day</td>
<td>120th day</td>
</tr>
<tr>
<td>Total No. of Patients</td>
<td>No. of Patients</td>
<td>Improved Percentage</td>
</tr>
<tr>
<td>Brightness of Liver</td>
<td>25</td>
<td>23</td>
</tr>
</tbody>
</table>

All the patients were subjected to Ultrasonography of Hepatobiliary system before and at the termination of therapy. Brightness of liver on the gray scale was noted objectively in all the 25 patients showing brightness of liver before starting the treatment. It was observed only in two patients that there was significant decrease in the liver brightness. This effect may be explained due to hindrance to absorption of fat from gastrointestinal tract because of Sabose-Ispaghhol. The hot temperament of the test drugs Afsantin, Luk Maghsool and Sandroos (Karim, 1185; Husain, 1914; Hakim, 1924; Chopra, 1958), which might have caused redistribution and dislocation of fat from hepatocytes.

**Conclusion**

This study shows the effect of Unani formulation has an encouraging potential in Non-Alcoholic Fatty Liver Disease management with no major adverse effects and tolerated this therapy well. Further long term studies to determine the relapse rate and the effect of Unani formulation on deranged liver function along with increased dose and/or addition/deletion of drug ingredients need to be done.

**References**


Hakim, Abdul Hakeem, 1924. Bustanul Mufridat, Khursheed Book Depot, Lucknow, pp. 73, 74, 351, 518-19.


Effectiveness of Unani Drugs, Namely, Oral Tab. Musaffi (Kit Medicine) and Local Application of Kaf-e-darya (cattle fish bone) + Badam-e-Talkh (Bitter Almond) + Arq Gulab (Rose Water) in Acne Vulgaris

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Abstract

A clinical trial was conducted on 50 patients of Grade I, II and III Acne Vulgaris with their age range from 10-40 years. The grade IV of the disease was excluded from the study. The already diagnosed patients were given Tab Musaffi in the dose of 2 tablets after meals along with local application of a paste of Unani made drugs, namely kaf-e-darya (cattle fish bone)+badam-e-talkh(bitter almond)+arq gulab (rose water) twice daily for 28 days. After completion of therapy, there was a significant recovery in the symptoms of acne vulgaris in grade I and II and little in grade III. The results show that this formulation can be tried in such patients as an alternate. The details have been discussed in the paper.

Key Words: Acne Vulgaris, Berberis aristata, Zinjiber zerumet, Cassia abscus, Acacia, catechu, Cattle fish, Prunus amygdalus

Introduction

Acne vulgaris is commonly called acne. It is a common skin disorder that affects all persons at least once during life time. It usually affects teenagers but substantial numbers of men and woman between the ages of 20-40 are also affected by this disorder (Cunliffe, 1979). Acne is caused by changes in the pilosebaceous units (skin structures consisting of hair follicles and its associated sebaceous gland). Many factors are rather than a single one combine to cause chronic inflammation of blocked pilosebaceous follicle. In this sebum secretion is increased androgens from the testes, Ovaries and adrenals are the main hormones which stimulate the sebum secretions, increased and abnormal keratinisation at the exit of the pilosebaceous follicle which obstructs the flow of sebum bacteria plays a pathogenic role (Davidson, 1995). The severity of Acne is mainly proportional to the amount of sebum production. The first sign of acne Vulgaris commonly occurs at the time of puberty (Rothman, 1993).

Acne lesions are commonly referred to as Pimples, Spots or it is affecting more than 85% of teenagers and adulthood. Acne vulgaris is polymorphic open and closed comedoes, papules, pustules and cysts are found. Its prevalence is similar in both sexes but the peak age of severity in females is 16-17 years and in male 17-19 years (Lawrence, 2001). Acne may be caused by irritating creams and oils. Pustules on the face can also be caused by tinea infection.
The lesions occur mainly over the face, neck, upper chest, back, shoulders etc. Comedones are the hallmark of acne vulgaris. Comedones typically are a bit larger and have black material in them. Closed comedones are tiny, fleshy colored non inflamed bumps that give the skin a rough appearance (Lawrence, 2001).

The treatment of acne vulgaris is based on the type and severity of the lesions. Comedones require treatment different from that of pustules and cystic lesions. Comedones papular acne is managed by local treatment alone, pustular cystic and scarring acne requires local and systemic treatment (Lawrence, 2001). Many topical antibiotics useful in the treatment of acne have been associated with serious short and long term adverse effects (Reisner, 1983).

According to Unani System of Medicine, in acne vulgaris disease, the oily glands over work and there secretion increase in quantity. These secretions remain with the cells and do not come out thus results in inflammation and small white or yellowish pustules develop in the skin. These pustules are pointed at the top and there bases are hard. When these pustules mature and when pressed, it releases some pus (Kabiruddin, 2007). The main cause of acne vulgaris are ghalba-e-khoon (excess of blood), fasad-e-khoon (impurity of blood), qilatt-e-khoon (deficiency of blood), shiddat-e-hararat and shiddat-e-baroodat (excess of heat and cold), suay-e-hazm (indigestion), kasafat-e-jild (impurity of skin), kasrat-e-afkar (excess of mental work), excessive use of gharam-gezao-wa--masroob (excess use of hot and spicy foods & drinks), hamal (pregnancy), aam-sehat-ki-kharabi (general weakness), lack of fresh air, hereditary oily skin, deficiency of Vit C, excess use of oily soaps, creams, mardana johar (male hormone), shamee ghaddoo (oily glands) etc (Azmi, Ynm).

Since there is no specific treatment available in Allopathic System and many patients report at this Institute for alternate treatment, so, this study was undertaken to evaluate the efficacy of this formulation in the patient of acne vulgaris of grades I, II and III in the year 2011. The duration of the therapy was 28 days and duration of the study was 180 days.

Aim of the Study

To provide safe and effective alternate therapy to patients of acne vulgaris.

Inclusion Criteria

1. Age 10-40 years.
2. Both sexes.
3. Acne Vulgaris

4. Sign & Symptoms
   – Burning and itching sensation
   – Local inflammation
   – Comedones, Papules & Pustules

5. Grading
   – Grade I  - Mild Acne (non-inflammatory comedones)
   – Grade II  - Moderate Acne (comedones and papules)
   – Grade III - Severe Acne (comedones, papules and pustules)

Exclusion Criteria
1. Age below 10 years and above 40 years.
2. Patients having psoriasis, vitiligo and other types of dermatitis.
3. Abnormal thyroid function.
4. Very severe Acne Grade-IV (nodules and cystic acne)

Withdrawal Criteria
1. Failure to follow the protocol.
2. Dropout due to any reason.
3. Any adverse reaction or untoward event.

Materials and Method
A clinical trial was conducted to evaluate the efficacy of the formulation in the patient of acne vulgaris with Grade I, II and III in Out Patients Department of this Institute during the period from April-June, 2011. The duration of the therapy was 28 days. Since the patients were already diagnosed so, no any investigation was conducted on these patients. The treatment was directly started with the formulation. The assessment of the efficacy of the formulation was as per the relief in the signs and symptoms, reduction in local inflammation and in number of comedones and papules, reduction in burning and itching sensation.
50 patients between 10-40 years of age with Grade I, II and III acne vulgaris were selected for the study from the OPD. Out of 50 patients, 20 males and 30 females with female to male ratio of 1.5:1. Among them, 20 patients had grade-I, 24 had grade-II and 6 patients had grade-III acne. The already diagnosed patients were given Tab Musaffi in the dose of 2 tablets after meals along with local application of a paste made of Unani drugs, namely kafe-darya(cattle fish bone)+badam-e-talkh(bitter almond)+arq gulab(rose water) twice daily for 28 days. Tablet Musaffi was given in the dose of 2 Tablets twice a day along with local application of paste on affected area in morning and evening after meals. Weekly follow-ups were made for four weeks and duration of the therapy was 28 days. The patients were asked to avoid spicy, oily food and were asked to take citrus and vitamin-c rich diet and avoid stress.

1. The Composition of Tab Musaffi

The composition of Tab. Musaffi (kit medicine) prepared and supplied by the CCRUM, New Delhi for such patients and was made available here, has been shown in the Table 1.

2. The Composition of Paste for Local Application

The composition of the paste for local application has been mentioned in Table 2.

Method of Preparation of Paste

Kaf-e-darya and maghaz-e-badam (kernel of almond) were powdered or mixed and then arq-e-gulab were added as required to make the paste. The paste so prepared was applied over the face two times daily after cleaning of the face.

Observations

It was observed that out of out of 50 patients, 16 patients were in the age range of 10-20 years, 29 were in the range of 21-30 and 5 were in the age range of 31-40(Table 3). Out of 50 patients, 20 were male and 30 were female and female to male sex ratio was 1.5:1 which indicates that this disease is more frequently seen in females (Table 3). Out of 50 patients of acne vulgaris, 16 were in the age – group of 10-20 years, 29 were in 21-30 years and 5 patients were in the age group of 31-40 years (Table 3). Among 50 patients of acne vulgaris, 20 patients had acne of grade-I, 24 had grade-II and 6 patients had grade-III of acne vulgaris. It was also observed that out of 50 patients, 20 had non-inflammatory acne (comedones), 24 patients had comedones with papules
and 06 patients had severe acne with comedones and papules with pustules (Table 4).

The Composition of Tab Musaffi

**Table 1**

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Unani Names (Botanical/Scientific Names)</th>
<th>Weight</th>
<th>Properties/Actions</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Rasaut (Berberis aristata)</td>
<td>125 mg</td>
<td>Blood purifier, anti-inflammatory, blood alternative, vascular astringent, divergent, febrifuge, local analgesic</td>
<td>Ahmed et al., 2005.</td>
</tr>
<tr>
<td>2.</td>
<td>Narkachoor (Zinjiber zerumet)</td>
<td>125 mg</td>
<td>Pimples, boils, skin diseases, anti-inflammatory, hypnotic, digestive</td>
<td>Ahmed et al., 2005; Nadkarni, 1926</td>
</tr>
<tr>
<td>3.</td>
<td>Chaksu (Cassia absus)</td>
<td>125 mg</td>
<td>Blood purifier, anti-inflammatory, alternative, styptic, haemostatic, astringent</td>
<td>Ahmed et al., 2005; Nadkarni, 1926</td>
</tr>
<tr>
<td>4.</td>
<td>Kattha Safaid (Acacia catechu)</td>
<td>125 mg</td>
<td>Blood purifier, astringent, useful in skin diseases, divergent, bed sores, chronic ulcer</td>
<td>Ahmed et al., 2005; Nadkarni, 1926</td>
</tr>
</tbody>
</table>

The Composition of Drugs of Local Application

**Table 2**

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Unani Names (Botanical/Scientific Names)</th>
<th>Properties/Actions</th>
<th>References</th>
</tr>
</thead>
</table>
Sex and Age wise distribution of the Patients

Table 3

<table>
<thead>
<tr>
<th>S. No</th>
<th>Age in years</th>
<th>Male (%)</th>
<th>Female (%)</th>
<th>Total</th>
<th>Sex</th>
<th>Female to Male Sex Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10-20</td>
<td>7(43.75)</td>
<td>9 (56.25)</td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>21-30</td>
<td>9(31.03)</td>
<td>20 (68.97)</td>
<td>29</td>
<td></td>
<td>Male = 20 Female = 30</td>
</tr>
<tr>
<td>3</td>
<td>31-40</td>
<td>4(80)</td>
<td>1 (20)</td>
<td>5</td>
<td></td>
<td>1.5:1</td>
</tr>
<tr>
<td>4</td>
<td>Total</td>
<td>20(40)</td>
<td>30(60)</td>
<td>50(100)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Grade wise distribution of the disease

Table 4

<table>
<thead>
<tr>
<th>S. No</th>
<th>Grade</th>
<th>State of Acne</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I</td>
<td>Mild acne with comedones</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>II</td>
<td>Moderate acne with comedones, papules.</td>
<td>24</td>
</tr>
<tr>
<td>3</td>
<td>III</td>
<td>Severe acne with comedones, papules and pustules.</td>
<td>6</td>
</tr>
</tbody>
</table>

Treatment Response

Table 5

<table>
<thead>
<tr>
<th>S. No</th>
<th>Grade</th>
<th>Main features</th>
<th>Mild Response</th>
<th>Moderate Response</th>
<th>Good Response</th>
<th>Excellent Response</th>
<th>No response</th>
<th>Drop out</th>
<th>Total Pts.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I</td>
<td>Mild Acne</td>
<td>0</td>
<td>3</td>
<td>7</td>
<td>7</td>
<td>0</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>II</td>
<td>Moderate Acne</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>24</td>
</tr>
<tr>
<td>3</td>
<td>III</td>
<td>Severe Acne</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td>5</td>
<td>10</td>
<td>12</td>
<td>11</td>
<td>7</td>
<td>5</td>
<td>50</td>
</tr>
</tbody>
</table>

Percentage Wise Response of the treatment

Table 6

<table>
<thead>
<tr>
<th>S. No</th>
<th>Grade</th>
<th>Main features</th>
<th>Mild Response</th>
<th>Moderate Response</th>
<th>Good Response</th>
<th>Excellent Response</th>
<th>No response</th>
<th>Drop out</th>
<th>Total Pts.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I</td>
<td>Mild Acne</td>
<td>0%</td>
<td>6%</td>
<td>14%</td>
<td>14%</td>
<td>0%</td>
<td>6%</td>
<td>40%</td>
</tr>
<tr>
<td>2</td>
<td>II</td>
<td>Moderate Acne</td>
<td>8%</td>
<td>10%</td>
<td>10%</td>
<td>8%</td>
<td>8%</td>
<td>4%</td>
<td>48%</td>
</tr>
<tr>
<td>3</td>
<td>III</td>
<td>Severe Acne</td>
<td>2%</td>
<td>4%</td>
<td>0%</td>
<td>0%</td>
<td>6%</td>
<td>0%</td>
<td>12%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td>10%</td>
<td>20%</td>
<td>24%</td>
<td>22%</td>
<td>14%</td>
<td>10%</td>
<td>100%</td>
</tr>
</tbody>
</table>
Result-wise distribution of the patients

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Result</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Relieved</td>
<td>11</td>
<td>14</td>
<td>25</td>
</tr>
<tr>
<td>2</td>
<td>Partially relieved</td>
<td>5</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td>3</td>
<td>Not relieved</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>4</td>
<td>Drop out</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>Total</td>
<td>20</td>
<td>30</td>
<td>50</td>
</tr>
</tbody>
</table>

Results

After completion of the study, it was found that out of 20 patients of grade I acne, 40% response was found in 17 patients, 3 patients were dropout. Out of 24 patients of grade II acne, total 48% response was found in 18 patients, and 4 patients have no response, 2 patients were dropped out. Out of 6 patients in grade III acne, total 12% response was reported and no response was found in 3 patients. Over all out of 50 patients (Table 5 and 6), over all out of 50 patients, 25 patients were cured in which 11 were male and 14 females, 13 patients were partially relieved in which 5 were males and 8 females. 7 patients including 3 males and 4 females showed no response to the treatment. 5 patients had dropped out (Table 7).

Discussion

Acne vulgaris is commonly called acne. It is a common skin disorder that affects all persons at least once during life time. It usually affects teenagers but substantial numbers of men and woman between the ages of 20-40 are also affected by this disorder (Cunliffe, 1979). Acne is caused by changes in the pilosebaceous units (skin structures consisting of hair follicles and its associated sebaceous gland). The first sign of acne vulgaris commonly occurs at the time of puberty (Rothman, 1993). Acne lesions are commonly referred to as pimples, and spots. It is affecting more than 85% of teenagers and adulthood. Its prevalence is similar in both sexes but the peak age of severity in females is 16-17 years and in male 17-19 years (Lawrence, 2001). Acne may be caused by irritating creams and oils. Pustules on the face can also be caused by tinea infection. The lesions occur mainly over the face, neck, upper chest, back, shoulders etc.

According to Unani System of Medicine, in acne vulgaris disease, the oily
glands over work and there secretion increase in quantity. These secretions remain with the cells and do not come out thus results in inflammation and small white or yellowish pustules develop in the skin. These pustules are pointed at the top and there bases are hard. When these pustules mature and when pressed, it releases some pus (Kabiruddin, 2007).

Since there is no specific treatment available in Allopathic and it is routinely managed by oral as well as local treatment (Lawrence, 2001). Many topical antibiotics useful in the treatment of acne have been associated with serious short and long term adverse effects (Reisner, 1983). Cysts can be incised and drained under local anesthesia (Davidson, 1995). Erythromycin is resistant strains in acne and has also intolerable gastrointestinal side effects in most of the patients (Eady, et al, 1989). In Unani treatment this disease may be treated by damvi imalaha (remove the congestion of blood of the affected part), tanqiya (detoxification) of body. The affected part can be washed with jali adviya (detergent drugs) like aard-e-karsana, post-baizai-e-murg, kharya mitti (calcium carbonate). The application of paste made of anti-inflammatory drugs like kutki safaid, sirka can be used over affected parts. Due to various side effects of the treatment patients of acne vulgaris has been reporting for alternate treatment of their problem at this Institute. So, this study was undertaken to evaluate the clinical efficacy of this formulation in the patient of acne vulgaris of grades I, II and III in the year 2011. The duration of the therapy was 28 days and duration of the study was 180 days.

After completion of the study, it was found that in Grade-I Acne, 6% of patients had moderate response (reduction in local inflammation, burning and itching sensation in comedones ), 14% with good response (reduction in number of comedones, papules and pustules) and 14% with excellent response (reduction in inflammation, burning and itching sensation, reduction in number of comedones, papules and pustules) and 6% cases were dropped out. The total response in Grade-I was 40%. In Grade-II, 8% of patients had mild response (reduction in local inflammation, burning and itching sensation in comedones), 10% moderate response (reduction in number of comedones, papules), 10% good response (reduction in number of comedones, papules and pustules) and 8% excellent response (reduction in inflammation, burning and itching sensation, reduction in number of comedones, papules and pustules), 8% had no response and 4% patients were dropped out. Total response in Grade-II was 48%. Similarly, in Grade-III, 2% of patients had mild response, 4% moderate response and 6% had no response. Total responses in Grade-III was 12 % (Table 5). It was also found that 25 patients were relieved of the symptoms, 13 were partially relieved, 7 were not relieved and 5 were dropped out (Table 7).
Conclusion

It is concluded that the formulation of drugs namely Oral Tab. *Musaffi* (Kit Medicine) and Local Application of *Kaf-e-darya* (cattle fish bone)+*Badam-e-Talkh* (Bitter Almond)+*Arq Gulab* (Rose Water) in Acne Vulgaris can be tried as a safe and alternate therapy.

Acknowledgement

The authors are thankful to Director General, Central Council for Research in Unani Medicine, New Delhi, for encouragement and facilities for the present investigation.

References


Antimicrobial Assay of Alcoholic and Hydroalcoholic Extract of a Unani Formulation by Agar Well Method

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Abstract

The worldwide use of natural products including medicinal plants has become more important in primary health care for various pharmacological effects including antimicrobial activity. Further, it is being appreciated that with increased incidence of resistance to antibiotics, natural products especially from medicinal plants could be interesting alternatives. In this regard a study was conducted to investigate antibacterial activity of a Unani formulation containing (i) Sonth (Zanjbeel) (Zingiber officinale) (ii) Suranjan (Colchicum luteum) and (iii) Elwa (Aloe vera). The alcoholic and hydro-alcoholic extracts dissolved in DMSO (Dimethyl Sulphoxaside) were used to determine antibacterial activity by Agar Well Method. Zone of Inhibition (in mm) was taken as the parameter of measurement against a number of bacterial strains viz. Staphylococcus aureus, Streptococcus mutans, Bacillus cereus, Corynebacterium xerosis, Escherichia coli, Proteus vulgaris, Pseudomonas aeruginosa, Klebsiella pneumoniae. The efficacy of Unani formulation against Bacillus cereus and Pseudomonas aeruginosa, was found even better than Ciprofloxacin and Amikacin, respectively. The study demonstrated that Unani formulation possesses significant antibacterial activity and can be used in infectious diseases caused by a number of Gram +ve and Gram -ve microorganisms.

Keywords: Unani Medicine, Zingiber officinale, Colchicum luteum, Aloe vera, Antimicrobial, Agar Well Method.

Introduction

Nature has been a source of medicinal agents for thousands of years and a good number of modern drugs have been isolated from natural sources, many of these isolations were based on the use of the agents in traditional medicine (Owolabi et al., 2007). Many works have been done which aim at knowing the different phytochemical constituents of medicinal plants possessing antimicrobial activity so as to use them for the treatment of microbial infections as a possible alternative to chemically synthetic drugs, to which many infectious microorganisms have become resistant (Akinpelu and Onakoya, 2006). Unani medicine also offers a number of single and compound preparations that are used successfully in the management of various infectious diseases. Although a number of single drugs have been investigated scientifically but the compound preparations have largely not been studied for antimicrobial and other pharmacological activities.

* Author for correspondence
In this regard a study has been conducted to find antibacterial activity of a pharmacopoeial Unani preparation containing (1) Ginger (*Zingiber officinale* Linn.— Dried Rhizome- 3.5 g) (2) Colchicum (*Colchicum luteum* Baker— Dried Corm- 3.5 g) and (3) Aloe (*Aloe vera* Linn.—Dried Exudate- 7.0 g) (Khan, 1870). This combination has been described to be useful in Wajaul Mafasil (Arthritis) and other joints ailments, and the physicians of Unani medicine are prescribing it for the management of joint diseases since long time. Further, an experimental study has shown significant analgesic, anti-inflammatory and anti-arthritic effect possessed by this compound formulation (Rahman et al., 2010, 2011). But certain other studies conducted on the ingredients of this formulation have demonstrated that they possess significant antibacterial activity against a number of Gram +ve and Gram -ve bacteria suggesting that this combination may also be used as an antibacterial agent.

*Z. officinale* (Zanjabeel) has been reported to inhibit the growth of both Gram-positive and Gram-negative bacteria significantly (Mascolo et al., 1989, Samy, 2005) along with possessing anti-inflammatory, antiemetic, antioxidant, antiulcer, anticarcinogenic properties (Ali et al., 2008; Evans, 2009; Rhode et al., 2007; Minaiyan et al., 2006). *C. luteum* is mainly used as anti-inflammatory and analgesic agent in arthritic conditions (Ghani, 2005; Konda and Rao, 2010) but its crude methanolic extract and subsequent fractions have been shown to possess antimicrobial activity against Lipoygenase and *Bacillus subtilis* (Ahmad et al., 2006). *A. vera* (Sibr or Elwa) is one of the earliest known purgatives used in Unani system of medicine but recently it has been shown to promote wound healing due to the presence of antibacterial, antifungal and antiviral properties (Agarry et al., 2005). Mpala et al. (2010) have also reported that *A. vera* has significant antimicrobial activity. There are several Unani pharmacopoeial preparations having anti-microbial property include these herbs such as Ushban, Sadri, Sharbat-e-Adrak, Qurs-e- Sual, (Anonymous, 2011) Jauhar-e-Kibreet Qawi, (Anonymous, 2007), Kushta Marjan Sada (Anonymous, 2008) etc.

In view of the above, the formulation was hypothesized to be effective in infectious diseases and the present study was designed to evaluate its efficacy against a number of bacterial strains viz. *Staphylococcus aureus*, *Streptococcus mutans*, *Bacillus cereus*, *Corynebacterium xerosis*, *Escherichia coli*, *Proteus vulgaris*, *Pseudomonas aeruginosa* and *Klebsiella pneumoniae*. 
Methodology

Collection of plant material

The raw materials were purchased from the local market of Aligarh. The sample was authenticated in Pharmacognosy section of Department of Ilmul Advia, Faculty of Unani Medicine, AMU, Aligarh by Professor S.H. Afaq and a voucher specimen was deposited in the Dept. of Ilmul Advia.

Preparation of extracts

All the ingredients of test formulation were powdered coarsely in an electric grinder. The powder of each drug was extracted separately in absolute alcohol (alcoholic) and in 50% alcohol (hydro-alcoholic) with the help of Soxhlet’s apparatus for 6 hours. The extracts were filtered and dried by evaporation under reduced pressure in a lyophilizer (Macro scientific works, Delhi) and the lyophilized extracts were dissolved in DMSO (Dimethyl sulfoxide) to the desired concentration (20 mg/ml) before the experimentation.

Microorganisms used in the study

The clinical bacterial strains used in the study were *Staphylococcus aureus*, *Streptococcus mutans*, *Bacillus cereus* and *Corynebacterium xerosis* from Gram positive and *Escherichia coli*, *Klebsiella pneuomoniae*, *Pseudomonas aeruginosa* and *Proteus vulgaris* from Gram negative bacteria. These strains were procured from the Department of Microbiology, Jawaharlal Nehru Medical College & Hospital and Interdisciplinary Biotechnology Unit, Aligarh Muslim University, Aligarh.

*S. mutans* were grown in Brain Heart Infusion (BHI) broth (LQ210 Himedia Labs, Mumbai, India) and the remaining strains were grown in Nutrient broth (M002 Himedia Labs, Mumbai, India) and incubated at 37°C for 24 hours followed by frequent sub-culturing to fresh media. Bacterial cultures were checked to confirm the presence of sufficient number of bacterial cells on nutrient broth and maintained on nutrient agar slant.

Antimicrobial susceptibility testing

Antibacterial tests were performed as per CLSI (Clinical and Laboratory Standard Institute) guidelines. The extracts were tested for their antimicrobial activity using agar well diffusion on solid media. Brain Heart Infusion (BHI) agar (SM 211 Himedia Labs, Mumbai, India) was used for *S. mutans* while Mueller
Hinton agar No.2 (M1084 Himedia Labs, India) and Nutrient agar for preparing plates for rest of the bacterial strains. The solid agar was punched with 6 mm diameter wells. The inoculums were spread on to agar plates using sterile swabs and then filled with 40 ml of the prepared extract. The concentration of the extract employed was 0.02 g/ml /well. All the plates were incubated at 37 °C for 24 hours. Ciprofloxacin disks (SD142 Himedia Labs, Mumbai, India) were used as standard drug for Gram positive, while Amikacin disks (SD035 Himedia Labs, Mumbai, India) were used for Gram negative bacteria. Wells containing respective solvent served as control. Growth inhibition was recorded by measuring the diameter of the inhibitory zones after the period of incubation of 24 hours.

Statistical analysis

The results have been expressed as Mean ± SE. The findings were analyzed to determine significance of difference by one-way ANOVA test followed by pairwise comparison of various groups by Tukey-Karmar test with 95% confidence limit. The analysis was carried out by using the software analyseit.com.

Results

Antibacterial activity against Gram positive bacterial strains

Both the extracts viz. alcoholic and hydroalcoholic of the formulation exhibited varying degree of inhibitory effect against all tested pathogenic strains which have been shown in Table–1. The antibacterial activity exhibited by these extracts was found to be significant and greater than DMSO (p<0.01) against all the tested bacterial strains.

Against S. mutans, the alc. extract showed significantly greater effect than hydroalcoholic extract (p<0.01), while against B. cereus both the extract showed an effect that was significantly better than that induced by the standard drug Ciprofloxacin (p<0.01).

Antibacterial activity against Gram negative bacterial strains

Both the extracts of the formulation demonstrated inhibitory effect against all tested Gram negative pathogenic strains (Table-2). The alcoholic and hydroalcoholic extracts exhibited significantly greater effect than that produced by DMSO (p<0.01) against all pathogenic organism especially against P. aeruginosa and P. vulgaris. Hydroalcoholic extract demonstrated better effect than the alc. extract (p<0.01) against E. coli.
Table 1: Antibacterial activity against Gram positive bacterial strains

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Microbial strains</th>
<th>Zone of inhibition (ZOI) in mm (Mean ± S.E.M)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hydro-alcoholic extract (50% alc.)</td>
</tr>
<tr>
<td>1.</td>
<td>Staphylococcus aureus</td>
<td>7.4±0.21 (ac*)</td>
</tr>
<tr>
<td>2.</td>
<td>Streptococcus mutans</td>
<td>10.4±0.09 (c*)</td>
</tr>
<tr>
<td>3.</td>
<td>Bacillus cereus</td>
<td>27.2±0.22 (cd*)</td>
</tr>
<tr>
<td>4.</td>
<td>Corynebacterium xerosis</td>
<td>13.8±0.17 (c*)</td>
</tr>
</tbody>
</table>

*p<0.01
a = against 50% alc. extract  b = against alc. extract
c = against DMSO (Dimethyl Sulphoxaside)  d = against Ciprofloxacin (Cf)

Table 2: Antibacterial activity against Gram negative bacterial strains

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Microbial strains</th>
<th>Zone of inhibition (ZOI) in mm (Mean ± S.E.M)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hydro-alcoholic extract (50% alc.)</td>
</tr>
<tr>
<td>1.</td>
<td>Escherichia coli</td>
<td>12.4±0.14 (bc*)</td>
</tr>
<tr>
<td>2.</td>
<td>Pseudomonas aeruginosa</td>
<td>26.8±0.15 (c*)</td>
</tr>
<tr>
<td>3.</td>
<td>Proteus vulgaris</td>
<td>13.4±0.14 (c*)</td>
</tr>
<tr>
<td>4.</td>
<td>Klebsiella pneumoniae</td>
<td>12.6±0.17 (c*)</td>
</tr>
</tbody>
</table>

*p<0.01
a = against 50 % alc. extract  b = against alc. extract
c = against DMSO  d = against Amikacin (Ak)

Discussion

In the present study antimicrobial activity of the alcoholic and hydro-alcoholic extracts of Unani formulation was quantitatively assessed using agar well method on the basis of Zone of Inhibition (ZOI) which was expressed in mm.
The study demonstrated that the alcoholic extract possessed more pronounced antimicrobial activity as compared to hydro-alcoholic extract. The results were found comparable with that of the standard drugs and the effect induced by the extracts against *B. cereus* (Gram positive) was even better than Ciprofloxacin and that against *Pseudomonas aeruginosa* it was found better than Amikacin. They also possessed moderate activity against certain Gram positive bacteria such as *C. xerosis* and *S. mutans* and few Gram negative bacteria such as *E. coli*, *P. vulgaris* and *K. pneumoniae*. The results of the present investigation suggested that the formulation containing *C. luteum*, *Z. officinale* and *A. vera* has a salient antimicrobial effect against *B. cereus* which is resistant to a number of allopathic drugs. As plant drugs which constitute the major chunk of Unani therapeutics are considered important because they are physiologically innocuous and safe and also because they may be useful against resistant microorganisms.

In previous studies the constituents of this formulation were studied alone or in combination with other natural products for their antimicrobial activity. The crude extract and subsequent fractions of *C. luteum* showed mild to moderate activity in an antibacterial bioassay with maximum antibacterial activity of 58% against *Bacillus subtilis* (Bashir *et al.*, 2006). The acetone extracts of *Aloe vera* leaves showed antibacterial activities against the selected human clinical pathogens *Staphylococcus aureus*, *Streptococcus pyogens*, *Pseudomonas aeruginosa* and *Escherichia coli* (Arunkumar and Muthuselvam, 2009). A number of studies have confirmed that the alcoholic extract of the *Zingiber officinale* and its flavonoids have antibacterial activities. Study conducted by Demin and Yingying (2010) revealed that the ethanolic extracts of ginger and crude flavonoids exhibited antimicrobial activity against *Escherichia coli*, *Staphylococcus aureus*, *Shigella flexneri*, *Proteus vulgaris* and *Pseudomonas aeruginosa*.

Our findings thus conformed that the ingredients of the compound preparation which are reported to possess antibacterial activity also retain the effect in combination form and even demonstrated better response than the allopathic antibacterial agents in respect of certain strains. This is probably the earliest report on this pharmacopoeial drug demonstrating antibacterial activity. This combination now can also be used as an antimicrobial agent against diverse types of microorganism. Further, the present study has revealed the importance of natural products to control antibiotic resistant bacteria, which are a major threat to human health.
Acknowledgement

The authors are thankful to the Dept. of Ilmul Advia, Faculty of Unani Medicine, Aligarh Muslim University, Aligarh, for providing support to carry out this work.

References


Evans, W.C., 2009. Trease and Evan’s Pharmacognosy, Edn.15. (Elsevier, a Division of Reed Elsevier India Private Limited), pp. 52,277-280,454,481.


Abstract

In the present study the combined effect of two well documented and well known herbal drugs Azadirachta indica Juss. & Trigonella foenum-graecum Linn. have been studied in Type 2 Diabetes mellitus patients. Medicinal plants have been mentioned by various authors for their hypoglycaemic activity. Therefore, we choose two medicinal plants to check the efficacy of these drugs in diabetes mellitus. The drug was given in powder form in the dose of 6gm twice a day for 3months. The results were analysed statistically. There was statistically significant reduction in the fasting and post prandial blood glucose (t=8.3, p < 0.001) (t=8.6, p<0.001) respectively. The significance on glycated haemoglobin was (t=4.4, P<0.001). The significance on total cholesterol was (t= 5.1, p< 0.001). The significance on effect of drug on glycosuria was (t=6.1, p<0.001).

Keywords: Unani Medicine, Diabetes, Antihyperglycaemic effect.

Introduction

The word diabetes is derived from “Ziabitus” which is a Unani term meaning to run through, while Mellitus is a latin word which means sweet like honey (Ahuja, 1983). Galen believed that diabetes is a disease of kidney; he stated that the sole cause of diabetes is altered hot temperament (Sue-Mizaj har) of Kidney. He stated that kidney shows a weakness similar to that of intestine as in case of “lecientria”, and also stated that along with altered hot temperament, its power of absorption (Quwwat-e-jaziba) is increased (Kirmani, 1935) due to which fluid is diffused more towards kidneys. In addition to this the power of retention (Quwwat-e-Masika) of kidneys are weakened and is unable to hold the urine which is excreted out in large quantity and a cycle of thirst and micturition is established (Jafri and Siddiqui, 1995). Review of literature reveals that diabetes was described on the basis of clinical triad of polyuria, polydipsia, and polyphagia, but Avicenna alone has been credited with two additional discoveries, firstly: physical, mental and sexual weakness and secondly: occurrence of carbuncles and gangrene as a complication of the disease (Schadewaldt, 1989). In the 19th century with the advancement of techniques and study of microbiology and advancements in the field of Genetics, type 2 diabetes mellitus has been defined as a “heterogeneous group of disorders characterized by variable degree of insulin resistance, impaired insulin secretion, and increased glucose production”. Diabetes
mellitus usually remains asymptomatic for a considerable period of time. Despite insulin resistance glucose level remains normal because beta cells compensate by increasing insulin output. As the disease progresses, insulin resistance worsens and post prandial hyperglycaemia sets in. Further, there is decline in insulin secretion with persistent insulin resistance resulting in fasting hyperglycaemia. Ultimately beta cells failure may ensue due to glucotoxicity (Braunwald, 2001) and the disease is well established. According to data released by International Diabetes Federation (IDF), the number of people around the world suffering from diabetes has gone up in the last two decades, from 30 million to 230 million and the greatest increase is in the developing countries of Africa, Asia and South America (Santora, 2006). As predicted by the WHO, the prevalence of diabetes in adults worldwide has risen from 135 million in 1995 to 300 million by the year 2025. Epidemiological data in India shows the same upward trend. Presently there are 32 million diabetics. It may increase to 80 million in 2030 (Rao et al., 2005). India has thus become the “Diabetic Capital” of the world. Data presented by the endocrinology unit of JNMC, AMU, Aligarh at the Continuing Medical Education in 2006 showed that in Aligarh 15-20% people are affected by diabetes mellitus (Alam, 2006). Some 90% of diabetic individuals have type 2 diabetes mellitus. For the Indian population factors which act as pre-disposing factors for this steep rise include genetic predisposition, urbanization, ethnicity, insulin resistance and central obesity and over and above physical inactivity.

Aims and objectives of the study

1. Although immense advancements in oral as well as in the brand of Insulin in Allopathic medicine has taken place in the recent past which revolutionized the treatment of diabetes mellitus and near normal glycaemic control can be achieved, but we the unani physician cannot use these drugs to the law of land. This prompted us to search an alternative drug in unani medicine.

2. Allopathic drugs have serious side effects if not given by a well versed allopathic physician which may either cause hyper or hypoglycaemia

3. *Trigonella foenum-graecum* Linn. has antilipaemic effect so, it is beneficial in controlling the blood sugar in mild type2 diabetes mellitus and also has advantage of antilipaemia because diabetes mellitus and hyperlipaemia usually go hand in hand.
Methodology

This study was carried out on 30 patients of Type2 Diabetes mellitus who attended the Ajmal Khan Tibbiya College, Hospital. Diagnosis was confirmed by WHO criteria. Patients with known Type1 diabetes mellitus, thyrotoxicosis, chronic renal failure, peptic ulcer, and pregnant ladies were excluded from the study. During the study the following approach was carried out in all the cases, that is detailed clinical history, physical examination, and bio-chemical investigations.

After the informed written consent, the patients were advised to take 6 g. drug in powder form twice a day in the morning and in the evening before meals for 3 months. The drugs were obtained from Dawakhana Tibbiya College, Aligarh Muslim University, Aligarh. The drugs used are Azadirachta indica Juss. & Trigonella foenum-graecum Linn. in equal amounts.

<table>
<thead>
<tr>
<th>Common name</th>
<th>Scientific name</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Neem</td>
<td>Azadirachta indica Juss., Juss.</td>
<td>1 Part</td>
</tr>
<tr>
<td>2. Methi</td>
<td>Trigonella foenum-graecum, Linn</td>
<td>1 Part</td>
</tr>
</tbody>
</table>


The follow up of patients was performed every fortnightly. Blood sugar (fasting, post prandial) and urine (routine, microscopic) examinations were performed monthly while lipid profile, HbA1C, blood urea, serum creatinine and liver function test were performed on 0 and 90th day. All the observations and results obtained were statistically evaluated, applying paired t-test, and Z-test.

Observations and Results

In the present study 30 patients of Type 2 Diabetes mellitus were taken. As shown in table 1 that maximum no. of patients belonged to 30-50 yrs of age (66.67%), and most of patients belonged to phlegmatic temperament (66.7%). Thirteen (43.3%) of patients had BMI $\geq$ 23, and (93.3%) of patients lived sedentary life style.

Effect of drug on symptom and signs

Out of thirty patients five had genital candidiasis which after ninety days of treatment showed an improvement in four patients, that is an improvement of 80% was observed. Another salient presentation was polyphagia which was present in fourteen patients before starting treatment and at the termination of therapy was present only in three patients, that is, there was an overall improvement of 78.5%. Another important symptom was generalised weakness which was seen in twenty seven patients. During the course of the treatment there was gradual improvement and at the end only in nine patients this symptom persist reflecting 66.65% improvement. Although, polydipsia is usually the most common feature of diabetes mellitus but in our study it was present only in seventeen patients which with the treatment over ninety days remain present in six patients, showing an overall improvement by 64.7%. Polyuria and nocturia was the next most common presenting feature which reduces from twenty four patients to nine patients showing an overall improvement of 62.5%. Loss in weight was found in eleven patients before the commencement of therapy. However, at the end of the study it was present only in six patients, that is, an overall improvement of 54.4% was observed. The least common symptom was paresthesia which was present only in six patients and it was only symptom which shows no improvement at all at the termination of trial (Table2).

Table 3 shows effect of drug on glycosuria: As it is evident from table all the patients had glycosuria which persisted only in twelve patients, that is to say in eighteen patients it was absent at the termination of therapy ($t=6.1$, $p<0.001$). The most objective parameter to assess the glycaemic control was estimation of Fasting and Post Prandial blood sugar. At the start of the therapy mean
fasting blood sugar was 195.6mg% which was reduced to 138.37mg% showing a mean differential fall by 57.23mg%. As regard post prandial blood sugar is concerned it was 282.27mg% at the beginning of the therapy which showed a steady fall and became 188.6mg%, showing a difference of 93.67mg% (Table 4) on applying t test it was (t=8.3, p<0.001, t=8.6, p<0.001) for fasting and post prandial blood sugar respectively. Table 5 shows effect of drugs on glycated haemoglobin, the mean glycated haemoglobin before starting the treatment was 8.35mg% which was reduced to 7.31mg% at the end of trial, on applying t test for significance it was (t=4.4, P<0.001). Table 6 shows effect on total cholesterol, before starting the treatment the mean total cholesterol was 195.9mg%, which showed a marginal fall and on the 90th day its level was 183.4mg% on applying ‘t’ test it was (t=5.1, p<0.001). We also tried to observe the effect of the our drug formulation on the normal euglycaemic persons to see whether it causes hypoglycaemia or not during the study it was observed that there was no such effect on the fasting blood sugar (Table 7).

**Table 1:** Base line demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>(n = 30)</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Male: Female</td>
<td>9:21</td>
<td>30:70</td>
</tr>
<tr>
<td>b. Age in yrs:</td>
<td>8</td>
<td>26.6</td>
</tr>
<tr>
<td>30-40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-50</td>
<td>11</td>
<td>36.6</td>
</tr>
<tr>
<td>50-60</td>
<td>11</td>
<td>36.6</td>
</tr>
<tr>
<td>c. Occupation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>Business</td>
<td>5</td>
<td>16.6</td>
</tr>
<tr>
<td>House Wife</td>
<td>13</td>
<td>43.4</td>
</tr>
<tr>
<td>Others</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>d. Food Habits:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vegetarian</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>Non Veg.</td>
<td>20</td>
<td>66.7</td>
</tr>
<tr>
<td>e. Temperament:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sanguine</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Phlegmatic</td>
<td>20</td>
<td>66.7</td>
</tr>
<tr>
<td>Biliary</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>Melancholic</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>f. Risk Factors:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ve Family History</td>
<td>11</td>
<td>36.6</td>
</tr>
<tr>
<td>Stress +ve</td>
<td>19</td>
<td>63.3</td>
</tr>
<tr>
<td>No exercise</td>
<td>28</td>
<td>93.3</td>
</tr>
<tr>
<td>BMI ≥ 23Kg/m²</td>
<td>13</td>
<td>43.3</td>
</tr>
</tbody>
</table>
Table 2: Showing effect on classical symptoms

(n = 30)

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>0 Day</th>
<th>15 Days</th>
<th>30 Days</th>
<th>45 Days</th>
<th>60 Days</th>
<th>75 Days</th>
<th>90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Polydipsia</td>
<td>17</td>
<td>12</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>No. of patients improved</td>
<td>-</td>
<td>5</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Improvement %</td>
<td>-</td>
<td>29.4</td>
<td>76.4</td>
<td>76.4</td>
<td>64.7</td>
<td>64.7</td>
<td></td>
</tr>
<tr>
<td>b. Polyphagia</td>
<td>14</td>
<td>13</td>
<td>9</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>No. of patients improved</td>
<td>-</td>
<td>1</td>
<td>5</td>
<td>10</td>
<td>12</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Improvement %</td>
<td>-</td>
<td>7.1</td>
<td>35.77</td>
<td>71.4</td>
<td>85.7</td>
<td>78.5</td>
<td>78.5</td>
</tr>
<tr>
<td>c. Polyuria with or without Nocturia</td>
<td>24</td>
<td>21</td>
<td>13</td>
<td>15</td>
<td>11</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>No. of patients improved</td>
<td>-</td>
<td>3</td>
<td>11</td>
<td>9</td>
<td>13</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Improvement %</td>
<td>-</td>
<td>12.5</td>
<td>45.6</td>
<td>37.5</td>
<td>54.1</td>
<td>62.5</td>
<td>62.5</td>
</tr>
<tr>
<td>d. Weight Loss</td>
<td>11</td>
<td>11</td>
<td>10</td>
<td>10</td>
<td>8</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>No. of patients improved</td>
<td>-</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Improvement %</td>
<td>-</td>
<td>0</td>
<td>9.09</td>
<td>9.09</td>
<td>27.2</td>
<td>45.45</td>
<td>54.54</td>
</tr>
<tr>
<td>e. Weakness</td>
<td>27</td>
<td>27</td>
<td>26</td>
<td>20</td>
<td>11</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>No. of patients improved</td>
<td>-</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>16</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Improvement %</td>
<td>-</td>
<td>0</td>
<td>3.7</td>
<td>25.9</td>
<td>59.2</td>
<td>66.6</td>
<td>66.6</td>
</tr>
<tr>
<td>f. Genital candidiasis</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>No. of patients improved</td>
<td>-</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Improvement %</td>
<td>-</td>
<td>0</td>
<td>40</td>
<td>60</td>
<td>60</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>g. Erectile dysfunction</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>No. of patients improved</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Improvement %</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>25</td>
<td>25</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>h. Paraesthesia</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>No. of patients improved</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Improvement %</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
### Table 3: Showing effect on glycosuria

<table>
<thead>
<tr>
<th></th>
<th>0 Days</th>
<th>30 Days</th>
<th>60 Days</th>
<th>90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycosuria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of affected</td>
<td>35</td>
<td>27</td>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>Improvement %</td>
<td></td>
<td>29</td>
<td>48</td>
<td>66</td>
</tr>
</tbody>
</table>

### Table 4: Showing effect of formulation on blood sugar.

<table>
<thead>
<tr>
<th></th>
<th>0 days</th>
<th>30 days</th>
<th>60 days</th>
<th>90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Blood Sugar Fasting</td>
<td>195.6±40.18</td>
<td>176.23±42.64</td>
<td>149.96±27.34</td>
<td>138.37±28.40</td>
</tr>
<tr>
<td>Mean Blood Sugar Post Prandial</td>
<td>282.27±57.18</td>
<td>245.0±57.84</td>
<td>204.1±43.94</td>
<td>188.6±53.71</td>
</tr>
<tr>
<td>Mean difference Fasting</td>
<td></td>
<td>19.37±26.99</td>
<td>45.63±31.44</td>
<td>57.23±37.83</td>
</tr>
<tr>
<td>Mean difference Post Prandial</td>
<td></td>
<td>37.27±44.54</td>
<td>78.17±43.97</td>
<td>93.67±59.56</td>
</tr>
</tbody>
</table>

### Table 5: Showing effect on glycated haemoglobin

<table>
<thead>
<tr>
<th></th>
<th>0 Days</th>
<th>90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1C Average</td>
<td>8.35±0.82</td>
<td>7.31±1.36</td>
</tr>
</tbody>
</table>

### Table 6: Showing effect on total cholesterol.

<table>
<thead>
<tr>
<th></th>
<th>0 Days</th>
<th>90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>T. Cholesterol</td>
<td>195.9±32.61</td>
<td>183.4±34.40</td>
</tr>
</tbody>
</table>

### Table 7: Showing effect on normal individual

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Mean Blood Sugar Fasting before giving drugs</td>
<td>81.2 mg/dl</td>
</tr>
<tr>
<td>Mean Blood Sugar Fasting after giving drug</td>
<td>81.6 mg/dl</td>
</tr>
</tbody>
</table>
Discussion

In the present study thirty patients suffering from type 2 diabetes mellitus were selected randomly from the moalejat and ilaj-bit-tadbeer department of Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh. After the informed written consent the drugs *Azadirachta indica* Juss. & *Trigonella foenum-graecum* Linn. was administered in the dosage of 6 g. per orally in the powder form, details of which have been given earlier.

As depicted in table 1, maximum no. of patients i.e. (22) were found between 40-60 yrs of age. As it is a well known fact that practically type 2 diabetes mellitus which was previously known as maturity onset diabetes is found mainly in the middle and old age. Therefore, our findings are consistent with the classical text. Regarding the occupation housewives numbering (13) were the maximum sufferers the possible reason may firstly be lack of physical exercise and mental stress born by them in the present day of nuclear family. On Temperamental analysis maximum no. of patients i.e. (20) belonged to the phelegmatic temperament, this may be because they are usually obese and relatively physically inactive. When the main risk factors were considered here was a positive family history of diabetes mellitus in eleven (11) patients followed by stress in nineteen (19), and no physical exercise in twenty eight (28) patients. As it is a well known fact that these factors pay a pivotal role in precipitating the pre diabetics into a full blown diabetes mellitus syndrome of type 2. Basal metabolic index (BMI) was 23 or more than 23 in thirteen (13) patients. However, according to Indian standards more than (23) is taken as abnormal. So, it also might be a causative factor in precipitating diabetes mellitus.

Decrease in polydipsia, polyphagia was found in 64.7% and 78.5% cases respectively which may be due to the hypoglycaemic effect of the alkaloids present in the *Azadirachta indica* Juss. possessing the insulin like activity (Anonymous, 1978). Obviously, the polyuria also decreased due to the decreased osmotic pressure of filtrate in renal tubule absorbing water from interstitial spaces of the kidneys. This seems to be the most convincing reason for decrease in polyuria (Table 2 a,b,c and, d).

With the importance in the glycaemic control decrease rate of weight of loss was found in eleven (11) patients where as decrease in weakness was present in one third of the patients. These effects may again be due to the fall in the blood sugar as per the passage of time i.e. 90 days (Table 2 d and e).
There were four (4) patients in whom there was an improvement in genital candidiasis as there was a decrease in blood sugar level as mentioned under (Table 2 a, b, and c). Here it is worth mentioning that no local or systemic drug administration was given for fungal infection. So, it is concluded that it was hyperglycaemia which predispose the fungal infection (Table 2 f). There was no improvement in paresthesia which may be due to the fact that either our drug combination or a relatively short duration of therapy could not affect the microangiopathy causing the paresthesia (Table 2 h). There was an improvement in the erectile dysfunction in two (2) out of four (4) patients which remains to be explained. Probably our drugs either had vasodilator effect or anti-atherosclerotic effect. However, it requires other thorough investigations like pudendal artery angiography and anti-atherosclerotic activity.

So far the effect of drugs on fasting, post prandial and glycated haemoglobin is concerned there was a steady decline in the blood sugar level there values are depicted in the table 4 and 5, as the glycated haemoglobin reflects the glycaemic control of preceding three months, hence, it is regarded as the most sensitive parameter in diagnosing and degree of control in the blood sugar. As depicted in table 5 average glycated haemoglobin before starting the treatment was 8.35mg% which decreased to 7.31mg%. Many writers describe the hypoglycaemic effect of Azadirachta indica Juss. & Trigonella foenum-graecum Linn. (Jarald et al., 2008; Rao et al., 2010). The possible mechanism involved in the decline of fasting, post prandial and glycated haemoglobin may be due to the insulin activity present in the Neem and 4-hydroxyisoleucine amino acid present in Methi (Basch et al., 2003) which increase the secretion of insulin from beta cells due to hyperglycaemia. Although, glycated haemoglobin did not reach within its normal limit and was found to be slightly higher i.e. 7.31. The desired effect may probably be achieved either by readjusting the dose of the given drugs or prolongation in the duration of therapy.

The drug was also screen for its anti lipemic effect and for this purpose total serum cholesterol was estimated before and at the termination of the trial, the mean cholesterol was 195.9mg% which was reduced to 183.4mg%. This marginal fall in cholesterol level was may be due to the fecal excretion of bile acids due to presence of Trigonella foenum-graecum Linn.

**Conclusion**

From the above study it is concluded that our drug combination is by and large effective in decreasing the blood sugar level in type2 diabetes mellitus patients without improving the microvascular complications. Hence, it is suggested
that the quantity of the drug should be reviewed and if needed dose may be readjusted. Long term and collaborative study with interdisciplinary approach is needed, and if after that the drugs are found safe and effective then it must be incorporated in main stream antidiabetic drugs, because these drugs are safe, cost effective, and natural.

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Abstract

An ethnopharmacological survey conducted during November, 2001 in the West Tarai Forest Division, Ramnagar, Nainital, has yielded first-hand information on folk medicinal claims prevalent amongst the tribal and other rural people. In the course of this survey, a number of wild plants were found to be commonly used in the area by traditional healers as folk drugs. In this report ethnomedicinal uses of 55 plant species belonging to 38 families of angiosperms are described. For each species are given the correct botanical and prevalent local names, part used, claimed medicinal use(s) and mode of administration. An scrutiny of data obtained in this study with the available ethnobotanical literature has revealed many new and uncommon traditional phytotherapeutic uses, unreported so far.

Keywords: Ethnopharmacological survey, Traditional Medicine, Ramnagar, Nainital, Kumaon.

Introduction

The Kumaon Himalaya of Uttarakhand has an ancient heritage of traditional herbal medicine. In Nainital district of this region, the use of plants in traditional medicine system of many cultures has been documented (Agnihotri et al., 2003; Ali et al., 2008; Anonymous, 2008; Bisht et al., 1999; Gupta, 1960; Pant and Pandey, 1998; Singh, 1993; Singh and Maheshwari, 1990, 1993, 1994). But, no such report is available on West Tarai Forest Division Ramnagar, Nainital. The only account about this area is that of Singh et al. (1987) on ethnobotany of Boxa tribe of Bajpur block, a small area in this division. Hence, the present report communicates information on most commonly used herbal preparations collected during an extensive ethnopharmacological survey carried out a few years ago in this forest tract.

The area of study forms one of the important forest divisions of Kumaon’s Tarai. It covers a part of Nainital and Udham Singh Nagar districts and lying between 28° 52’ - 29° 27’ 15” N latitude and 78° 46’ 15” - 79° 33” E longitude along the base of outer hills of Siwalik ranges. There are seven forest ranges viz. North Jaspur, South Jaspur, Kashiupur, Ampokhra, Ramnagar, Bannakhera and Belparao (Fig. 1). The division has dense tracts of intact natural forests which are mainly of northern tropical dry deciduous type. These forests are inhabited by two tribes the ‘Vangujars’ and the ‘Boxas’. The age-old practice of traditional phytotherapy in the treatment of different disease and conditions of humans and cattle is still prevalent amongst these people.

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Methodology

An ethnopharmacological survey of the study area was undertaken during November, 2001. During the course of this field study, a number of tribal settlements and villages were visited. Data on folk medicinal uses of local plants were gathered through direct field interviews with reliable informants who were traditional healers and other knowledgeable village elders. The information collected includes common name of the plant or the crude drug, medicinal use(s), part used, other ingredients added (if any), method of drug preparation, mode of administration, dosage and duration of treatment, etc. Plant specimens were collected and later authenticated. All the voucher herbarium specimens were prepared and deposited in the Herbarium of the Survey of Medicinal Plants Unit, Regional Research Institute of Unani Medicine, Aligarh (U.P.), India.

Fig. 1: Map of West Tarai Forest Division, Ramnagar, Nainital, showing the areas surveyed for present study

Results

This study reports first-hand information on contemporary folk medicinal uses of 55 plants belonging to 38 families of angiosperms from the investigated
area. In the following listing all the plants are arranged in alphabetical order by their scientific names. For each species are given correct botanical name, family, prevalent local name, locality from which a particular use was recorded, voucher specimen number followed by folk medicinal use(s) and mode of administration. As far as possible, the probable dosage and duration of these crude drugs are also given.

**Achyranthes aspera** L. (Amaranthaceae), ‘Chorchitta’, Jaspur (SMPUA6525). Aerial parts are crushed and boiled in water. The liquid is strained and given for burning micturition.

**Acorus calamus** L. (Araceae), ‘Bach’, Bannakhera (SMPUA6769). Dried pieces of rhizome are ground to make a fine powder. About 5 g of this powder are given with honey for hoarseness of voice.

**Aegle marmelos** (L.) Corr. (Rutaceae), ‘Belpatri’, Jaspur (SMPUA6518). Dried fruit pulp is roasted on open fire, cooled and ground to make a powder. This is given with water for diarrhoea.

**Albizzia odoratissima** (L.f.) Benth. (Mimosaceae), ‘Kala Siras’, Chhoi (SMPUA6633). Bark decoction is drunk as blood purifier.

**Anogeissus latifolia** (Roxb. ex DC.) Wallich ex Guill. & Perr. (Combretaceae), ‘Bankli’, Jaspur (SMPUA6651). Plant yields gum-resin which is collected, dried and ground to make a powder. About 5 g of this powder are given twice daily for one month to treat backaches.

**Artemisia nilagirica** (C.B. Clarke) Pamp. (Asteraceae), ‘Patji’, Ampokhra (SMPUA6681). Leaf powder is boiled in water till it become semisolid. Pills of gram size are prepared and two pills are given two times a day for constipation.

**Asparagus racemosus** Willd. (Liliaceae), ‘Satmuli’, Jaspur (SMPUA6598). In cases of spermatorrhoea, powdered root (10 g) is given with water twice daily till the cure is obtained.

**Bauhinia variegata** L. (Caesalpiniaceae), ‘Kachnal’, Ampokhra (SMPUA6665). Decoction of stem bark is given as blood purifier in scabies.

**Callicarpa macrophylla** Vahl (Verbenaceae), ‘Dayya’, Chhoi (SMPUA6534). Ripe fruits are chewed for mouth blisters.

‘communis’ and ‘tidhara’ (*Ehphorbia royleana* Boiss.) are crushed and boiled in mustard oil. After cooling, it is lightly massaged to relieve muscular pain.

*Careya arborea* Roxb. (Lecythidaceae), ‘Kumbha’, Chhoi (*SMPUA6582*). For treating bone fracture in cases of cattle, paste of stem bark of ‘kumbha’ and ‘meda’ (*Litsea glutinosa*) is plastered around the limb after setting the bones right.

*Casearia tomentosa* Roxb. (Flacourtiacea), ‘Chilla’, Ampokhra (*SMPUA6707*). Seed paste is applied on scalp to kill lice.

*Celosia argentea* L. (Amaranthaceae), ‘Shirvali’, Tirath (*SMPUA6671*). Seeds mixed with ‘taalmakhana’ (seeds of *Hygrophila auriculata* (Schum.) Heine) are ground to make a powder. About 10g of this powder are given three times a day for 21 days to treat spermatorrhoea.

*Chlorophytum tuberosa* (Roxb.) Baker (Liliaceae), ‘Safed Musli’, Jaspur (*SMPUA6606*). Root powder (10g) is given twice daily for one month to treat leucorrhoea.

*Cissampelos pariera* L. (Menispermaceae), ‘Jaljamni’, Bannakhera (*SMPUA6537*). Leaf juice coagulates on being allowed to stand in a cup for about 4-5 hours. It is given two times a day for 7 days to treat spermatorrhoea.

*Cleome viscosa* L. (Capparaceae), ‘Jakhiya’, Chhoi (*SMPUA6624*). Leaf juice is lightly massaged on limbs of children to strengthen the bones.

*Clerodendrum cordatum* D. Don (Verbenaceae), ‘Bhant’, Chhoi (*SMPA6787*). Aqueous decoction is drunk for common fever.

*Colebrookea oppositifolia* J. E. Smith (Lamiaceae), ‘Bhekmalu’, Chhoi (*SMPUA6801*). For treatment of pterygium in cattle, leaf juice is instilled in affected eye.

*Cordia dichotoma* Forst. (Boraginaceae), ‘Labhera’, Phika (*SMPUA6577*). Ripe fruits are given to eat in spermatorrhoea.

*Crateva adansonii* DC. (Capparaceae), ‘Barna’, Phanto (*SMPUA6587*). Fruits of ‘barna’, root of ‘satawar’ (*Asparagus racemosus*), seeds of ‘konch’ (*Mucuna pruriens* (L.) DC.) and ‘misri’ (crystalline sugar) in equal quantities are ground to make a powder; 10g of this preparation are given with milk once daily for sexual weakness.

*Crotalaria prostrata* Rottl. (Fabaceae), ‘Gilbichhua’, Jaspur (*SMPUA6711*). Decoction of aerial parts is drunk in urticaria.
Curculigo orchioides Gaertn. (Hypoxidaceae), ‘Kali Musli’, Jaspur (SMPUA6542). Root powder is used as aphrodisiac and also given for leucorrhoea.


Debregeasia longifolia (Burm.f.) Wedd. (Urticaceae), ‘Tushiyari’, Chhoi (SMPUA6797). Stem twigs are used as splints.

Euphorbia nivula Buch.-Ham. (Euphorbiaceae), ‘Thur’, Jaspur (SMPUA6533). Paste prepared by pounding the fresh phylloclade is applied on boil to speed up suppuration and healing.

Ficus semicordata Buch.-Ham. ex Roxb. (Moraceae), ‘Jarphal’, Jaspur (SMPUA6720). Latex is given with milk for spermatorrhoea.

Flemingia bracteata (Roxb.) Wight (Fabaceae), ‘Salparni’, Jaspur (SMPUA6600). About 50g aerial parts are boiled in one cup of water, strained and cooled. It is drunk for catarrh.

Helicteres isora L. (Sterculiaceae), ‘Marorphali’, Phanto (SMPUA6546). Fruits are crushed; boiled in water and strained the resulting decoction is given for catarrh.

Holarrhena pubescens (Buch.-Ham.) Wall. ex G. Don (Apocynaceae), ‘Kura’, Jaspur(SMPUA6541). Seed decoction is drunk for malaria fever.

Lannea coromandelica (Houtt.) Merr. (Anacardiaceae), ‘Jhingan’, Chhoi (SMPUA6585). Fresh leaves mixed with pieces of stem bark are ground and the paste is applied locally for healing wounds.

Litsea glutinosa (Lour.) Robins. (Lauraceae), ‘Meda’, Bannakhera (SMPUA6528). About 250g of the stem bark are boiled in 2l of milk till it become dried and mixed with 50g crystalline sugar. This preparation is given in the dose of 25g twice daily for 30-40 days for prolapsed uterus.

Moringa oleifera Lam. (Moringaceae), ‘Senjna’, Ampokhra (SMPUA6754). Lukewarm leaf decoction is used to take bath in joint pain.

Nyctanthes arbor-tristis L. (Oleaceae), ‘Harsinghar’, Chhoi (SMPUA6781). Leaf decoction is given orally to relieve sciatica.

Oroxylum indicum L. (Bignoniaceae), ‘Tarlu’, Jaspur (SMPUA6572). Seed paste is applied locally for abdominal swelling.
Ougeinia oojeinensis (Roxb.) Hochr. (Fabaceae), ‘Sanan’, Phanto (SMPUA6714). Dried gum is roasted and powdered. About 3g of this powder are given with water twice a day for spermatorhoea.

Piper longum L. (Piperaceae), ‘Piplamul’, Ampokhra (SMPUA6656). Fresh root is chewed to treat cough as well as to quench thirst.

Pterocarpus marsupium Roxb. (Fabaceae), ‘Bijasal’, Phanto (SMPUA6621). The gum is obtained from the tree. It is mixed in water and taken once daily in diabetes.

Pueraria tuberosa (Roxb. ex Willd.) DC. (Fabaceae), ‘Bilarikand’, Chunakhan (SMPUA6767). Root paste is applied on boil for speed up suppuration and healing.


Ricinus communis L. (Euphorbiaceae), ‘Andi’, Timuria (SMPUA6722). Seed pulp is given orally to check conception.

Semecarpus anacardium L.f. (Anacardiaceae), ‘Bhilwa’, Jaspur (SMPUA6591). Seed powder (5g) mixed with crystalline sugar is given for sexual weakness.

Senna occidentalis (L.) Link (Caesalpiniaceae), ‘Kasondi’, Patrampur (SMPUA6555). Leaves mixed with seeds of ‘babchi’ (Psoralea corylifolia L.) are ground to make a paste and applied on vitiligo.

Shorea robusta Roxb. ex Gaertn.f. (Dipterocarpaceae), ‘Sal’, Jaspur (SMPUA6705). Equal quantities of the gum-resin of ‘sal’ and ‘babool’ (Acacia nilotica subsp. indica Benth.) Brenan) are ground to make a fine powder and mixed with honey. Pills of gram size are prepared; two pills are given two times a day to treat gastric ulcer.

Sida cordifolia L. (Malvaceae), ‘Khurenti’, Ampokhra (SMPUA6669). Leaves are boiled with mustard oil and mashed. After cooling, it is applied on cut and wounds for healing.

Spermatidyon suaveolens Roxb. (Rubiaceae), ‘Padara’, Ramnagar (SMPUA6743). Leaf paste is applied on wounds.

Sterculia villosa Roxb. (Sterculiaceae), ‘Udal’, Jaspur (SMPUA6746). Gum of the tree is given in the dose of 5g twice daily for three consecutive days in burning micturition.

Syzygium cumini (L.) Skeels (Myrtaceae), ‘Jaman’, Patrampur (SMPUA6732). Fresh leaf juice is gargled with water against mouth blisters.

Terminalia bellirica (Gaertn.) Roxb. (Combretaceae), ‘Bahera’, Phika (SMPUA6571). Poultice of stem bark is used for joint pain.

Toona ciliata M. Roem. (Meliaceae), ‘Tun’, Chhoi (SMPUA6579). Aqueous decoction of inner stem bark is given orally for menorrhagia.

Tribulus terrestris L. (Zygophyllaceae), ‘Gokhru’, Patrampur (SMPUA6730). Infusion of the fruits is drunk for burning micturition.

Urtica dioica L. (Urticaceae), ‘Sisorn’, Ramnagar (SMPUA6737). Cooked leaves are mashed and made into pills of about 3g each with honey; two pills are given twice daily for 30-45 days to treat joint pain.

Vetiveria zizanioides (L.) Nash (Poaceae), ‘Khas’, Jaspur (SMPUA6590). Sherbet of the root is used as cooling agent.

Woodfordia fruticosa (L.) Kurz. (Lythraceae), ‘Dhawa’, Jaspur (SMPUA6566). Dried flowers are ground with gum-resin of ‘semal’ (Bombax ceiba L.); one spoonful of this preparation is given twice daily for leucorrhoea.

Wrightia arborea (Dennst.) Mabb. (Apocynaceae), ‘Dudhi’, Ramnagar (SMPUA6566). About 10g of the seed powder are given with water twice daily in spermatorrhoea.

Discussion

This part of the Kumaon region is blessed with congenial climate and very fertile soil. There are several population clusters of tribal spread across the division. The inhabitants of the area have much passion for medicinal plants and use them to meet their various health needs. Majority of the medicinal plants most frequently used by the natives are wild species. Although, a few are weeds e.g. Achyranthes aspera, Calotropis procera, Celosia argentea, Cleome viscosa, Ricinus communis, Senna occidentalis, Sida cordifolia, Sphaeranthus indicus, Tribulus terrestris which found in waste grounds near villages or cultivated fields. Many of the medicinal uses reported herein are best known to rural communities throughout the area; nevertheless these
are new and reported for the first time from the area investigated. However, knowledge on some medicinal plants is endemic to certain localities or villages. The data were collected from native informants who usually spend their much time working in the forest. These traditional uses were analyzed and compared with the available literature on medicinal and economic plants of the country (Anonymous, 1948-1976, 2001; Chopra et al., 1956; Jain, 1991; Kirtikar and Basu, 1935; Nadkarni, 1954; Watt, 1889-1892) and it was found that uses of a considerable number of plants have not previously been reported. Scientific screening of such plants is essential to evaluate their therapeutic potential. Such observations may be useful from drug discovery point of view. Since new ethnmedicinal information can serve as drug lead for discovery of novel plant-based pharmaceutical.

During the course of fieldwork it was observed that the useful areas of fertile land in many places are considerably reducing day-by-day for wild plants to spread naturally due to expansion of agriculture, dwellings and industrialisation. Moreover, this ancestral knowledge which exists as oral is in danger of being lost because of rapid cultural changes among the indigenous societies under the influence of increasing developmental activities. Therefore, urgent scientific field surveys should be conducted among the native people of other ethnopharmacologically unexplored or under explored areas of this region in particular and in other areas of Uttarakhand in general in order to rescue and document the wealth of knowledge on traditional medicine before it will be forgotten.

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Abstract

The Unani system of medicine is an age-old, time-tested system of medicine dating back 5000 years to Greece. Unani system of medicine has described many herbs in its literature which can be used to enhance the beauty of skin and hair as well as to treat their different pathological conditions of skin and hairs. The present review focuses on 21 taxa of potential herbs for cosmetic purposes, which are described in Unani literature as well as in ethnobotanical literature. Information on botanical name, focal name, family, part used and mode of application are given for each species discussed in tabular form. Need for scientific validation of this information is re-stressed before their use in beauty care.

Key Words: Herbs, Cosmetics, Skin care, Hair care.

Introduction

With the beginning of the civilization, mankind had the magnetic dip towards impressing others with their looks. At the time, there were no fancy fairness creams or any cosmetic surgeries. The only thing they had was the knowledge of nature. Beautification has always been an eternal quest for men and women throughout the ages. The concept of beauty and cosmetics is old as mankind and civilization. Women are obsessed with looking beautiful, so they use various beauty products that have herbs to look charming and young since centuries. Cosmetics have been used since the Stone Age. The earliest known cosmetics come from the 1st Dynasty of Egypt (3100 – 2907 BC) (http://www.syl.com/hb/differentchemicalsubstancesincosmeticscanhavebadpotentialhealtheffects.html). Turmeric appears in an Assyrian herbal dating from about 600 BC and was also mentioned by a Unani Physician Dioscorides (Bone, 1991).

Unani is one of the most well known traditional medicine systems and draws on the ancient traditional systems of medicine of China, Egypt, India, Iraq, Persia and Syria. It is also called Greco-Arab medicine. The World Health Organization (WHO) has recognized the Unani System of Medicine (USM) as an alternative system to cater the health care needs of human population. Unani is still popular in many Arab and East Asian countries. In fact Unani medicine and herbal products are gradually more being used in many countries where modern medicine is easily available. India has accepted it as one of the alternative health care system and has given it official status. The ancient
Unani literature has also given emphasis on beautification and cosmetics. Many famous Unani physicians such as Ibne Sina (Avicenna), Ismail jurjani, Al-Razi (Rhazes) etc has mentioned in their literature about beautification and cosmetics. They have described many herbs in their literature to treat skin and hair diseases as well as to enhance the beauty of skin and hairs.

Herbal ingredients are preferentially used in cosmetic formulations intended for consumers with sensitive or dry skin, with the aim to improve skin condition and appearance. They are reported to promote physiological functions of the skin and may offer a balanced complex of health effects as moisturizing, free radical scavenging, calming and anti-inflammatory, improving skin elasticity, anti-aging, healing sunburn or chemical induced irritation (Leung and Foster, 2003).

Cosmetics

According to European Commission Directives, the cosmetic products are defined as a any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition (European Commission, Directives 93/35/EEC,1993).

According to the Act, a cosmetic is defined as an article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting structure or function (Chen, 2009).

The main objective of cosmetic application is decorative to enhance the general appearance of face and other body parts to minimize the skin defects to a considerable extent. It is applied to maintain or improve skin and hair.

Adverse Effects Caused By Some Synthetic Cosmetics

Many cosmetics contain synthetic chemicals that react adversely to skin. The demand for natural and organic products is increasing. For this reason we can find lots of natural and organic products in the markets. Synthetic ingredients in cosmetics effected skin even faster. Some synthetic ingredients
are so commonly used, that consumer would not think twice about using them; whether they are hazardous or not. Parabens is the most common ingredients that can find in any kind of cosmetic; it is used as cosmetic preservative. Using parabens not only harm our skin, but our environment as well. Many consumers prefer products with parabens-free, because parabens are highly toxic and can cause allergic reactions and skin rashes to sensitive skin (Chermahini and Majid et al., 2011). Scientific research shows that parabens indeed have oestrogenic effects and can lead to unfavourable reproductive and developmental problems. In addition, it is hypothesized and tested that underarm cosmetics containing paraben like antiperspirant deodorants, can lead to breast cancer since trace paraben concentrations were found when isolated malignant breast tumours were studied (Harvey and Everett, 2004).

Hair dyes include dyes modifiers, antioxidants, alkalizers, soaps, ammonia, wetting agents, fragrance, and a variety of other chemicals used in small amounts that impart special qualities to hair such as softening the texture or give a desired action to the dye. The chemicals that are normally used in the dye are amino compounds (4-amino-2-hydroxytoluene and m-Aminophenol). Metal oxides, such as titanium dioxide and iron oxide, are also often used as colorants in the process. Continuous usage of such compounds containing dye on natural hair causes so many side effects such as skin irritation, erythrema, loss or damage of hair and skin cancer (Nilani and Saravanan, 2010).

Sodium lauryl sulphate is known to most that have looked at the label of shampoo bottle; it is rather harsh detergent. SLS causes skin to flake and causes substantial roughness on the skin, it actually corroded the hair follicle and impairs its ability to grow hair (Arora, 2011).

Hydroquinone has been used for decades as a skin lightening agent. Since January 1, 2001, its use in cosmetics has been banned. This ban is as a result of mid-term effects such as leukoderma-en-confetti/occupational vitiligo and exogenous ochronosis. However, a recent literature search on hydroquinone as a skin lightening agent suggests that possible long-term effects such as carcinogenesis may be expected as well (Westerhof and Kooyers, 2005).

There are more preservatives in synthetic cosmetics, they may cause some allergic reaction. According to a study of cosmetic reactions conducted by the North American Contact Dermatitis Group, preservatives are the second most common cause of allergic and irritant reactions to cosmetics. In a word, more preservatives exist, more risk we have (Chen, 2009).
Herbal Cosmetics

Herbal Cosmetics, herein after referred as Products are formulated using various permissible cosmetic ingredients to form the base in which one or more herbal ingredients are used to provide defined cosmetic benefits only, shall be called as “Herbal Cosmetics” (Shivanand, 2010). The use of bioactive phytochemicals from a variety of botanicals has dual function as they serve as a cosmetic for the care of body and its parts. Apart from this the botanical ingredients present their influence biological functions of skin and provide nutrients necessary for the healthy skin or hair. In general botanicals or herbs provide different vitamins, anti-oxidants, various oils, essential oils, dyes, tannins, alkaloids, carbohydrates, proteins, terpenoids and other bioactive molecules. Moreover herbal cosmetics are gaining popularity because of their safe, non toxic and eco friendly characteristics.

Tips for Healthy Hair and Skin

The beauty of skin and hair basically depends on individual’s health, diet, habits, job routine, climatic conditions and maintenance. Cosmetics are used externally along with internal cleansing, some preliminary recommendations are:

Do not curb natural urges like urination, bowel movements, tears, hunger, sleep etc; Avoid constipation, it reduces skin glow; keep yourself hydrated, drink plenty of water.; do not miss your beauty sleep.; early to bed and early to rise makes you beautiful and reduces skin fatigue; regular oil massage is essential. Massages or head bath with oil improve complexion, makes the skin supple; Include fruits, fresh vegetables and milk in your diet. Avoid fried items & never share your cosmetics and dresses with others to avoid infection (http://ayurvedham.com/english/ayurveda/herbal-cosmetics.html).

Herbs/Botanicals Used for Skin and Hair Care

In Unani and ethnobotanical literature the following herbs have been reported as beneficial for skin:

*Aloe barbadensis* (Aloe vera or Elwa); *Azadirachta indica* (Neem); *Curcuma longa* (Haldi); *Citrus limon* (Limon); *Crocus sativus* (Zafran); *Matricaria chamomilla* (Baboona); *Carica papaya* (Papita); *Cucumis sativus* (Khira); *Mentha arvensis* (Pudina); *Rosa damascena* (Gulab); *Santalam album* (Sandal safed) [Table 1].
Various herbs that have been reported as beneficial for hairs are as follows:

*Acacia concinna* (Shikakai); *Aloe barbadensis* (Aloe vera or Elwa); *Cocos nucifera* (Nariyal); *Eclipta alba* (Bhangra); *Embellica officinalis* (Amla); *Hibiscus rosa sinensis* (Gurhal); *Lawsonia inermis* (Mehandi); *Sapindus trifoliatus* (Reetha); *Trigonella foenum graecum* (Methi); *Olea europaea* (Zaitoon) [Table 2].

### Table 1: Botanicals for skin care

<table>
<thead>
<tr>
<th>Herb Name</th>
<th>Vernacular Names</th>
<th>Family</th>
<th>Parts Used</th>
<th>Phytochemicals</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zard Chob (U) (Curcuma longa)</td>
<td>Turmeric(E) Haldi(H) Haridra(A) Manjal(T) Pasupu(Tel) Arisina(K) (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Zingiberaecea (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Rhizome (Ghani; Hakim, 2002; Kabiruddin, 2007; Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002).</td>
<td>Volatile oil (3-5%), turmerone (60%), curcumin, curcuminoids, bitter principles, resin (Chopra, 2002; Khare, 2007; Chavallier, 1996).</td>
<td>Antioxidant, anti-inflammatory, used extensively in facial creams for fairness and ointments (Ghani; Hakim, 2002; Kabiruddin, 2007; Sr. Frank, 1999; Chopra, 2002; Khare, 2007).</td>
</tr>
<tr>
<td>Herb Name</td>
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<tr>
<td>Utraj (U) (Citrus limon)</td>
<td>Lemon (E) Nimbu (H) Periya, Elumuchhai (T), Bijapuram (Tel) Dodda Nimbe (K) (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002.)</td>
<td>Rutaceae (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007.)</td>
<td>Fruit peel, juice, volatile oil (Ghani; Hakim, 2002; Kabiruddin, 2007; Sr. Frank, 1999.).</td>
<td>Volatile oil (2.5% of the peel), limonene (70%), alpha terpinene, alpha pinene, citral, coumarins, bioflavonoids, vitamins A, B1, B2, B3, C, mucilage (Chopra, 2002; Khare, 2007; Chavallier, 1996.).</td>
<td>Antiseptic, bacteriostatic, skin bleach, sunburn, freckles, to cleanse the skin and close the pores that’s why used in skin creams &amp; cleansers (Ghani; Hakim, 2002; Kabiruddin, 2007; Sr. Frank, 1999.).</td>
</tr>
<tr>
<td>Babuna (U) (Matricaria chamomilla Linn)</td>
<td>Chamomile (E) (Khare, 2007.).</td>
<td>Asteraceae (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007.)</td>
<td>Flowers (Ghani; Hakim, 2002; Sr. Frank, 1999.).</td>
<td>Volatile oil, chamazulene, apigenin, alpha-bisabolol, flavonoids, bitter glycosides, tannins (Chopra, 2002; Khare, 2007; Chavallier, 1996.)</td>
<td>Anti-inflammatory, antioxidant, used in facial steams to reduce puffiness and cleanse the pores of impurities (Ghani; Hakim, 2002; Sr. Frank, 1999; Khare, 2007.).</td>
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<tr>
<td>Khiyaar (U)</td>
<td>Cucumber (E)</td>
<td>Cucurbitaceae (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Whole fruit (Sr. Frank, 1999).</td>
<td>Enzyme erepsin, proteolytic enzyme, ascorbic acid oxidase, succinic and malic dehydrogenase, phytosterol, curcurbitacins, aminoacids, vitamins (Sr. Frank, 1999; Chopra, 2002; Khare, 2007).</td>
<td>Hydrating, astringent, refreshing and Anti-inflammatory, Fresh cucumber slices are used as refreshing, cooling, soothing eye compress, in face creams for chapped skin or sunburn (Hakim, 2002; Sr. Frank, 1999).</td>
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<tr>
<td>Sandal Safed (U) (Santalam album Linn)</td>
<td>White sandalwood (E) Chandana (A) Chandana (T) Chandanamu (Tel) Agarugandha (K) (Nadkami, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Santalaceae (Sr. Frank, 1999; Nadkami, 2005; Chopra, 2002; Khare, 2007)</td>
<td>Heartwood (Ghani; Sr. Frank, 1999; Khare, 2007)</td>
<td>Volatile oil (3-6%) contain α &amp; β santalol, sesquiterpenols, resins, tannins (Chopra, 2002; Khare, 2007; Chavallier, 1996).</td>
<td>Anti-bacterial, anti-fungal, Anti-inflammatory, anti-oxidant, paste of heartwood used in face pack to improve complexion, essential oil used in creams, lotions for beautification, smoothness and protection from sunburn (Ghani; Sr. Frank, 1999; Khare, 2007).</td>
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<tr>
<td>Shikakai or Kharnub nabi (U) (Acacia concinna)</td>
<td>Shikakai (H)</td>
<td>Mimosaceae</td>
<td>Pods (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Saponins, alkaloids, gum, colouring matter, tannins, resins (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Decoction is used for washing hairs, promote hair growth, prevent hair greying and remove dandruff (Ghani; Sr. Frank, 1999; Khare, 2007).</td>
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<tr>
<td>Sibr or Gheekwar (U) (Aloe barbadensis)</td>
<td>Aloe vera (E)</td>
<td>Liliaceae</td>
<td>Leaf &amp; leaf inner jel (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Anthroquinones (aloe, aloin, emodin) resins, tannins, polysaccharides, glucosamine (Sr. Frank, 1999; Khare, 2007; Chavallier, 1996).</td>
<td>It stimulates hair growth and employed in hair treatments (Sr. Frank, 1999; Nadkarni, 2005).</td>
</tr>
<tr>
<td>Narjeel (U) (Cocos nucifera)</td>
<td>Coconut palm</td>
<td>Palmaceae</td>
<td>Oil from endosperm (Kabiruddin, 2007; Sr. Frank, 1999; Nadkarni, 2005; Khare, 2007).</td>
<td>Enzymes i.e. invertin, oxydase, catalase, potassium, minerals, vitamins (Sr. Frank, 1999; Nadkarni, 2005; Khare, 2007).</td>
<td>It promotes hair growth that's why used in alopecia and hair loss. It’s oil is good for thickening thin hair and giving it lustre (Kabiruddin, 2007; Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
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<tr>
<td>Herb Name</td>
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<td>Family</td>
<td>Parts Used</td>
<td>Phytochemicals</td>
<td>Uses</td>
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<tr>
<td>Bhangra (U) (Eclipta alba Hassk)</td>
<td>Trailing eclipta plant (E) Bhringaraj (A) Karisalaankanni (T) Guntagaliyaeru (Tel) Kadiggaragaraga (K) (Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Compositae or Asteraceae</td>
<td>Leaves (Ghani; Hakim, 2002; Nadkarni, 2005; Khare, 2007).</td>
<td>Ecliptine, resin, reducing sugar, sterol (Chopra, 2002; Khare, 2007).</td>
<td>It's useful for hair nourishment, alopecia &amp; renders the hair black that's why used as an ingredient in shampoos (Ghani; Hakim, 2002; Nadkarni, 2005; Khare, 2007).</td>
</tr>
<tr>
<td>Hina or Mehandi (U) (Lawsonia inermis Linn or Lawsonia alba)</td>
<td>Henna (E) Mendika, Madayanti (A) Marthondi (T) Madarangi (K) (Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Lythraceae</td>
<td>Leaves (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Lawsonone, flavonoids, phenolic acids, tannins (Sr. Frank, 1999; Chopra, 2002; Khare, 2007; Chavallier, 1996).</td>
<td>Leaves paste used for hair dyeing, conditioning and promotes hair growth (Hakim, 2002; Sr. Frank, 1999; Nadkarni, 2005; Khare, 2007).</td>
</tr>
<tr>
<td>Reetha (U) (Sapindus trifoliatus Linn)</td>
<td>Soapnut tree (E) Arishtaka, Reethakranja (A) Puvamkottai (T) Kukudu (Tel) Amtalakaayi (K) (Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Sapindaceae</td>
<td>Fruit (Sr. Frank, 1999).</td>
<td>Saponin (Sr. Frank, 1999).</td>
<td>Extract of fruit works as natural shampoo, used as hair cleanser, used as detergent from earliest ages (Sr. Frank, 1999).</td>
</tr>
<tr>
<td>Herb Name</td>
<td>Vernacular Names</td>
<td>Family</td>
<td>Parts Used</td>
<td>Phytochemicals</td>
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<tr>
<td>Amla or Amlaj (U) (Embilca officinalis)</td>
<td>Indian gooseberry (E) Aamlaki, Dhatri (A) Nelli (T) Nellikaayi (Tel) Nellikay (K) (Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Euphorbiaceae (Sr. Frank, 1999; Nadkarni, 2005; Chopra, 2002; Khare, 2007).</td>
<td>Fruit (Kabiruddin, 2007; Sr. Frank, 1999; Nadkarni, 2005).</td>
<td>Rich source of vit-C, nicotinic acid, minerals, and amino acids (Sr. Frank, 1999; Chopra, 2002; Khare, 2007; Chavallier, 1996).</td>
<td>It has the property of strengthening and promoting hair growth (Kabiruddin, 2007; Sr. Frank, 1999; Nadkarni, 2005).</td>
</tr>
</tbody>
</table>

**Conclusion**

The present review focuses on the potential of 21 herbs for cosmetic purposes, which are described in ancient Unani literature as well as in ethnobotanical literature. Information on botanical names, family, part used made of application, supported with literature search, are given in tabular form. Such species is also provided with Unani, English, Ayurvedic, Hindi, Tamil, Telgu & Kannada names for easy recognition. All these species are widely used for skin and hair care as natural cosmetics.
Acknowledgement

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Abstract

Quality of herbal drugs is a burning issue nowadays. Quality is not something which can be achieved by a magic wand. It has to be built in from the concept till the end of manufacturing process by systematic and comprehensive studies. Ingredient identification in a herbal compound formulation is a pre-emptive attempt towards quality assurance that not only ensures the reproducible therapeutic efficacy but also ensures the safety. Present paper reports ingredient identification in Namak Ajeeb which is considered as Kasir-e-Riyah (carminative) and Hazim (digestive) in Unani System of Medicine. It is recommended in case of Waj-ul-med (gastralgia), Qulanj (colic) and Waj-ul-Kulya (nephralgia). All the ingredients that are required in the preparation were examined separately (both macroscopically as well as microscopically) followed by the microscopic examination of the formulation as a whole. The study has provided key diagnostic histological characters which may serve as an important tool in laying down the standards for quality assurance of this important Unani drug.

Key words: Ingredient identification, Namak Ajeeb, Quality assurance

Introduction

Due to increasing realization of health hazards and toxicity associated with the indiscriminate use of synthetic drugs and antibiotics, there has been a renewed interest in the use of herbs and herbal drugs throughout the world. Because of this sweeping green wave a large number of herbal drugs and other plant derived herbal products are sold all over the world.

On account of consciousness for herbal products at global level, the quality of herbal drugs has become one of the issues of great concern for the scientists, professionals and drug enforcement authorities. Quality is not something which can be achieved by magic wand. It has to be built in from the concept till the end of manufacturing process by systematic and comprehensive studies. Ingredient identification in a herbal compound formulation is a pre-emptive attempt towards quality assurance, that not only ensures the reproducible therapeutic efficacy but also ensures the safety. Present paper reports ingredient identification in ‘Namak Ajeeb’ a Unani formulation which is considered as Kasir-e-Riyah (carminative) and Hazim (digestive) in Unani system of medicine and is recommended in case of Waj-ul-med (gastralgia), Qulanj (colic) and Waj-ul-Kulya (nephralgia). Present

Ingredient Identification in ‘Namak Ajeeb’: A Quality Assurance Approach

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*1 Author for correspondence
studies are in continuation of several Unani drugs investigated earlier by the authors and published. All the ingredients that are required in the preparation were examined separately (both macroscopically as well as microscopically) followed by the microscopic examination of the formulation as a whole. This will provide a key of diagnostic histological characters which serves as an important tool in laying down the standards for quality assurance of the drug ‘Namak Ajeeb’ investigated in the present work.

**Methodology**

All the ingredients of the drug studied were procured from the local raw drug dealers, New Delhi. Each ingredient was authenticated (by examining both macroscopically and microscopically) and powdered separately. ‘Namak Ajeeb’ was prepared as per formulation composition given in NFUM part VI (Anonymous, 2011).

**Formulation Composition:**

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Ingredients</th>
<th>Scientific/English Name</th>
<th>Part used</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Namak-e-Toam</td>
<td>Sodium Chloride</td>
<td>Crystal</td>
<td>8 kg.</td>
</tr>
<tr>
<td>2.</td>
<td>Naushadar</td>
<td>Ammonium chloride</td>
<td>Crystal</td>
<td>2.75 kg.</td>
</tr>
<tr>
<td>3.</td>
<td>Tukhm-e-karafs</td>
<td><em>Apium graveolens</em> Linn.</td>
<td>Seed</td>
<td>500 g.</td>
</tr>
<tr>
<td>4.</td>
<td>Nankhwah</td>
<td><em>Trachyspermum ammi</em> Linn.</td>
<td>Fruit</td>
<td>500 g.</td>
</tr>
<tr>
<td>5.</td>
<td>Filfil siyah</td>
<td><em>Piper nigrum</em> Linn.</td>
<td>Berries</td>
<td>500 g.</td>
</tr>
<tr>
<td>7.</td>
<td>Zeera siyah</td>
<td><em>Carum carvi</em> Linn.</td>
<td>Fruit</td>
<td>500 g.</td>
</tr>
<tr>
<td>8.</td>
<td>Taj Qalmi</td>
<td><em>Cinnamomum cassia</em> Blume</td>
<td>Stem bark</td>
<td>250 g.</td>
</tr>
</tbody>
</table>

Further, a pinch of Namak Ajeeb was taken on a slide and mounted in different reagents viz. (Safranin, Iodine, Ferric Chloride). The cells/ tissues/ cell contents etc. were examined under a microscope according to the methods laid down by Johansen (1940) and Trease and Evans (1983). The resulting photographs were taken from the microscope with computer attachment.
Observations

Ingredients:

1. Tukhm-e-Karafs (*Apium graveolens* Linn.)

   Part used: Seed

   Macroscopy: Dried Seed/Fruit, mostly separated mericarps, cremocarp brown, ovoid, laterally compressed, approx. 1.0 – 1.5 mm. in length, 1.5 mm. in thickness. Each mericarp has five straight, prominent ridges; odour and taste aromatic. (Nadkami, 1986; Kirtikar and Basu, 1988).

   Microscopy: Sectional view of fruit shows:

   Epicarp - Single layered, rectangular, thin walled parenchyma cells covered by irregular cuticle. Mesocarp - Several layered, moderately thick walled parenchyma cells, polygonal-oval, sclereids ovoid – elongated, thick walled, innermost layer of mesocarp consists of large, elongated parenchyma cells. Endocarp - Single layered, square to rectangular shaped, thin walled parenchyma cells. Testa - Single layered, thin walled, elongated rectangular cells. Endosperm - Several layered, rectangular – polygonal, thick walled parenchyma cells filled with oval to round aleurone grains and microspheroidal crystals of calcium oxalate.

2. Nankhwah (*Trachyspermum ammi* Linn.)

   Part used: Fruit

   Macroscopy: Dried fruit consists of two mericarps, grayish brown, ovoid, compressed, length – approx. 2mm. width – 1mm. with pale coloured protuberances, each mericarp consists of 5 ridges and 6 vittae, odour: characteristic, thymolic, taste: pungent.

   Microscopy: T. S. of fruit shows:

   Epicarp - Single layered, tangentially elongated tubular cells covered by thick cuticle, unicellular trichomes present. Mesocarp - Several layered, consists of moderately thick walled, rectangular – polygonal tangentiallyyl elongated cells having vascular bundles and vittae. Testa - Single layered, thin walled, tangentially elongated cells. Endosperm - Thin walled parenchyma cells filled with aleurone grains and oil globules.
3. Filfil siyah (*Piper nigrum* Linn.)

Part used: Berries

Macroscopy: Fruits globular, hard, dark brown to black, 3-5 mm. in diameter with a characteristic coat of deep set wrinkles; odour aromatic, taste pungent. (Nadkarni, 1986; Kirtikar and Basu, 1988).

Microscopy: T.S. of fruit shows:

Epicarp-Single layered epidermis covered by cuticle; epidermal cells polygonal (tabular) containing dark brown- blackish content followed by 2- 3 layers of thin walled parenchyma cells intermingled with thick walled isodiametric to radially elongated lignified stone cells. Mesocarp - Broad zone of tangentially elongated parenchyma cells having larger secretion sacs with suberised walls and oil or resin contents. Cells in the inner mesocarpic region are compressed having few fibro vascular bundles. Endocarp - Single row of beaker shaped stone cells (cells whose radial and inner walls of cells were more strongly lignified than the outer ones). Testa - single layer of yellow coloured cells. Perisperm - Broad zone of thin walled, radially elongated parenchyma cells filled with abundant starch grains, aleurone grains, oleoresin cells containing oil globules and masses of resin.

4. Zanjabeel (*Zingiber officinale* Rosc.)

Part used: Rhizome

Macroscopy: Rhizome irregularly branched (sympodial), laterally compressed, different sizes, externally pale yellowish-buff, longitudinally striate, ends of branches with depressed stem scars, fracture short, mealy, uneven with projecting fibres, odour agreeably aromatic with characteristic pungent taste.

Microscopy : A cross section of rhizome shows:

Phellem or outer cork : Few layered, dark brown, irregular parenchyma cells. Phellogen or inner cork: Few layered, colourless parenchyma cells, radially arranged in regular rows. Phelloderm or cortex : Several layered, thin walled, round- polygonal, parenchyma cells with intercellular spaces containing abundant starch grains which are mostly simple, fairly large, flattened, oblong or sub-rectangular to oval or sac shaped with terminal beak like projection in which eccentric hilum is situated. Numerous oleoresin cells and vascular bundles present. Endodermis : Single layered
with radial walls thickened, starch grains absent. (Stele broad central zone, thin walled, round to polygonal, parenchyma cells with intercellular spaces same as cortex) just inside the endodermis i.e. to the periphery of the ground tissue a ring or narrow zone of vascular bundle present. Larger, closed, collateral, fibrovascular bundles were observed irregularly scattered throughout the remainder of the stele.

5. Zeera siyah (*Carum carvi* Linn.)

Part used : Fruit

Macroscopy : Dried fruit, greenish brown, slightly curved, elongated mericarp, odour and taste aromatic and characteristic.

Microscopy : The fruit has typical structure with six vittae and five primary ribs in each mericarp, small schizogenous secretion canal present in each rib just above the vascular bundle.

T. S. of fruit shows:

Pericarp : Single layered epidermis, tabular cells covered by cuticle. Mesocarp – Several layered parenchyma cells without reticulate thickenings.

Endocarp : Elongated sub rectangular cells arranged parallel to each other.

Endosperm : Thick walled cellulosic parenchyma cells containing fixed oil and aleurone grains upto 10μ in diameter; small rosette crystals of calcium oxalate present.

6. Taj Qalmi (*Cinnamomum cassia* Blume)

Part used : Stem bark


Microscopy : T. S. of bark shows phellem consisting of few layers of cork cells, polygonal – tubular cells arranged in alternating layers of thick and thin walled cells with reddish-brown contents; phellogen and phelloderm not distinguished; cortex several layered, parenchymatous with abundant
oval – round, simple, starch grains. 20μ in diameter, scattered sclereids with more lignified and pitted tangential and lateral walls present in this region, pericycle fibre embedded among stone cells. Secondary phloem consists of parenchymatous cells with starch grains and acicular crystals; medullary rays 1 -3 celled, narrow on inner side and wider towards periphery.

7. Jaiphal (*Myristica fragrans* Houtt)

Part used : Seed

Macroscopy : Seed ellipsoid, length – 20-30 mm, width – approx. 20mm., greenish-brown, marked with small irregular dark brown patches and lines reticulately furrowed, a groove running along the perisperm with infoldings appearing as dark ruminations in the endosperm; odour – strong and aromatic; taste – pungent and aromatic.

Microscopy : T. S. of endosperm shows several layers of peripheral perisperm, flattened polyhedral cells containing prismatic crystals, inner layers of perisperm consists of thin walled parenchyma cells infolding into the tissue of endosperm to form ruminations containing a vascular strand and numerous large oil cells; endosperm parenchymatous with occasional tannin, idioblasts and abundant starch grains that are simple or compound, round, approx 20μ in diameter. Aleurone grains small and irregular but each cell contains one large grain with a well developed crystalloid.

8. Jawitri (*Myristica fragrans* Houtt)

Part used : Aril

Macroscopy : Reddish pieces , approx. 2-4 cm. in size, flat, smooth, irregularly slit, slightly flexible or brittle, rich in oil, when pressed exudes reddish or orange coloured oily substance; odour strong with agreeable taste.

Microscopy : The cross section of aril shows single layered epidermis on either side; simple thick walled cells without intercellular space in between, oil cavities present in abundance.

Test Sample (Formulation)

Microscopic examination of ‘Namak Ajeeb’ shows following components of diagnostic characteristics:-
Epicarp: Fragment of epicarp in surface view showing striated cuticle.

Parenchyma cells: Parenchyma cells of different size and shape, some in the form of groups of parenchyma cells densely packed with polyhedral masses of numerous starch grains, parenchyma cells of the endosperm slightly thick walled, tightly packed and filled with aleurone grains and oil globules, few parenchyma cells thin walled, either single or in groups having scattered starch grains.

Starch grains: Abundant starch grains, present either scattered or within the parenchyma cells, mostly simple, fairly large, flattened, oblong to oval shaped with a pointed hilum situated at the narrower end.

Sclereids: Abundant, various size and shape, either single or in groups, few sclereids irregularly shaped, moderately thick walled with numerous well marked pits, few were small oval – rectangular shaped, thick walled showing striations and wide lumen.

Fibre: Pieces of fibres of various sizes few thick walled lignified with uneven lumen.

Vittae: Fragment vittae showing polygonal thin walled cells having slight thickness at the corners.

Endocarp cells: Elongated cells of the endocarp with their long axis parallel to one another.

Fig 1. X100 Fragment of epicarp of ‘Tukhm-e-Karafs’
Fig 2. X40 Fragment of vittae of ‘Tukhm-e-Karafs’

Fig 3. X40 Fragment of endocarp of ‘Tukhm-e-Karafs’

Fig 4. X40 Endosperm cells showing Aleurone grains & oil globules of ‘Nankhwah’
Fig 5. X40 Parenchyma cells filled with starch

Fig 6. X40 Stone cells of ‘Filfil Siyah’ grains in ‘Filfil Siyah’

Fig 7. X40 Starch grains of ‘Zanjabeel’
Fig 8. X40 Fibers in groups of ‘Zanjabeel’

Fig 9. X40 Fragment of Vittae of ‘Zeera Siyah’

Fig 10. X100 Sclereids from mesocarp of ‘Zeera Siyah’
Fig 11. X100 Cells from endocarp of ‘Zeera Siyah’

Fig 12. X40 Parenchyma cells filled with aleurone grains & oil globulaes of ‘Zeera Siyah’

Fig 13. X40 A piece of fibre of ‘Taj Qalmi’
Fig 14. X40 Sclereids of ‘Taj Qalmi’

Fig 15. X40 Parenchyma cells filled with starch grains of ‘Taj Qalmi’

Fig 16. X40 Fragment of Perisperm of ‘Jaiphal’
Results and Conclusion

Namak Ajeeb is yellowish-brown powder with salty taste and pungent odour. On the basis of histological characters studied, presence of following ingredients was established in ‘Namak Ajeeb’:-

Fragment of epicarp in surface view showing striated cuticle, fragment of vittae composed of polygonal, thin walled cells showing slight thickness at the corners, elongated cells of the endocarp in surface view (Tukhm-e-Karafs) Fig. 1-3.

Parenchyma cells of the endosperm filled with aleurone grains and oil globules (Nankhwah) Fig. 4.
Group of parenchyma cells densely packed with polyhedral masses of numerous starch grains, group of stone cells (Filfil siyah) Fig. 5, 6.

Abundant starch granules which are mostly simple, fairly large, flattened, oblong to oval in shape with a small pointed hilum situated at the narrower end, pieces of non lignified, thin walled fibers present in groups (Zanjabeel) Fig. 7, 8.

Fragments of vittae, sclereids of the mesocarp which are irregularly shaped, moderately thick walled with numerous well marked pits, elongated cells of the endocarp with their long axes parallel to one another, parenchyma cells of the endosperm filled with aleurone grains and oil globules (Zeera siyah) Fig. 9 – 12.

Pieces of fibre which are thick walled, lignified with uneven lumen, group of sclereids, starch granules scattered in parenchyma cells (Taj Qalmi) Fig. 13 – 15.

Fragment of perisperm, parenchyma cells of the endosperm packed with starch granules (Jaiphal) Fig. 16, 17.

Parenchyma cells filled with oil globules (Javitri) Fig. 18.

Acknowledgements

The authors are deeply indebted to the Director General, Central Council for Research in Unani Medicine, New Delhi, for providing necessary research facilities and encouragement.

References


Abstract

Standardization of herbal formulations is essential in order to assess the quality of drugs for therapeutic value. The World Health Organization (WHO) has given a detail protocol for the standardization of herbal drugs comprising of a single drugs, but very little literature is available for the standardization of poly-herbal drugs. Jawarish-e-Javed is one of the ancient most commonly used Unani formulation prescribed for the ailment of stomachic, digestive and brain disorders. The poly herbal drug Jawarish-e-Javed was prepared in different batches with the combination of nine ingredients. Due to lack of scientific standards of the drug the three different batch samples were subjected to evaluate physico-chemical, TLC/HPTLC finger printing, heavy metal, microbial load, aflatoxins and pesticidal residues. The physico-chemical data such as moisture content was 22.46%, alcohol soluble extractives 38.78% and water soluble extractive 38.78% shows presence of polar compounds and inorganic materials respectively. The content of total ash was 1.73% and acid insoluble ash 0.75% shows negligible amount of siliceous matter present in the drug. HPTLC finger prints of chloroform and alcohol extracts shows 13 peaks with the developing systems toluene: ethyl acetate – 9:1 and 6:4 respectively. All three different batch samples were found to be safe when tested for the heavy metal contamination, microbial load, aflatoxins and pesticide residues. The data evolved can be adopted for laying down the pharmacopoeial standards and TLC/HPTLC finger prints for Jawarish-e-Javed.

Key words: Jawarish-e-Javed, TLC/HPTLC finger print, Physico-chemical parameters, Aflatoxins, and Pesticidal residues.

Introduction

Herbal medicines are in great demand in the developed as well as developing countries for primary health care because of their wide range of biological activities, higher safety margins and lesser cost effect (Thaibinh, 1998). Several medicinal plant products have been used for many years in daily life to treat the various diseases (Nair et al., 2005).

The traditional system of medicine such as Ayurveda, Unani, Siddha and Homeopathy (AYUSH) continue to serve a large portion of the population, particularly in rural areas. A variety of reasons have been cited for the need for scientific validation and standardization of the single and poly herbal drugs. Jawarish-e-Javed is used in the ailments of stomachic, digestive and brain disorders.
disorders. The present paper deals the pharmacopoeial standards, TLC/HPTLC finger print, heavy metals, microbial load, aflatoxins and pesticide residues.

**Materials and Methods**

All the ingredients were procured from the local market and identified. Specimens of all ingredients of the formulation have been deposited in the museum of Drug Standardization Research Unit (DSRU) at Regional Research Institute of Unani Medicine, Chennai, Tamil Nadu, India. The drug Jawarish-e-Javed was prepared as per the formulation composition given in NFUM, Part-IV using 9 ingredients (Table. 1).

**Table 1:** Ingredients of Jawarish-e-Javed

<table>
<thead>
<tr>
<th>Unani name/Voucher specimen number</th>
<th>Botanical name</th>
<th>Part used</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jauzbuwa (DSM005)</td>
<td><em>Myristica fragrans</em> Houtt.</td>
<td>Endosperm</td>
<td>25 g</td>
</tr>
<tr>
<td>Bisbasa (DSM006)</td>
<td><em>Myristica fragrans</em> Houtt.</td>
<td>Arillus</td>
<td>25 g</td>
</tr>
<tr>
<td>Qaranful (DSM020)</td>
<td><em>Syzygium aromaticum</em> (L.) Merr. L M Perry</td>
<td>Flower bud</td>
<td>25 g</td>
</tr>
<tr>
<td>Darchini (DSM040)</td>
<td><em>Cinnamomum zeylanicum</em> Blume.</td>
<td>Inner stem bark</td>
<td>25 g</td>
</tr>
<tr>
<td>Sumbul-ut-Teeb (DSM091)</td>
<td><em>Nardostachys jatamansi</em> DC</td>
<td>Rhizome</td>
<td>25 g</td>
</tr>
<tr>
<td>Sad Kufi (DSM090)</td>
<td><em>Cyperus rotundus</em> Linn.</td>
<td>Rhizome</td>
<td>25 g</td>
</tr>
<tr>
<td>Aamla Munaqqa (DSM007)</td>
<td><em>Emblica officinalis</em> Gaertn</td>
<td>Fruit</td>
<td>25 g</td>
</tr>
<tr>
<td>Dana Heel Khurd (DSM075)</td>
<td><em>Eletaria cardamomum</em> (L.) Maton.</td>
<td>Seeds</td>
<td>25 g</td>
</tr>
<tr>
<td>Qand safaid (DSM104)</td>
<td><em>Sugar</em></td>
<td>--</td>
<td>500 g</td>
</tr>
</tbody>
</table>

**Method of Preparation of the drug**

All the ingredients were taken of pharmacopoeial quality. Cleaned, dried, powdered and sieved through 80 mesh. Mixed the powders of all the ingredients of Jauzbuwa, Bisbasa, Qaranful, Darchini, Sumbul-ut-Teeb, Sad Kufi, Aamla Munaqqa, Dana Heel Khurd and kept separately. Dissolved the specified quantity of ingredient Qand Safaid on slow heat in 600 ml of water, at the boiling stage added 0.1% citric acid and mixed thoroughly. At the stage of 70% consistencies of quiwam, 0.1% sodium benzoate was added and mixed.
thoroughly to prepare the quiwam of 76% consistency. Removed the vessel from the fire, while hot condition the mixed powders of all the ingredients were added and mixed thoroughly to prepare the homogenous product. Allowed it to cool to room temperature and packed in tightly closed containers to protect from light and moisture.

Chemical analysis

The analytical data like moisture content, ash values, alcohol and water soluble extractives, PH values, bulk density and estimation of sugar were arrived by employing the standard procedure (Anonymous, 1998 and Anonymous, 1986).

TLC/HPTLC finger print analysis

Preparation of extracts for TLC

The formulations of the three batch samples were extracted with chloroform and alcohol. The extracts were concentrated and made up to 10 ml in a volumetric flask separately. These solutions were used for the TLC/HPTLC finger print analysis.

The TLC/HPTLC finger print analysis of chloroform and alcohol extracts of the formulations were performed using aluminium plate precoated with silica gel 60 F254 (E.merck) employing CAMAG Linomat IV sample applicator. The chromatogram were developed using the developing systems toluene: ethyl acetate (9: 1) and toluene: ethyl acetate (6: 4) for chloroform and alcohol extracts respectively. The plates were dried at room temperature and observed the spots at UV-254 nm, UV-366 nm and the plates were scanned at 254 nm to record the finger print spectrum. Finally the plate were dipped in vanillin-sulphuric acid and heated at 105° till coloured spots appeared (Wagner H and Bladt S, 1984 and Sethi P D, 1996).

Estimation of Microbial Load

The estimation of microbial load viz. total bacterial count (TBC), total fungal count (TFC), Enterobacteriaceae, *Escherichia coli*, *Salmonella* spp and *Staphylococcus aureus* were determined as per WHO, 1998.

Estimation of Heavy Metals

The procedure was used for the analysis of heavy metals like lead, cadmium, mercury and arsenic as per WHO, 1998 and AOAC, 2005.
Instrument details and operating parameters

Thermo Fisher M Series, 650902 V1.27 model Atomic Absorption Spectrometer (AAS) was used for the analysis. The operating parameters:

**Lead and Cadmium: Instrument technique** - Flame technique; wavelength (Lead) - 217 nm; wavelength (Cadmium) - 228.8 nm; slit width - 0.5 mm; lamp current (Pb) - 4.0 mA; lamp current (Cd) - 3.0 mA; carrier gas and flow rate - air and acetylene, 1.1 L/min; sample flow rate - 2 ml/min. Mercury: Instrument technique - Cold vapour technique; wavelength - 253.7 nm; slit width - 0.5 mm; lamp current - 3.0 mA; carrier gas and flow rate - argon, 1.1 L/min; sample flow rate - 5ml/min. Arsenic: Instrument technique - Flame vapour technique; wavelength - 193.7 nm; slit width - 0.5 mm; lamp current - 6.0 mA; carrier gas and flow rate - acetylene, argon, 1.1 L/min; sample flow rate - 5ml/min. The Hallow cathode lamp for Pb, Cd, Hg and As analysis were used as light source to provide specific wavelength for the elements to be determined.

Analysis of Aflatoxins

The procedure was followed for the analysis of aflatoxins B1, B2, G1 and G2 as per Official Analytical Methods of the American Spice Trade Association (ASTA), 1997.

Instrument details and operating parameters

Thermo Fisher High Performance Liquid Chromatography (HPLC) was used for the aflatoxins analysis. Column - Ultra C18, 250 X 4.6 mm, 5 μm particles; mobile phase - water: acetonitrile: methanol (65: 22.5: 22.5); flow rate - 1 ml/min; temperature - 35º C; detector - fluorescence detector at 360 nm; injection - 20 μl (Aflatoxins mixture and sample)

Analysis of pesticide residue

The procedure was followed for the analysis of pesticidal residues as per AOAC, 2005. Pesticidal residues were analyzed by Gas Chromatography-Mass Spectra (GC-MS)(Instrument-Agilent, detector-mass selective detector, column specification-DB5MS, carrier gas- helium, flow rate-1ml/min, column length- 30 m, internal diameter-0.25 mm, column thickness-0.25 μm).
Results and Discussion

Physico-chemical parameters

The drug is blackish brown in colour, semisolid, characteristics of its own odour and sweetish bitter in taste. Physico-chemical parameters of Jawarish-e-Javed are tabulated in Table 2. Quantitative standards revealed that the moisture content was 22.46%, ash content was 1.73% and acid insoluble ash (0.75%) indicates the negligible amount of siliceous matter present in the drug. The water soluble extractive value of the drug 58.85% indicates the presence of inorganic content and the alcohol soluble extractive value 38.78% indicates the extraction of polar constituents.

Table 2: Physico-chemical parameters of the Jawarish-e-Javed

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Parameters</th>
<th>Jawarish-e-Javed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Batch - I</td>
</tr>
<tr>
<td>1</td>
<td>Moisture (% W/W)</td>
<td>22.25</td>
</tr>
<tr>
<td>2</td>
<td>Extractive values (% W/W)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alcohol soluble matter</td>
<td>38.76</td>
</tr>
<tr>
<td></td>
<td>Water soluble matter</td>
<td>58.78</td>
</tr>
<tr>
<td>3</td>
<td>Ash values (% W/W)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total ash</td>
<td>1.65</td>
</tr>
<tr>
<td></td>
<td>Acid insoluble ash</td>
<td>0.77</td>
</tr>
<tr>
<td>4</td>
<td>pH values</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1% Aqueous solution</td>
<td>5.78</td>
</tr>
<tr>
<td></td>
<td>10% Aqueous solution</td>
<td>4.29</td>
</tr>
<tr>
<td>5</td>
<td>Sugar estimation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reducing sugar (% W/W)</td>
<td>33.12</td>
</tr>
<tr>
<td></td>
<td>Non reducing sugar (% W/W)</td>
<td>15.45</td>
</tr>
<tr>
<td>6</td>
<td>Bulk Density</td>
<td>1.2922</td>
</tr>
</tbody>
</table>

All values are mean of three determinations

TLC/HPTLC finger print studies of chloroform extract

The TLC studies of chloroform extract are tabulated in Table-3. All the three batch samples shows identical spots in UV-254 nm, UV-366 nm and visible light (after derivatised with vanillin – sulphuric acid reagent). In UV – 254, 366 nm and visible light it shows 10, 12 and 9 spots respectively with different Rf values (Fig. 1). The finger print of the chloroform extract shows 13 peaks of which peaks at Rf 0.03, 0.28, 0.43, 0.74 and 0.85 were the major peak
whereas peaks at $R_f$ 0.06, 0.11, 0.20, 0.34, 0.38, 0.59, 0.65 and 0.99 were moderately smaller peaks (Fig. 2). The HPTLC densitometry chromatogram of chloroform extract of three batch samples were recorded at 254 nm (Fig. 3).

**Table 3:** $R_f$ values of the chloroform extract

<table>
<thead>
<tr>
<th>Solvent System</th>
<th>Rf Values</th>
<th>UV – 366 nm</th>
<th>After derivatisation with vanillin – sulphuric acid reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toluene: Ethyl acetate (9:1)</td>
<td>0.90 Green 0.94 Fluorescent blue 0.78 Violet</td>
<td>0.70 Brown</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.81 Green 0.87 Fluorescent blue 0.70 Brown</td>
<td>0.61 Grey</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.70 Green 0.73 Blue 0.63 Brown</td>
<td>0.70 Brown</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.63 Green 0.63 Blue 0.54 Grey</td>
<td>0.54 Grey</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.49 Green 0.58 Fluorescent blue 0.45 Violet</td>
<td>0.45 Violet</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.45 Green 0.54 Pink 0.35 Grey</td>
<td>0.35 Grey</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.31 Green 0.45 Fluorescent blue 0.30 Blue</td>
<td>0.30 Blue</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.26 Green 0.38 Brown 0.22 Grey</td>
<td>0.22 Grey</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.21 Green 0.34 Brown 0.13 Violet</td>
<td>0.13 Violet</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.13 Green 0.30 Blue</td>
<td>0.30 Blue</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.12 Blue</td>
<td></td>
</tr>
</tbody>
</table>

Fig. 1 TLC photos of chloroform extracts of three batch samples at different wavelength of light.(After derivatisation with vanillin – sulphuric acid reagent)
TLC/HPTLC finger print studies of alcohol extract

The TLC studies of alcohol extract are tabulated in Table-4. All the three batch samples shows identical spot in UV-254 nm, UV-366 nm and visible light (after derivatised with vanillin – sulphuric acid reagent). In UV – 254, 366 nm and
visible light it shows 6, 8 and 9 spots respectively with different \( R_f \) values (Fig. 4). The finger print of the chloroform extract shows 13 peaks of which peaks at \( R_f \) 0.06 and 0.80 were the major peak whereas peaks at \( R_f \) 0.01, 0.27, 0.33, 0.45, 0.51, 0.56, 0.66, 0.70, 0.88, 0.91 and 0.97 were moderately smaller peaks (Fig. 5). The HPTLC densitometry chromatogram of chloroform extract of three batch samples were recorded at 254 nm (Fig. 6)

**Table 4:** \( R_f \) values of the alcohol extract

<table>
<thead>
<tr>
<th>Solvent System</th>
<th>( R_f ) Values</th>
<th>UV- 254 nm</th>
<th>UV – 366 nm</th>
<th>After derivatisation with vanillin – sulphuric acid reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toluene: Ethyl acetate (6:4)</td>
<td>0.91 Green</td>
<td>0.96 Blue</td>
<td>0.96 Grey</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.82 Green</td>
<td>0.93 Violet</td>
<td>0.92 Brown</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.77 Green</td>
<td>0.80 Fluorescent blue</td>
<td>0.82 Brown</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.65 Green</td>
<td>0.72 Blue</td>
<td>0.66 Brown</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.55 Green</td>
<td>0.62 Blue</td>
<td>0.62 Violet</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.21 Green</td>
<td>0.54 Fluorescent blue</td>
<td>0.55 Grey</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.27 Light blue</td>
<td>0.37 Grey</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.10 Blue</td>
<td>0.14 Grey</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.10 Light grey</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. 4: TLC photos of alcohol extracts of three batch samples at different wavelength of light
Microbial load, Heavy Metals, Aflatoxins and Pesticidal residues

Estimation of microbial load viz. Total bacterial count (TBC), Total fungal count (TFC), Enterobacteriaceae, Escherichia coli, Salmonella spp and Staphylococcus aureus were found to be within the permissible limit as stated by WHO (Table-5). The heavy metals viz. lead was present within the permissible limit where as cadmium, mercury and arsenic were not found in the drug (Table-6). The studies of other parameters like estimation of aflatoxins such as B1, B2, G1 and G2 and pesticide residue such as organo chlorine
group, organo phosphorus group, alachlor, aldrin, chlordane, DDT, endosulfan, heptachlor, lindane and malathion were not detected from the drug.

Table 5: Microbial Load

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Results</th>
<th>WHO Limits for internal use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Bacterial Count (TBC)</td>
<td>$2 \times 10^2$ cfu/g</td>
<td>$1 \times 10^5$ cfu/g</td>
</tr>
<tr>
<td>Total Fungal Count (TFC)</td>
<td>Absent</td>
<td>$1 \times 10^3$ cfu/g</td>
</tr>
<tr>
<td>Enterobacteriaceae</td>
<td>Absent</td>
<td>$1 \times 10^3$ cfu/g</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>Absent</td>
<td>$1 \times 10^1$ cfu/g</td>
</tr>
<tr>
<td><em>Salmonella</em> spp</td>
<td>Absent</td>
<td>Absent</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Absent</td>
<td>Absent</td>
</tr>
</tbody>
</table>

Table 6: Analysis of Heavy Metals

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Parameters</th>
<th>Value (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Lead</td>
<td>0.0123</td>
</tr>
<tr>
<td>2.</td>
<td>Cadmium</td>
<td>Not detected</td>
</tr>
<tr>
<td>3.</td>
<td>Arsenic</td>
<td>Not detected</td>
</tr>
<tr>
<td>4.</td>
<td>Mercury</td>
<td>Not detected</td>
</tr>
</tbody>
</table>

All values are mean of three determinations

Conclusion

The physicochemical methods viz., moisture content, ash values, extractive values, sugar content, PH values and bulk density etc. are useful tools in standardization of Jawarish-e-Javed to maintain the batch-to-batch consistency and quality of the products. The physico-chemical parameters will be helpful for fixing pharmacopoeial standards of the drug. TLC/HPTLC finger print profile of chloroform and alcohol extracts provides a suitable method for monitoring the identity and purity and also standardization of the drug. Heavy metals, aflatoxins, pesticidal residues and microbial load were found to be within the permissible limit of WHO, indicating that the drug is free from toxic materials and which can be used in the ailments of stomachic, digestive and brain disorders.

Acknowledgement

The authors are thankful to the Director General, Central Council for Research
in Unani Medicine, New Delhi, for providing necessary research facilities to carry out the present studies.

References


Abstract

Wounds are physical injuries that result in an opening or break of the skin. Present paper deals with the herbal remedies used for wound healing among Kani tribes in Kanniyakumari district, Tamil Nadu. The paper is based on the outcome of ethnobotanical survey carried out among the Kani tribe of Kanniyakumari district, Tamil Nadu. As a result of survey trips 33 plant species were collected which are widely used for wound healing. The documented medicinal plants are used for wound healings either single or in combination with other drugs. The plants recorded from the study area are arranged alphabetically by botanical name, family, voucher specimen no., Unani name, local name, part used and mode of application. Pharmacological activities of plants from published literature have also been given. Scientific validation of such folk drug plants species is suggested that may form the basis for their use as alternative treatment.

Key words: Ethnobotany, Kani tribals, Wound healing, Kanniyakumari, Tamil Nadu.

Introduction

Ethnobotany envisages to study the relationship between human and plants in nature. Ethnic people are highly knowledgeable about the plants and their medicinal values and this knowledge is passed through oral communication from generation to generation, who live in remote villages and forests. Traditional folk medicines are mostly undocumented which have been handed from one generation to another. Large section of the Indian population still relay on traditional herbal medicines. Today, a substantial number of drugs are developed from plants which are active against a number of diseases. The majority of these plants involve the isolation of the active ingredients (chemical compounds) found in a particular medicinal plant.

Research on wound healing agents is one of the developing areas in modern biomedical sciences and many traditional practitioners across the world particularly in countries like India and China have valuable information of many lesser-known, hitherto, unknown wild plants for treating wounds and burns (Kumar et al., 2007). Traditional forms of medicine practiced for centuries in Africa and Asia are being scientifically investigated for their potential in the treatment of wounds related disorders (Krishnan, 2006).
Some of the commonly available drugs used in the healing of wounds are ibuprofen (non-steroidal anti-inflammatory drug), colchicines, corticosteroids, antiplatelets (aspirin), anticoagulants (heparin), warfarin and vasoconstrictors eg., nicotine, cocaine and adrenaline (Grey and Harding, 2006). Although ethnobotanical studies have been accomplished in and around Kanniyakumari forest among the tribal people by the researchers (Jeeva et al., 2006; Kingston et al., 2006, Venkatesan et al., 2009, 2010). However, no systematic studies have been undertaken to assess the management of wounds among tribals of the area. The present study was, therefore, undertaken with the aim to develop an inventory of plants used by folk healers in Kanniyakumari forests to document the folk therapies practiced for various wounds and related injuries among the tribals of the area. Information on pharmacological activities of such wound healing plants have also been included based on published literature.

**Methodology**

**Study area and ethnic people**

The study was conducted during 2008 and 2011. It was aimed to collect information about medicinal plants used by folk healers in the Southern-Western Ghats of Kanniyakumati district, Tamil Nadu. The district lies between 77°15' and 77°36' eastern longitudes and 8°03' and 8°35' northern latitudes.

The ethnomedicinal information was gathered from the indigenous people of the study area called Kani or Kanikaran, one of the oldest groups of the ethnic people in South India. They reside in remote and inaccessible forest areas and practice indigenous phytotherapy to treat common ailments. During the course of field exploration folk information on plants were gathered from the healers inhabiting the forest areas and have sound knowledge of herbal remedies.

In Kanniyakumari, the Kani tribals are inhabited in the villages of : Konjanr, Kodayar, Kodithurai or Kani kudiruppu, Keeripari, Ulakkaiaruvi, Veerapuli and Maramalai. The knowledge about medicinal plants is rather specialized and is limited to a few members in the community who are recognized as ‘Vaidhyar’ (also known as medicine men, informant and traditional healer). Traditional healers commonly begin their training as children or teenagers working as assistants to their mothers, fathers and to other relatives who are recognized healers. After having trained for a number of years, the apprentice will be ceremonially granted the authority to use a given treatment. This individual will be recognized by others in their culture as having mystical power to heal, as well as having the power to train others.
Data collection

The ethnomedicinal information was collected through interviewing traditional healers and for the purpose questionnaires were used to gather and record their knowledge. Details of medicinal plants used, mode of treatment, methods of preparation and types of administration were documented by interacting with them as well as through direct observations. The information got from the tribals was recorded in field notebooks and compared with the previous reports (Jain, 1991; Viswanathan, 2004; Venkatesan et al., 2009). The collected plants were identified by the local people with their vernacular names, photographs and identified for the preparation of herbarium. The voucher specimens were deposited in the herbarium of Regional Research Institute of Unani Medicine, Chennai, for future reference and study.

Results

Leaves are the main part of the folk plants used for the treatment of diseases. The reasons why leaves are used mostly is that they are easily accessible and are active in production of secondary metabolites (Ghorbani, 2005). The methods of preparation fall in two categories, viz. plant parts apply as paste, juice extracted from the fresh parts of the plant, plant parts used to prepare extract in the combination of water and powder made from dried material. Majority of the remedies reported in the present study for wound healing were applied externally.

Kanniyakumari forests have a variety of medicinal plants which are used by the Kani tribals in their primary healthcare. The present study identified 33 species of plants used by folk healers to treat wounds and related injuries such as cuts, burns, bruises, boils, sores, abscess, etc. Medicinal uses of these plants species have been presented in table- 1. The pharmacological action of the plant/part on wound healing have been shown in Table 2.

Discussion

The study of ethnomedical systems and herbal medicines as therapeutic agents is of a paramount importance in addressing health problems of traditional communities and third world countries as well as industrialized societies. Previous reports on the ethnobotany of kanniyakumari district and adjoining areas are an evidence for the presence of numerous ethnomedicinal plants used by the Kani tribals (Henry and Swaminathan, 1981; Jeeva et al., 2006; Kingston, 2006; Venkatesan et al., 2009 & 2010). Present study
revealed that wounds are one of the major problems among the Kani people, due to their life in the forest. While entering into the forests they get injured. The traditional healers residing among them treat such wounds. In Indian traditional medicine, the species of the following genera are commonly used to treat wound and related injuries include Abutilon, Achyranthes, Acorus, Aegle, Aerva, Aloe, Azadirachta, Bambusa, Boerhavia, Butea, Caesalpinia, Calotropis, Carissa, Cassia, Curcuma, Cynodon, Datura, Dodonaea, Eclipta, Euphorbia, Ficus, Leucas, Morinda, Ocimum, Opuntia, Pergularia, Plumbago, Pongamia, Sida, Smilax, Terminalia, Tridax, Vitex and Zizyphus (Jain, 1991).

Kumar et al. (2007) and Biswas and Mukherjee (2003) reported that about 163 species of plants were used as wound healing plants in Indian Systems of Medicine (ISM) such as Ayurveda, Siddha, Unani, and folk medicine. Kani tribals in Kanniyakumari forest are also frequently using the leaves of Ficus racemosa, root of Mirbilis jalapa and stem latex of Tylophora indica in the treatment of wounds. According to various traditional medicinal practices throughout the world, wounds have been treated mostly topically with different medicinal herbs or with their extracts solely or in combination with some other plant parts. Kani tribals also prepare medicines in combination of several plant parts and they believe that combination of different plant parts cures diseases rapidly. Faced with increasing burden on health care, wound healers are examining all possible resources. The plants such as Calotropis procera (Rasik et al., 1999), Heliotropium indicum, Plumbago zeylanica and Acalypha indica (Suresh Reddy et al., 2002), Cassia fistula (Senthil Kumar et al., 2006), Cissus quadrangularis, Guiera senegalensis and Butyrospermum parkii (Inngjerdingen et al., 2004), Napoleona imperialis, Ocimum gratissimum and Ageratum conyzoides (Chah et al., 2006) have long been used both orally and topically for healing of wounds and burns in the folk medicine by the tribal communities of various countries. Of the 33 plant species reported by Kani tribals for wound healing, the plants such as Acalypha indica, Adhatoda zeylanica, Aloe vera, Aristolochia indica, Calotropis gigantea, Datura fastuosa, Euphorbia hirta, Ocimum tenuiflorum, Pongamia pinnata, and Terminalia arjuna were investigated experimentally by various researchers in wounded animals (Reddy et al., 2002; Subhashini et al., 2010; Choi et al., 2001; Shirwalkar et al., 2003; Pathak and Argal, 2007; Vimal et al., 2009; Sharma and Sikarwar, 2008; Shetty et al., 2008; Srinivasan et al., 2001; Chaudhari and Mengi, 2006.). These studies showed significant wound healing activity (Table- 2).

Role of plant compounds in wound healing

The process of wound healing is promoted by several natural products which are composed of active principles like triterpenoids, alkaloids, flavonoids and...
biomolecules (Sumitra et al., 2005). Asiaticoside from Centella asiatica (Shukla et al., 1999), β-sitosterol (Krishnan, 2006) and glycoprotein (Choi et al., 2001) from the gel of Aloe vera, oleanolic acid from Anredra diffusa (Letts et al., 2006), quercetin, isorhamnetin and kaempferol from Hippophae rhamnoides (Fu et al., 2005), curcumin from Curcuma longa (Jagetia and Rajanikant, 2004), proanthocyanidins and reseveratrol from Vitis vinifera (Khanna et al., 2002), acylated iridoid glycosides from Scrophularia nodosa (Stevenson et al., 2002), phenolic acids from Chromolaena odorata (Phan et al., 2001), (+)-epi-α-bisabolol from Peperomia galioides (Villegas et al., 2001), fukinolic acid and cimicifugic acids from Cimicifuga sps. (Kusano et al., 2001) and Xyloglucan from Tamarindus indicus (Burgalassi et al., 2000) are some of the important plant derived wound healing compounds which were tested in animal models. Diallo et al. (2002) stated that polysaccharides are also partly responsible for the process of wound healing; for example, arabinogalactans from the root of Angelica acutiloba, acidic heteroglycans from the leaves of Panax ginseng, acemannan from the gel of Aloe vera and general polysaccharides from the leaves of Plantago major are reported to have wound healing activity. Many traditional remedies are based on systematic observations and methodologies and have been time-tested but for many of them, scientific evidence is lacking and there are only few prospective randomized controlled trials that have proved the clinical efficacy of these traditional wound healing agents (Khalil et al., 2007). Kumar et al. (2007) stated that the major problem with pharmacological validation of the wound healing plants was that the exact mechanism of the healing process of wound was not clearly understood; hence most of the researchers restricted the screening of plants to simple healing of wounds and did not go into details. The validation by scientific method of the usefulness of plants species reported in the present study may be undertaken that may form the basis for their possible use as alternative treatment.

Table 1: Medicinal plants used for wound healing among Kani tribals in Kanniyakumari district.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Botanical Name/Family Name/Voucher Specimen Number</th>
<th>Unani Name</th>
<th>Local Name</th>
<th>Part used and Mode of Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Acalypha indica L./Euphorbiaceae/RRIUM CH-9904</td>
<td>Kuppi</td>
<td>Kuppaimani</td>
<td>Leaves made into paste with turmeric powder applied on wound.</td>
</tr>
<tr>
<td></td>
<td>Plant Name</td>
<td>Common Name</td>
<td>Parts Used</td>
<td>Application</td>
</tr>
<tr>
<td>---</td>
<td>------------</td>
<td>-------------</td>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>2</td>
<td><em>Achyranthes aspera</em> L./Amranthaceae/RRIUM CH-8979</td>
<td>Atkumah</td>
<td>Nayuruvi</td>
<td>Leaf paste mixed with calcium externally applied on wound.</td>
</tr>
<tr>
<td>3</td>
<td><em>Adhatoda zeylanica</em> Medic./Acantaceae/RRIUM CH-8982</td>
<td>Arusa</td>
<td>Adathoda</td>
<td>Paste of tender leaves applied on wound.</td>
</tr>
<tr>
<td>4</td>
<td><em>Aloe vera</em> (L.) Burm.f./Liliaceae/RRIUM CH-9942</td>
<td>Gheekwar</td>
<td>Karthali</td>
<td>Leaves gel externally apply on wound.</td>
</tr>
<tr>
<td>5</td>
<td><em>Alstonia scholaris</em> (L.) R.Br./Apocynaceae/RRIUM CH-9968</td>
<td>Kashim</td>
<td>Elilaipalai</td>
<td>Latex externally applies on chronic wound.</td>
</tr>
<tr>
<td>6</td>
<td><em>Andrographis paniculata</em> Burn.f./Acanthaceae/RRIUM CH-8931</td>
<td>Kalmegh</td>
<td>Nila vembu</td>
<td>Leaf extract externally applied on skin rashes.</td>
</tr>
<tr>
<td>7</td>
<td><em>Aristolochia indica</em> L./Aristolochiaceae/RRIUM CH- 9037</td>
<td>Isharmul</td>
<td>Karuda kodi</td>
<td>Leaves are made in to paste applied on scabies wound.</td>
</tr>
<tr>
<td>8</td>
<td><em>Azadiracta indica</em> A.Juss./Meliaceae/RRIUM CH-10098</td>
<td>Neem</td>
<td>Vambu</td>
<td>Leaves made in to paste with turmeric powder applied on cut injuries.</td>
</tr>
<tr>
<td>9</td>
<td><em>Calotropis gigantea</em> R.Br./Euphorbiaceae/RRIUM CH-8883</td>
<td>Madar</td>
<td>Erruku</td>
<td>Latex applied on Dog bite (rabies) wound to cure.</td>
</tr>
<tr>
<td>10</td>
<td><em>Cassia tora</em> L./Caesalpiniaeace/RRIUM CH-8930</td>
<td>Panwad</td>
<td>Usaithakarai</td>
<td>Powder of fruits mixed with 'neem oil' externally applied on diabetic wound.</td>
</tr>
<tr>
<td>11</td>
<td><em>Catunaregam spinosa</em> (Thunb.) Tirvengadam./Rubiaceae/RRIUM CH- 8879</td>
<td>Mayeenphal</td>
<td>Karai</td>
<td>Fruit past applied on wounds.</td>
</tr>
<tr>
<td>12</td>
<td><em>Cissus quadrangularis</em> L./Vitaceae/RRIUM CH-9067</td>
<td>Hadjoda</td>
<td>Pirandai</td>
<td>Plant extract externally applied on burning injury.</td>
</tr>
<tr>
<td></td>
<td><strong>Coccinia grandis</strong> (L.) J. Voigt/ Cucurbitaceae/ RRIUM CH-9949</td>
<td>Kunduri</td>
<td>Kovai</td>
<td>Leaf paste externally applied on wounds and cut injuries.</td>
</tr>
<tr>
<td>---</td>
<td>-------------------------------------------------</td>
<td>---------</td>
<td>-------</td>
<td>-----------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td><strong>Croton tiglium</strong> L./ Euphorbiaceae/ RRIUM CH- 8946</td>
<td>Salateen</td>
<td>Nervalam</td>
<td>Seed oil externally applied on wounds.</td>
</tr>
<tr>
<td></td>
<td><strong>Cuscuta reflexa</strong> Roxb./ Cuscutaceae/ RRIUM CH- 8973/</td>
<td>Kasoos</td>
<td>Ottuchedi</td>
<td>Plant extract applied on burn injuries.</td>
</tr>
<tr>
<td></td>
<td><strong>Datura fastusa</strong> L./Solanaceae/ RRIUM CH-9942</td>
<td>Dhatura Siyah</td>
<td>Karuoomathai</td>
<td>Roasted leaves bandaged on wound as tincture.</td>
</tr>
<tr>
<td></td>
<td><strong>Eclipta prostrata</strong> L./Asteraceae/ RRIUM CH- 8989</td>
<td>Bhangra</td>
<td>Karisalnkan</td>
<td>Plant extract applied on wounds as tincture.</td>
</tr>
<tr>
<td></td>
<td><strong>Euphorbia hirta</strong> L./ Euphorbiaceae/ RRIUM CH-8947</td>
<td>Dudhi Kalan</td>
<td>Amman pachiarasi</td>
<td>Latex and leaf paste externally applied on cut injuries.</td>
</tr>
<tr>
<td></td>
<td><strong>Ficus racemosa</strong> L./Moraceae/ RRIUM CH- 10131</td>
<td>Gular, Jamiz</td>
<td>Atthi</td>
<td>Aqueous extract of bark applied on wounds.</td>
</tr>
<tr>
<td></td>
<td><strong>Leucas aspera</strong> (Wild.) Link/ Lamiaceae/ RRIUM CH- 8992</td>
<td>Thumba, Chota halkusa</td>
<td>Thumbai</td>
<td>Leaves are made into paste with calcium and externally applied on wounds.</td>
</tr>
<tr>
<td></td>
<td><strong>Mimosa pudica</strong> L./Mimosaceae/ RRIUM CH-9091</td>
<td>Lajwanti</td>
<td>Thottal vadi</td>
<td>Leaves are made into paste and externally applied on cut injuries.</td>
</tr>
<tr>
<td></td>
<td><strong>Mirabilis jalapa</strong> L./ Nyctaginaceae/ RRIUM CH- 8994</td>
<td>Gul-e-Abbas</td>
<td>Anthimalli</td>
<td>Root paste externally applied on cut injuries.</td>
</tr>
<tr>
<td></td>
<td><strong>Moringa pterygosperma</strong> Gaertn../ Moringaceae/ RRIUM CH-10021</td>
<td>Sahajana</td>
<td>Murungai</td>
<td>Root paste used as bandaged medicine for wound.</td>
</tr>
<tr>
<td></td>
<td><strong>Ocimum tenuiflorum</strong> L. /Lamiaceae/ RRIUM CH- 10039</td>
<td>Raihan</td>
<td>Neelathulasi</td>
<td>Leaf extract applied on wound.</td>
</tr>
<tr>
<td>No.</td>
<td>Species Name</td>
<td>Common Name 1</td>
<td>Common Name 2</td>
<td>Use</td>
</tr>
<tr>
<td>-----</td>
<td>--------------------------------------------------</td>
<td>------------------------</td>
<td>---------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>25</td>
<td><em>Plumbago zeylanica</em> L. / Plumbaginaceae / RRIUM CH-8977</td>
<td>Sheetraj hindi</td>
<td>Kodivi</td>
<td>Leaves made into paste with neem oil externally applied on diabetic wound.</td>
</tr>
<tr>
<td>26</td>
<td><em>Pongamia pinnata</em> (L.) Pierre. / Papilionaceae / RRIUM CH-9075</td>
<td>Karanji</td>
<td>Pongan</td>
<td>Seed oil applied on chronic wounds.</td>
</tr>
<tr>
<td>27</td>
<td><em>Ricinus communis</em> L. / Euphorbiaceae / RRIUM CH-9018</td>
<td>Arand, Bedanjeer</td>
<td>Amanakku</td>
<td>Paste of tender leaves externally applied on wounds.</td>
</tr>
<tr>
<td>28</td>
<td><em>Rubia manjesta</em> Roxb. ex Fleming / Rubiaceae / RRIUM CH-9023</td>
<td>Majeeth</td>
<td>Manjeti</td>
<td>Crushed flower paste applies on wound.</td>
</tr>
<tr>
<td>29</td>
<td><em>Terminalia arjuna</em> (Roxb. ex DC.) W&amp;S. / Combretaceae / RRIUM CH-9083</td>
<td>Arjun</td>
<td>Arjuna</td>
<td>Leaves are made into paste with coconut oil and used as banded medicine for chronic wounds.</td>
</tr>
<tr>
<td>30</td>
<td><em>Tinospora cordifolia</em> (Willd.) Hook / Minispermaceae / RRIUM CH-9099</td>
<td>Gilo</td>
<td>Senthil</td>
<td>Leaf paste externally applied on wounds.</td>
</tr>
<tr>
<td>31</td>
<td><em>Tribulus terrestris</em> L. / Zygophyllaceae / RRIUM CH-9951</td>
<td>Khar-e-Khasak</td>
<td>Nerunji</td>
<td>Leaves are made into paste with neem oil and externally applied on wounds.</td>
</tr>
<tr>
<td>32</td>
<td><em>Tylophora indica</em> (Burm.f) Merr. / Asclepiadaceae / RRIUM CH-9909</td>
<td>Anantamul</td>
<td>Velaipalai</td>
<td>Latex externally applied on cut injuries.</td>
</tr>
<tr>
<td>33</td>
<td><em>Wrightia tinctoria</em> R.Br. / Apocynaceae / RRIUM CH-8880</td>
<td>Inderjo shirin</td>
<td>Veppalai</td>
<td>1. Leaves are soaked in coconut oil for one month and applied on chronic wounds. 2. The latex externally applied for delivery wounds.</td>
</tr>
</tbody>
</table>
Table 2: Pharmacological action of the plants/parts on wounds healing.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Botanical Name</th>
<th>Wound &amp; related therapies practiced in folk medicine</th>
<th>Plant part, extracts and animal models used</th>
<th>Studied wound healing/related activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><em>Acalypha indica</em> L.</td>
<td>Skin diseases and Wound healing</td>
<td>Alcoholic extract of whole plant in excision and incision rat models.</td>
<td>Wound healing activity (Suresh Reddy <em>et al.</em>, 2002).</td>
</tr>
<tr>
<td>2</td>
<td><em>Adhatoda zeylanica</em> Medic.</td>
<td>Wound healing properties and Asthma</td>
<td>Phytochemical activities of leaves wound healing in Swiss albino mice</td>
<td>Wound healing activity (Subhashini <em>et al.</em>, 2010).</td>
</tr>
<tr>
<td>3</td>
<td><em>Aloe vera</em> (L.) Burm.f.</td>
<td>Skin diseases and Wound healing</td>
<td>Crude extract of Plant in rates</td>
<td>The wound-healing effect of a glycoprotein (Choi <em>et al.</em>, 2001).</td>
</tr>
<tr>
<td>4</td>
<td><em>Aristolochia indica</em> L.</td>
<td>Wound healing and skin diseases</td>
<td>The ethanol extract of the shade-dried leaves wound healing in rats</td>
<td>Wound healing activity (Shirwaikar <em>et al.</em>, 2003).</td>
</tr>
<tr>
<td>5</td>
<td><em>Calotropis gigantean</em> (L.) R. Br.</td>
<td>Earache, Wound healing toothache and headache, sprain, stiff joints and pains</td>
<td>Ethanolic extract of the flowers in acetic acid induced writhing and hot plate test in mice.</td>
<td>Analgesic activity (Pathak and Argal, 2007).</td>
</tr>
<tr>
<td>6</td>
<td><em>Datura fastuosa</em> L.</td>
<td>Wound healing and asthma</td>
<td>Ethanol extract of aerial parts of on Wistar albino rats</td>
<td>Wound healing activity (Vimal <em>et al.</em>, 2009).</td>
</tr>
<tr>
<td>7</td>
<td><em>Euphorbia hirta</em> L.</td>
<td>Wound healing activity</td>
<td>Ethanolic extract of leaves in rats.</td>
<td>Wound healing activity (Sharma and Sikarwar, 2008).</td>
</tr>
<tr>
<td>8</td>
<td><em>Ocimum tenuiflorum</em> L.</td>
<td>Wound healing and cough</td>
<td>Alcoholic and aqueous extract of leaves in rates</td>
<td>Wound healing activity (Shetty <em>et al.</em>, 2008).</td>
</tr>
<tr>
<td>10</td>
<td><em>Terminalia arjuna</em> (Roxb. ex DC.) W&amp;A.</td>
<td>Wound healing and teeth ache</td>
<td>Photochemical constituents for wound healing</td>
<td>Wound healing activities (Chaudhari and Mengi, 2006).</td>
</tr>
</tbody>
</table>
Acknowledgements

The authors are grateful to the Director General, Central Council for Research in Unani Medicine (CCRUM), New Delhi and Deputy Director, Regional Research Institute of Unani Medicine, Chennai, for providing necessary facilities. Thanks are also due to the Principal Chief Conservator of forests, Tamil Nadu and District Forest Officer, Kanniakumari district, for granting permission to conduct survey in the forest areas. First-hand information provided by Kani tribal ‘medicine men’ is gratefully acknowledged.

References


Standardization of Habb-Ul-Aas (Myrtus communis Linn., Fruits): A Unani drug**

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Abstract

Habb-ul-Aas botanically known as Myrtus communis Linn., belongs to family Myrtaceae. The fruit is one of the important single drugs used in Unani System of Medicine. Fruit contains the wide range of phyto-constituents and therapeutically used in the ailments of diarrhea, dysentery, internal ulceration, rheumatism, bronchitis, cough, palpitation and headache. Present study was aimed to authenticate the fruit of Myrtus communis and to evaluate its scientific standards by employing pharmacognostical, physico-chemical and quality control methods. Microscopic studies show the presence of schizolysigenous oil glands in the surface view of epidermal cells, mesocarpic parenchyma cells, stone cells, druses of calcium oxalate crystals and cotyledonary parenchyma cells. The fruit contains moisture (14.62%), total ash (3.54%), acid in-soluble ash (0.25%) and solubility in alcohol (21.65%) and water (25.56%). TLC studies of chloroform and alcohol extracts show various spots at 254nm, 366nm and visible light (Vanillin – Sulphuric acid reagent). The quality control parameters such as microbial load, heavy metal, aflatoxins and pesticidial residues were not detected from the drug.

Key words: Habb-ul-Aas, Myrtus communis L., Pharmacognostical, Physico-chemical, Quality control methods.

Introduction

Herbal medicines are prepared using a variety of plant materials like leaves, stem, roots, barks, fruits and seeds. Plant material contains many biological active ingredients which are responsible for treating mild or chronic ailments. As the plant materials have many therapeutic values, they have to be investigated using modern sophisticated analytical instruments and also by employing the scientific parameters. To ascertain the quality of a drug three attributes viz. authenticity, purity and assay are desirable.

Habb-ul-Aas is an important herbal drug used in Unani system of medicine to cure the variety of ailments like gastric ulcer, diarrhea, dysentery, vomiting, deep sinus, leucorrhoea and also for cosmetic purpose (like hair fall control) (Sabiha et al., 2011). The drug is used in the preparation of various Unani

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Fruit contains many phyto-chemicals like citric acid, malic acid, resin, tannin, fixed oil, phenols, flavonoids, anthocyanins, arabinosides, kaempferol, quercetin, myricetin, caffeic acid, myricetin 3-O-rhamnoside, esculetin-6-O-glucoside, hesperetin-7-O-rhamnoglucoside, hesperetin-2-O-methylchalcone-4-O-rhamnoglucoside (Montoro et al., 2006; Hinou et al., 1988; Martin et al., 1999). The reported various pharmacological activities like anti-oxidant (Serce et al., 2010), anti-diabetic, anti-mutagenic and anti-microbial activity have been proved the therapeutic efficacy of the drug (Sabiha et al., 2011).

Present study was an attempt to standardize the drug by employing pharmacognostical, physico-chemical and quality control parameters to ascertain the quality of fruit of Habb-ul-Aas.

**Materials and Methods**

(i) Collection of the plant material

Raw drug samples were procured from different raw drug dealers of Chennai, Hyderabad and New Delhi. The fruits (Chennai –DSM70A-; Hyderabad – DSM70B-; New Delhi – DSM70C) were authenticated by the botanist and deposited in the Museum of Drug Standardization Research Unit, Regional Research Institute of Unani Medicine, Chennai, Tamil Nadu, India.

(ii) Pharmacognostical studies

Botanical identification of the fruit was carried out using available literature (Brandis D, 1988; Kritikar and Basu, 1998). The pharmacognostical studies viz. macroscopic, microscopic and powder microscopy were carried out using standard method (Johansen, 1940). Free hand sections of the fruit were taken and microscopical drawings were made using Camera Lucida and observations were recorded.

(iii) Physico-chemical parameters

Physico-chemical parameters like foreign matter, total ash, acid in-soluble ash, loss on drying at 105°C, solubility in alcohol and water were carried out as per standard method (Anonymous, 1987).
TLC analysis

(i) Preparation of extract

Powdered drug samples (2g) soaked in chloroform and alcohol separately for 24 hours and filtered. The filtrates were concentrated and made up to 5 ml in standard flask separately.

(ii) Method of developing the plates

Chloroform and alcohol extracts were applied on precoated silica gel 60 F$_{254}$ TLC plate (E Merck) as absorbent and developed the plates using the solvent systems toluene : ethyl acetate (9 : 1) and chloroform : methanol (19 : 1) respectively (Wagner, 1984).

(iii) Quality control parameters

The parameters like microbial load, heavy metals, aflatoxin and pesticide residues were carried out using standard methods of WHO and AOAC guidelines (Anonymous, 1998 and 2000).

Results and Discussion

Macroscopic: Fruits berry, small, black, ellipsoidal or globose up to 13mm length and 9mm width with 4 to 5 partite persistent calyx at the top; surface wrinkled; seeds 1 to many seeded each seed ivory or pale yellow to white, very hard, looks like reniform, length up to 4mm and breadth up to 3mm (Fig. 1), taste sweet and no characteristic odour.

Microscopic

*Calyx*: T. S. of persistent calyx (Fig. 2) shows a single layer of epidermal cells on both the surfaces, cortex consisting of several layers of polygonal parenchyma cells, schizolysigenous oil glands and druses of calcium oxalate crystals present, vascular tissue present in the centre.

*Fruit*: T. S. of fruit (Fig. 3) circular in outline; an epicarp with epidermis single layered, consisting of small, thick walled, polygonal parenchyma cells covered with a thin layer of cuticle; mesocarp consisting of three different zones (Fig. 4), outer zone consisting of 2 to 4 layers of rectangular, thick walled, polygonal parenchyma cells; middle zone consisting of big cells of oval to polygonal, thin walled, parenchyma cells with intercellular spaces; most of the mesocarpic
cells filled with reddish brown contents; a vascular bundles found scattered in the mesocarpic regions; inner zone consisting of few layers of thin walled, small, parenchyma cells compare to the other region; numerous druses of calcium oxalate crystals scattered in this region; schizolysigenous oil glands present in the epicarp and mesocarp region; endocarp (Fig. 5) consisting of 10 to 15 layers of thick walled stone cells; cotyledons consisting of compactly arranged polygonal parenchyma cells with a single layer of epidermis on both the surfaces, cotyledonary parenchyma cells filled with aleurone grains and oil globules.

*Powder:* Pale brown; epidermal cells in surface view (Fig. 6), mesocarpic parenchyma cells in surface view (Fig. 7), stone cells of length upto 150μ and breadth upto 70μ (Fig. 8); druses of calcium oxalate crystals upto 30μ (Fig. 9); cotyledonary parenchyma cells in surface view (Fig. 10) and spiral vessels upto 10μ (Fig. 11).

Physico-chemical parameters

Moisture content of the drug shows 14.62% and alcohol soluble extractives (21.65%) might be due to the extraction of polar constituents. Water soluble extractives (25.63%) indicate the presence of inorganic constituents. Physico-chemical data of the drug are shown (Table –1).

Thin Layer Chromatography analysis

Thin Layer Chromatographic studies of chloroform and alcohol extracts of all the three region samples showed identical spots in various detectors. The Rf values of both the extracts were tabulated in Table 2 & 3.

Quality control parameters

The microbial contents were found to be within the permissible limit (Table – 4). The other parameters such as heavy metals, aflatoxin and pesticide residue were not detected from the drug (Table – 5, 6 & 7) which indicates the drug is free from toxic substances.
HABB-UL-AAS (*Myrtus communis* Linn.)

**Fruit**

Fig. 1 - Surface view

- Entire Fruit
- Seed

1 cm

Fig. 3 - T.S. of Fruit

A Diagramatic Sketch

**T. S. of Fruit**

Fig. 4 - Epicarp and Mesocarp

- Epidermis
- Oil gland
- Outer mesocarp
- Middle mesocarp
- Vascular bundle
- Druses
- Inner mesocarp

100 μ

Fig. 2 - T. S. OF CALYX

- Epidermis
- Vascular tissue
- Cortex
- Druses

100 μ

Fig. 5 - T. S. OF SEED

- Stone cells
- Cotyledonary parenchyma
- Vascular tissue

100 μ
HABB-UL-AAS (*Myrtus communis* Linn.)

Fruit

**Powder**

**Fig. 6 - Epidermal cells in surface view**

**Fig. 7 - Mesocarpic parenchyma cells in surface view**

**Fig. 8 - Druses of calcium oxalate crystals**

**Fig. 9 - Stone cells**

**Fig. 10 - Cotyledonary parenchyma cells in surface view**

**Fig. 11 - Spiral vessels**
Table 1: Physico-chemical parameters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Source of samples</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chennai Mean value</td>
<td>Hyderabad Mean value</td>
<td>Delhi Mean value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign matter (% W/W)</td>
<td>Nil</td>
<td>--</td>
<td>Nil</td>
<td>--</td>
<td>Nil</td>
</tr>
<tr>
<td>Total ash (% W/W)</td>
<td>3.29 3.53 3.84</td>
<td>3.55 3.45 3.58</td>
<td>3.55 3.42 3.54</td>
<td>3.52</td>
<td></td>
</tr>
<tr>
<td>Acid in-soluble ash (%W/W)</td>
<td>0.25 0.26 0.27</td>
<td>0.26 0.23 0.27</td>
<td>0.26 0.21 0.23</td>
<td>0.23</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Rf Values of chloroform extract

<table>
<thead>
<tr>
<th>Solvent system &amp; Detector</th>
<th>Rf Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>UV 254nm</td>
<td>UV 366nm</td>
</tr>
<tr>
<td>0.93 Pink</td>
<td>0.83 Light blue</td>
</tr>
<tr>
<td>0.82 Pink</td>
<td>0.63 Red</td>
</tr>
<tr>
<td>0.72 Light pink</td>
<td>0.49 Blue</td>
</tr>
<tr>
<td>0.67 Light pink</td>
<td>0.38 Red</td>
</tr>
<tr>
<td>0.53 Yellowish green</td>
<td>0.19 Violet</td>
</tr>
<tr>
<td>0.42 Violet</td>
<td></td>
</tr>
<tr>
<td>0.36 Yellowish green</td>
<td></td>
</tr>
<tr>
<td>0.28 Pink</td>
<td></td>
</tr>
<tr>
<td>0.19 Pink</td>
<td></td>
</tr>
</tbody>
</table>

Toluene: Ethyl acetate (9 : 1) V. S. reagent

A – Chennai; B – Hyderabad; C - Delhi
### Table 3: R<sub>f</sub> Values of alcohol extract

<table>
<thead>
<tr>
<th>Solvent system &amp; Detector</th>
<th>UV 254nm</th>
<th>UV 366nm</th>
<th>Visible light (V. S. Reagent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloroform : Methanol (19 : 1) V. S. reagent</td>
<td>0.84 Light pink</td>
<td>0.84 Light blue</td>
<td>0.84 Violet</td>
</tr>
<tr>
<td></td>
<td>0.56 Light pink</td>
<td>0.31 Blue</td>
<td>0.76 Grey</td>
</tr>
<tr>
<td></td>
<td>0.23 Pink</td>
<td>0.17 Light blue</td>
<td>0.45 Light grey</td>
</tr>
<tr>
<td></td>
<td>0.17 Yellowish green</td>
<td></td>
<td>0.35 Grey</td>
</tr>
<tr>
<td></td>
<td>0.12 Yellowish green</td>
<td></td>
<td>0.23 Violet</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.12 Grey</td>
</tr>
</tbody>
</table>

A – Chennai; B – Hyderabad; C - Delhi

### Table 4: Microbial load

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Parameter Analyzed</th>
<th>Results</th>
<th>WHO Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Total Bacterial Count</td>
<td>2,600 CFU / gm</td>
<td>105 CFU / gm</td>
</tr>
<tr>
<td>2</td>
<td>Total Fungal Count</td>
<td>Nil</td>
<td>103 CFU / gm</td>
</tr>
<tr>
<td>3</td>
<td>Enterobacteriaceae</td>
<td>Absent</td>
<td>103 CFU / gm</td>
</tr>
<tr>
<td>4</td>
<td>Salmonella Spp.</td>
<td>Absent</td>
<td>Nil</td>
</tr>
<tr>
<td>5</td>
<td>Staphylococcus aureus</td>
<td>Absent</td>
<td>Nil</td>
</tr>
</tbody>
</table>

### Table 5: Heavy metals

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Parameter Analyzed</th>
<th>Results</th>
<th>WHO &amp; FDA Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Arsenic</td>
<td>Nil</td>
<td>10 ppm</td>
</tr>
<tr>
<td>2</td>
<td>Cadmium</td>
<td>Nil</td>
<td>0.3 ppm</td>
</tr>
<tr>
<td>3</td>
<td>Lead</td>
<td>0.0142 ppm</td>
<td>10 ppm</td>
</tr>
<tr>
<td>4</td>
<td>Mercury</td>
<td>Nil</td>
<td>1.0 ppm</td>
</tr>
</tbody>
</table>

### Table 6: Estimation of Aflatoxins

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Aflatoxins</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>B1</td>
<td>Not detected</td>
</tr>
<tr>
<td>2</td>
<td>B2</td>
<td>Not detected</td>
</tr>
<tr>
<td>3</td>
<td>G1</td>
<td>Not detected</td>
</tr>
<tr>
<td>4</td>
<td>G2</td>
<td>Not detected</td>
</tr>
</tbody>
</table>
Table 7: Analysis of Pesticide Residues

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Pesticide Residues</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Organo Chlorine Group</td>
<td>ND</td>
</tr>
<tr>
<td>2</td>
<td>Organo Phosphorus Group</td>
<td>ND</td>
</tr>
<tr>
<td>3</td>
<td>Acephate</td>
<td>ND</td>
</tr>
<tr>
<td>4</td>
<td>Chlordane</td>
<td>ND</td>
</tr>
<tr>
<td>5</td>
<td>Dimethoate</td>
<td>ND</td>
</tr>
<tr>
<td>6</td>
<td>Endosulphan</td>
<td>ND</td>
</tr>
<tr>
<td>7</td>
<td>Endosulfan</td>
<td>ND</td>
</tr>
<tr>
<td>8</td>
<td>Endosulfon</td>
<td>ND</td>
</tr>
<tr>
<td>9</td>
<td>Ethion</td>
<td>ND</td>
</tr>
<tr>
<td>10</td>
<td>Endosufon sulphate</td>
<td>ND</td>
</tr>
<tr>
<td>11</td>
<td>Fenthion</td>
<td>ND</td>
</tr>
<tr>
<td>12</td>
<td>Lindane</td>
<td>ND</td>
</tr>
<tr>
<td>13</td>
<td>Methoxychlor</td>
<td>ND</td>
</tr>
<tr>
<td>14</td>
<td>Phorate sulfoxide</td>
<td>ND</td>
</tr>
<tr>
<td>15</td>
<td>Phorate sulfone</td>
<td>ND</td>
</tr>
<tr>
<td></td>
<td>ND – Not detected</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion

The pharmacognostical parameters which are reported for the first time will be useful in setting some diagnostic indices for the identification of the fruit of Habb-ul-Aas. Results of the comparative study on physicochemical, TLC and quality control parameters of three region samples will help to lay down the pharmacopoeial standards.

Acknowledgement

The authors are extremely thankful to the Director General, CCRUM, New Delhi, for providing necessary research facilities.

References


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