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CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE
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Contents

Editorial

In recent decades, traditional medicines have acquired major role as important therapeutics across the globe, and this had led to the phenomenal growth in their demand. And with this, issues of their quality, safety and efficacy have received renewed attention of scientists. All these ongoing investigations in India and abroad have generated lot of new research data in recent times, and there is an enormous need for exchange of this vital information amongst academicians and researchers engaged in the scientific validation of traditional drugs, particularly the Unani medicine. In this context, Central Council for Research in Unani Medicine, through its clinical, drug research, literary research, survey & cultivation of medicinal plants programme is contributing significantly for over three decades. *Vitiligo, sinusitis, filariasis, eczema, malaria, infective hepatitis, asthma* are some of the conditions where Unani therapies have earned recognition.

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 had 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, 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 14 original and review papers in the areas of: *Clinical research, Experimental pharmacology, Drug standardization, Pharmacy, Ethnopharmacology* 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.

June 25, 2016

(Prof. Rais-ur-Rahman)
Editor-in-Chief

Clinical Efficacy of Kalonji (*Nigella sativa* Linn. Seed) in Primary Dysmenorrhoea

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Abstract

Primary dysmenorrhoea (*Usr-e-Tams Ibtedayee*) refers to the occurrence of painful menstrual cramps of uterine origin during menstruation in the absence of an identifiable pathological lesion. It is widely prevalent, as more than 70% of teenagers and 30-50% of menstruating women suffer from varying degree of discomfort. Only 5-15% is severely incapacitated. It affects more than 50% of post pubescent women in the age group of 18-25 years. It is common in adolescent and characterized by spasmodic pain beginning with onset of menstruation and lasting 12-24 hrs. In spite of the prevalence of this disease at mass level, the choice of treatment available in western medicine is comparatively few. Even the drugs available for the purpose are not devoid of major side effects. *Tibb-e-Unani* claims to possess a number of effective and safe therapeutic agents that are commonly used in the treatment of primary dysmenorrhoea. But most of them, despite being used successfully in the therapy, have yet not been scientifically studied. Therefore, in the present study an attempt has been made to evaluate a single Unani drug *Nigella sativa* Linn seed (Kalonji) on 30 patients for its efficacy in primary dysmenorrhoea. The patients were treated with powder of the test drug, in a dose of 2 gm, by oral route, twice a day for seven days, starting 2 days before the onset of menstruation up to 5th day of menses, for three consecutive cycles. Patients treated with the test drug showed significant reduction in important clinical features such as pain in suprapubic region, pain in thigh, backache and headache. The findings suggested that Kalonji is effective in ameliorating the primary dysmenorrhoea.

Keywords: Primary dysmenorrhoea, *Nigella sativa*, Kalonji, *Usr-e-Tams Ibtedayee*

Introduction

Primary dysmenorrhoea (*Usr-e-Tams Ibtedayee*) a common gynaecological complaint, refers to the occurrence of painful menstrual cramps of uterine origin during menstruation in the absence of an identifiable pathological lesion (Khodakrami *et al.,* 2009; Kumar & Malhotra, 2008; Dutta, 2013; Berek, 2007). In classical Unani literature, it has been described that *Usr-e-Tams* (dysmenorrhoea) is a type of *Waja-e-Rahem* (uterine pain) that develops due to menstruation. It has been described to be a disease in which pain is felt in lower abdomen or pelvic region. It may be due to *iltihab-e-rahem* (metritis), *warm-e-gisha-e-batan-e-rahem* (endometritis), *iltihab-e-safaq-e-rahem* (perimtritis), *basur-e-rahem* (uterine eruption), *dubayala* (uterine abscess), *nasurrahem* (uterine

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fistula), *quruhrahem* (uterine ulcer), *shiqaque* (rupture of uterus), *bawasirrahem* (uterine polyp), *sula'arahem* (uterine tumor), *Inqalab* (inversion), *izm-e-rahem* (uterine hypertropy), *sartan* (uterine cancer), *insedad-e-fam-e-rahem* (atresia of os) etc (Azmi, 1995). It may be due to *riyah* (flatulence), *sil* (tuberculosis), *muhase* (acne), *masse* (warts), *sailanekhoon* (bleeding), *rataque* (cryptomenorrhoea), *mailanerahem* (displacement of uterus), *khula* (laxation), *ehtebas-e-tams* (amenorrhoea) etc (Razi, 2001); also due to different types of *su-e-mizaj* (distemperaments), *ratubat* (fluids) and complications of previous illness etc. (Ibn Sina,1992). The uterine pain (*Waja-e-rahem*) also occurs during menstruation and after labour (Khan, 2011).

Dysmenorrhoea (*Usr-e-Tams*) is derived from the Greek word Dys, meaning difficult/ pain/ abnormal; mens meaning month and rrhoea meaning flow (Zaidi *et al*., 2012). Thus it means painful menstruation (Khan, 2000). It is a major cause of absenteeism from work thus decreasing efficiency and quality of life among the affected women (Sabaratnam *et al*., 2005; Babli *et al*., 2000). It is a common gynaecological complaint (Saraiya *et al*., 2003), with severe painful cramping sensation in the lower abdomen. It is often accompanied by other associated symptoms including sweating, tachycardia, headache, nausea, vomiting and diarrhoea, all occurring before or during the menstruation (Berek, 1996). It is of two types. If the pain is of uterine origin and linked to menstruation but without any visible pelvic pathology, it is known as primary (*Ibtedayee*) or true dysmenorrhoea, and if the pain is associated with pelvic pathology it is said to be secondary (*Saanwi*) dysmenorrhoea (Khan, 2000).

Primary dysmenorrhoea (*Usr-e-Tams Ibtedayee*) is widely prevalent disorder among the younger women. More than 70 % of teenagers and 30 to 50% of menstruating women suffer from varying degree of discomfort. Only about 5-15% of population is affected by severe incapacitating type which interferes with women's daily activities. It is common in adolescent and characterized by spasmodic pain beginning with onset of menstruation and lasting 12-24 hrs (Padubidri and Daftary, 2008). It usually appears within 1-2 years of menarche, when ovulatory cycles are established. The disorder affects the younger women but may persist into the 40s (Berek, 2007). It affects more than 50% of post pubescent women in the age group of 18-25 years (Padubidri and Daftary, 2008). The pain is felt mainly in hypogastrium and is often referred to inner and front aspects of thighs (Kumar & Malhotra, 2008). Other symptoms are uterine cramping, nausea, vomiting, backache, diarrhoea, giddiness, syncope and fainting. It is now clear that the pathogenesis of pain is attributable to biochemical derangement (Padubidri and Daftary, 2008). Prostaglandin (PG) and arachidonic acid metabolites play an important role in in the causation of dysmenorrhea (Khodakrami *et al*., 2009).

In spite of the high prevalence of dysmenorrhoea, the choice of treatment available in modern medicine is comparatively less. Even the drugs available for the purpose are not devoid of side effects.The disease is usually treated with prostaglandin synthetase inhibitor (NSAID) and oral contraceptives which have their own side effects like headache, peptic ulceration, gastric irritation, erosion, chronic renal failure, hepatic failure, bleeding, skin rashes, asthma, weight gain, hypertension, vascular complications etc. (Tripathi, 2008). Such a situation warrants some alternative treatment of primary dysmenorrhoea. A number of Unani drugs are used successfully to manage *Usr-e-Tams* since long but their scientific evaluation has not been carried out so far. *Nigella sativa* seed (Kalonji) is one such drug that possesses *musakkin* and *dafealam* (analgesic) (Abdul Hakim, 2011), *mudirr-e-haiz* (emmenagogue), *mudirr-e-bol* (diuretic) *muhallil-e-warm* (anti-inflammatory) properties and described to be effective in *Usr-e-Tams* (Ghani, 2011). Therefore, a comprehensive study schedule has been designed to evaluate its efficacy in primary dysmenorrhoea.

Materials and Methods

The patients who visited the OPD of department of Ilmul Qabalat wa Amraz-e-Niswan, Mohammadia Tibbia College and Assayer Hospital, Mansoora, Malegaon, Nasik during 2014-2015, were screened for the primary dysmenorrhoea on the basis of clinical signs and symptoms.

After taking the informed consent, 60 diagnosed patients of 14-37 years of age group were included in the study. They were informed about the disease, examination performed and type of treatment given. The patients suffering from hormonal & metabolic disorders, any organic pelvic pathology, sensitivity to NSAID and any systemic diseases like Hypertension, Diabetes mellitus and sexually transmitted disease, were excluded from the study. The Institutional Ethics Committee (IEC) granted the permission to conduct the study. The patients were divided into two groups of 30 patients each with the help of computer randomized tables/ numbers (Table 1). The patients in group I were treated with one Tab of Combiflam (Paracetamol 325 mg + Ibuprofen 400 mg), by oral route, once a day after meal from beginning of menstruation up to seven days, for three

Table 1: Treatment Schedule

Group	Drug Treatment	Dose	Duration
Group I	Combiflam (PCM 325 mg + Ibuprofen 400 mg)	I Tab x OD	7 Days x 3 Menstrual Cycle
Group II	*Nigella sativa* Linn. seed (Kalonji) Powder	2 sgm x BD	7 Days x 3 Menstrual Cycle

consecutive menstrual cycles. This group served as standard group. The patients in group II were treated with powder of *Nigella sativa* seed, in a dose of 2 gm, by oral route, twice a day for seven days, starting before 2 days of menstrual period upto 5th day of menses, for three consecutive cycles and served as test group (Table 1). *Nigella sativa* seed was procured from local market of Malegaon, dried at room temperature and reduced to coarse powder by grinding.

The patients were advised for follow up before and after menstrual period of three consecutive cycles. The progress of each patient was recorded. The patients were carefully interviewed at each visit and their statement about the painful menstruation, pain in suprapubic region, thighs, back: nausea, vomiting, diarrhoea, headache and syncope / fainting were recorded.

Certain investigations such as Hb%, TLC, DLC, ESR, Random Blood Sugar, Blood Urea, Serum Creatinine, SGOT. SGPT, Alkaline Phosphatase, VDRL, Pelvic USG, Urine & Stool examination and Pap smear in selected cases were done to establish the safety of the drug and to exclude the patient afflicted with other than primary dysmenorrhea. These investigations were carried out before starting and after stopping the treatment.

All the symptoms and signs were graded on points scale and the changes were noted in case record form (CRF) on every follow up. The findings or clinical observations were tabulated on a computerized format. Finally, recorded findings were statistically analyzed using Chi square test.

Results and Discussion

The test drug was studied for its efficacy in the management of primary dysmenorrhoea. The clinical findings were tabulated, analysed and compared with the standard drug Combiflam (Table 2). On the day of registration pain in suprapubic region was found in all (100%) patients included in the study, while after treatment it was found significantly decreased, as only 36.66% and 46.66% of the patients in group I and II, respectively had the pain. It means pain was relieved in 63.33% and 53.33% of the cases in group I and II, respectively. Pain in thigh on day zero was found in 80% and 100% of the cases in group I and II, respectively, whereas after treatment it decreased significantly and 66.66% and 73.33% of the cases were relieved, respectively. Backache on day zero was found in 76.66% patients in both the groups, whereas after treatment only 21.73% and 60.86% of the patients of group I and II, respectively were having this problem. Prior to the treatment headache was found in 16.66% and 20% of the patients in group I and II, respectively, which reduced in group II and disappeared in group I after the treatment. On day zero, nausea / vomiting was found only in 6.66% and 13.33% of the cases in group I and II, respectively. After treatment

Table 2: Effect of standard and test drugs on clinical features

Clinical Features	Group I (Standard Control)						Group II (Test)					
	Baseline		Post treatment		Improve-ment		Baseline		Post treatment		Improve-ment	
	No	%	No	%	No	%	No	%	No	%	No	%
Pain in suprapubic region	30	100	11	36.66	19	63.33	30	100	14	46.66	16	53.33
Pain in thigh	24	80	08	33.33	16	66.66	30	100	08	26.66	22	73.33
Backache	23	76.66	05	21.73	18	78.26	23	76.66	14	60.86	09	39.13
Headache	05	16.66	Nil	00	05	100	06	20	01	16.66	05	83.33
Nausea/Vomiting	02	6.66	01	50	01	50	04	13.33	04	100	Nil	00
Syncope	01	3.33	Nil	00	01	100	01	3.33	01	100	Nil	00

in test group, I it was found absent in 50% of the patients but no improvement was recorded in the test group. Prior to the treatment syncope was found only in 3.33% of the patients in group I & II, which disappeared in standard group but no response was observed in test group after the treatment (Table 2).

The results of the study revealed that the *Nigella sativa* seed (Kalonji) is effective in relieving most of the clinical features of primary dysmenorrhea (*Usr-e-Tams Ibtedayee*), which is evidenced by decrease in pain of suprapubic region, thigh, back and head. All the parameters were found to be significantly improved suggesting that oral administration of *Nigella sativa* seed is effective in relieving the symptoms of dysmenorrhoea. Little or no response was observed in some of the symptoms such as nausea and syncope etc. Since it was not a generalized problem and very few patients were affected with these symptoms therefore it is possible that they may have arisen because of some reasons, other than the dysmenorrhoea. But the overall response of the drug was found significant. Thus, the study validated its therapeutic use as proposed by Unani physicians, in the treatment of primary dysmenorrhoea.

The test drug Kalonji was found almost as effective as the standard drug in relieving most of the symptoms. The effect of *Kalonji* may be attributed to its *mudirr-e-bol* (diuretic), *mudirr-e-haiz* (emmenagogue), *muhallil-e-warm* (anti-inflammatory) (Ghani, 2011), *musakkin* and *dafe alam* (analgesic) (Abdul Hakim, 2011) properties. In various scientific studies it has been shown to possess anti-inflammatory (Prajapati *et al*., 2003), emmenagogue, diuretic (Anonymous, 1996), analgesic, immune stimulant (Randhava, 2008) and immunomodulatory (El-Kadi & Kandil, 1987) actions. Thymoquinone isolated from *Nigella sativa* seed is reported to inhibit the generation of thromboxane A_2 and leukotriene B_4, thus suggesting an inhibitory effect on both the cyclo-oxygenase and lipo-oxygenase

pathway (El-Dakhakhny*et al*., 2002). Studies have shown that inhibition of prostaglandin synthesis occurs through the inhibition of cyclo-oxygenase enzyme (Sultana *et al*., 2010). Prostaglandin (PG) and arachidonic acid metabolites play an important role in the pathogenesis of dysmenorrhea (Khodakrami *et al*., 2009). The intensity of menstrual cramps and associated symptoms are directly proportional to the amount of PGF_2 á released. Maximum amount of prostaglandin is released during the first two days of menstrual cycle, which is equal to the time of greatest discomfort (Sultana *et al*., 2010). Prostaglandins are known to increase myometrium contractions and also constrict small endometrial blood vessels which produce ischemia and breakdown of endometrium, bleeding and pain. Increase level of prostaglandin E_2 has been reported to increase the sensitivity of the nerve endings to pain (Kumar & Malhotra, 2008) which may be one of the reasons for dysmenorrhoea. Women suffering from this pain have high concentration of PGF_2 in menstrual blood. PGE_2 causes uterine contractions, cervical narrowing; increases vasopressin release which causes ischemia and pain. Thus, suppression of PG synthesis cures the problem (Khodakrami *et al*., 2009). Although the exact mechanism through which the test drug acts has not been described in Unani literature but the pharmacological actions described in Unani medicine have been verified by many workers suggesting that the basis of treatment as described in classical Unani literature is in conformity with the recent scientific reports. Therefore the mechanism of action suggested in a number of studies (El-Dakhakhny *et al*., 2002; Sultana *et al*., 2010; Khodakrami *et al*., 2009) may be the pharmacological basis of its efficacy in cases of dysmenorrhoea.

Conclusion

In the light of the above finding and discussion, it can be concluded that *Nigella sativa* seed (Kalonji) is effective and safe in relieving the symptoms of *Usr-e-Tams Ibtedayee* primary (dysmenorrhea). Thus the study validated the claim of Unani medicine that 'Kalonji' because of being analgesic, anti-inflammatory and emmenagogue etc. is effective in the management of dysmenorrheal complaints.

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Acute Toxicity Study of Aqer Qerha (*Anacyclus pyrethrum* DC.) Root in Swiss Albino Mice

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Abstract

Aqer Qerha (root of *Anacyclus pyrethrum* DC.) is a well known drug of Unani system of medicine used commonly in the diseases of nervous system and those related to sexuality. Although few side effects have been related to it in the literature but toxicity studies have not been conducted to prepare a toxicity/safety profile of the drug. In the present study, acute toxicity study of hydro alcoholic extract of *Aqer Qerha* root (HEAQ) was carried out in albino mice. HEAQ was administered orally to Swiss albino mice at various dose levels to determine acute toxic effects and the median lethal dose. The LD_{50} observed for the drug used by oral route was 3.579 g/kg, while the tolerated dose was 2.34 g/kg with no lethal effect. It was concluded that HEAQ is safe per orally.

Keywords: LD_{50}, *Anacyclus pyrethrum*, Albino mice, Hydro alcoholic extract, Acute toxicity.

Introduction

The drug *Aqer Qerha* consists of dried roots of *Anacyclus pyrethrum* DC., family Asteraceae (Anonymous, 2007). It is an important medicinal plant used in both Unani and Ayurvedic systems of medicine. It is a native to North Africa, cultivated in Mediterranean, and Arabian countries. It was introduced in India and now cultivated in a few regions like North India, Himalayas, and has been grown on an experimental scale at the elevation of 900 m at Katra (Jammu and Kashmir) (Anonymous, 985). In Unani System of Medicine it is used in the treatment of a number of diseases on account of having different pharmacological effects. It has been described to be muqawwi-e-bah (aphrodisiac), *muhallil-e-awram* (anti-inflammatory), *Moqawwi* and *moharrik-e-aasab* (tonic and stimulant of nerves), *mudire luabe dehan* (sialogogue), *munaqqi fuzlate dimagh* (eliminator of morbid matter from brain), *mufatteh sudad* (deobstuent) *mukhaddir* (anaesthetic) and *muhammir* (rubifecient). So it used in *laqwa* (facial paralysis), *falij* (hemiplegia), *sara* (epilepsy), *wajaul mafasil* (arthritis), *istirkha-e-luhat* (flaccidity of uvula), *luknat-e-zuban* (stammering), z*ofe bah* (erectile dysfunction), *wajaul asnan* (toothache), and in a number of diverse pathological conditions. It is used as a single drug and in combination of other drugs in different dosage forms including gargle, decoction, liniment, *majun*, oil etc. by Unani Physicians (Kalam 2015a; Ibn Baitar 1999; Kabiruddin; 2007, Ghani; 1971; Ibn Sina 1998; Razi 1991). It has been studied for its anticonvulsant (Kalam 2015b), local anaesthetic (Venkatakrishna, 2001), anti inflammatory (Bendjeddou, 2003), abortifecient (Duke, 2002), anti bacterial (Boulos, 1983), skeletal and visceral malformation

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in the foetuses, anabolic and aphrodisiac activities etc (Sharma *et al.,* 2009, Sharma *et al.,* 2010). Use of the drug in patients with insulin-dependent diabetes mellitus reduces the dose of insulin (Khare, 2007). Antidiabetic property of aquous extract of the plant has been evaluated in Alloxan induced diabetic rats (Tyagi et al., 2011). The inhibitory effect of chloroform extract of the root has also been found on tobacco induced mutagenesis. Its therapeutic activity has been described to owe mainly to an alkaloid 'pellitorine' (pyrethrine). *Aqer Qerha* is in use for quite sometimes for its interesting and diverse pharmacological and therapeutic effects and a number of preparations are available in the market in which it is included as an important ingredient. Unani physicians claim to manage many diseases with oral and local application of *Aqer Qerha.* A number of scientific studies have been conducted to demonstrate various pharmacological effects that it possesses. However, toxicity studies of this important and commonly sued drug have been scarcely conducted. Therefore the present study was undertaken to determine the acute toxicity of the hydro alcoholic extract of the root of *Aqer Qerha* in Swiss mice. Both the maximum tolerated dose and LD50 were calculated.

Material and Methods

Plant material

Samples of *Aqer Qerha* root were procured from the local market of Bangalore, Karnataka. Dr. Shiddamallayya N., Botanist at Regional Research Institute of Ayurveda, Bangalore, authenticated the samples. The identification certificate of the test drug samples was issued by the said botanist, under reference No.- SMPU/NADRI/BNG/Drug, Authentication/2009-10/942. The specimen of the plant material was retained in the RRI for reference purpose. A voucher specimen has been deposited at department of Ilmul Advia, National Institute of Unani Medicine, Bangalore.

Preparation of extract

The drug was pulverized in electric grinder at the pharmacy of NIUM, to prepare its coarse powder. Hydro alcoholic extract of the test drug was prepared with the help of Soxhlet apparatus. For this purpose 100 gm of powdered drug was extracted in 1:1 ethanol and distilled water (200 ml ethanol: 200 ml distilled water) at the temperature of 70-80^{o}C for 7 hrs. The liquid extract was cooled and filtered by Whatman filter paper 44, and then placed on a water bath until the entire solvent evaporated. The extract was weighed and the yield percentage was calculated with reference to the crude drug. The yield percentage of extract was found to be 16% w/w.

Animals

Adult Swiss mice of either sex, weighing 25-30 g were used for acute toxicity study. They were procured from Central Animal Research Facility (CARF) of National Institute of Mental Health and Neurosciences (NIMANS), Bangalore, India and housed in the Animal House Facility at NIUM, Bangalore. They were acclimatized to the laboratory condition for 5 days before starting the experimental studies. Animals were maintained in a standard environmental condition at a room temperature of 23 ± 2 ^{o}C with 12h light and 12h dark cycle. Food and water were provided *ad libitum*. The Institutional Animal Ethics Committee (IAEC), NIUM, Bangalore, Karnataka, approved the experimental protocol vide Reg. No 953/C/06/CPCSEA.

Methodology

Acute toxicity study was carried out as described by Gosh (1984). Six animals were taken in a group and test drug was administered initially in the dose of 600 mg/kg of body weight deduced through the extrapolation from human clinical dose after multiplying it with a factor of 12 for mice **(**Freirich et al., 1966). The dose was increased by 1.707 from previous dose till half the animals died in the group as described by Miller and Tainter (1944). The animals were observed for first 2 hours and then at 6th and 24th hours for any toxic symptoms and mortality. After 24 hours, the number of deceased rats was counted in each group and percentage of mortality was calculated. The dose at which half of the animals died was deduced from the log dose curve, which was considered as median lethal dose.

Table 1 : Acute toxicity study of hydro alcoholic extract of Aqer Qerha root in mice

Group	Dosage (mg/kg)	Log dose	Animals dead	Animals survived
Group 1	600	2.778	0	6
Group 2	920	2.963	0	6
Group 3	1360	3.133	0	6
Group 4	2010	3.303	1	5
Group 5	3040	3.483	2	4
Group 6	3800	3.579	3	3
Group 7	4000	3.602	3	3
Group 8	4200	3.623	6	0

N = 6 in each group

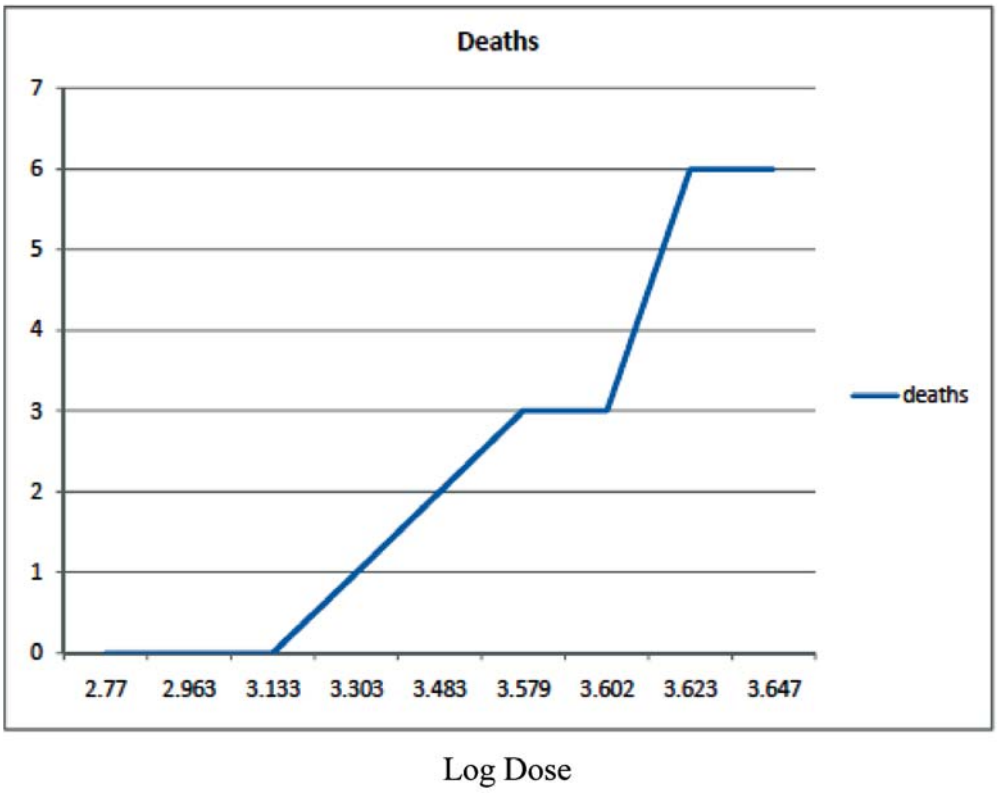

Figure 1: Acute Toxicity Study of HEAQ in mice

Observations and Results

On oral administration the drug was tolerated to the extent of 2.34 gm/kg, as no casualty was observed at this dose. The log dose of the lethal dose was found in the range between 3.579 and 3.602, so the mean of the log dose was fixed at 3.595 g/kg. The findings indicated that in therapeutic dose of the test drug which is much lower than the maximum tolerated dose is quite safe (Table 1 and Figure 1).

Discussion

Acute toxicity study indicates that HEAQ has no toxic effect at the dose it is used in clinical practice to treat the diseases. The maximum therapeutic dose for mice was calculated to be 600 mg/kg as per formula of Freirich et al (1966) taking maximum therapeutic dose for human as 3 g, while the tolerated dose of 2.34 g/kg is three times higher than this dose. The findings indicated that the therapeutic dose of *Aqer Qerha* is quite safe and even a higher dose may be used if a pathological condition requires so. The LD_{50} was determined to be 3.595 gm/kg. in mice, which is too high and indicates that therapeutic index will also be high and therefore the test drug will have wide therapeutic dose range. It validated the Unani description wherein the drug has been recommended to be

used in the range of 1-3 g (Usmani, 2008), though the physicians commonly use a lower dose. It has been found in many studies that the therapeutic dose as described in Unani literature and is practiced by the physicians failed to produce desired degree of pharmacological activity in experimental animals. However when the dose was increased the desired effect was produced. It indicates that Unani physicians probably to avoid the likely toxicity of a drug may have opted for a lower dose in clinical practice. This appears to be true in present study as well because a dose three times higher than the maximum human dose was found to be safe. The findings suggest that the test drug can be used in a wide therapeutic dose range and that the maximum dose may also be increased, but of course after proper clinical studies. In Unani literature the toxicity of drugs is usually described in a subjective way for example it is harmful for liver, kidney or lung etc in higher dose but exact toxic or lethal dose is generally not described. The present study categorically demonstrated the maximum tolerated dose and the median lethal dose. This will help to use the drug for maximum therapeutic effect without fear of any toxicity.

Conclusion

The tolerated oral dose of Aqer Qerha was found to be of 2.34 gm/kg in albino mice, while the LD_{50} was calculated to be 3.579 g/kg. The findings suggested that the test drug can be used safely in wide therapeutic dose range and that its maximum dose can be further increased for maximum therapeutic response.

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Clinical Evaluation of Unani Pharmacopoeial Formulation, *Habb-e-Shifa* in *Nazla-e-Har* (Common Cold) – A Preliminary Study

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Abstract

Habb-e-Shifa is a Unani Pharmacopoeial drug used frequently in Unani System of Medicine to treat many ailments. It has four ingredients, namely, Rewand chini, Zanjabeel, Samagh-e-Arabi and Tukhm-e-Jauzmasil as the main ingredient. The present study was carried out to evaluate the safety and efficacy of *Habb-e-Shifa* in the patients of *Nazla-e-Har* (common cold). In this study *Habb-e-Shifa* (pill) was given orally with water, in the dose of one pill BD up to 50kg of b.w. and 2 pills BD above 50kg b.w. for seven days. The safety was assessed clinically on the 3rd and 7th day of the treatment. There were no adverse effects recorded in the CRF and laboratory (biochemical and pathological) parameters done at the baseline and end of the study. The efficacy was assessed by measuring the reduction in the signs and symptoms associated with common cold. *Habb-e-Shifa,* significantly reduced the associated symptoms of common cold like sore throat (35.22%), hoarseness of voice (31.11%), sneezing (55.41%), running nose (48.46%), headache (51.94%), malaise (62.93%), flushing of face (67.00%) and fever (<102ÚF) (62.00%). Severity of the disease was evaluated with the visual analogue scale (VAS). The present study concludes that *Habb-e-Shifa* is a safe drug, in the given dosage levels, and has a potency to treat the common cold. It is also useful in alleviating sign and symptoms associated with common cold.

Keywords: Common cold, Habb-e-shifa, Antipyretic, Analgesic

Introduction

Nazla-o-Zukam (common cold) is one of the most frequent acute illnesses which commonly affects three to four times a year in adults. The disease is usually defined as “an acute inflammatory condition of upper respiratory tract involving nose, throat, sinuses and larynx (Davidson, 1999; Kumar and Clark, 1998). The disease is caused by infection of a wide range of viruses but 60-70% of cases are due to 200 antigenically distinct viruses from eight genera. The most common of these are rhinovirus (30-80%), coronavirus, (H”15%), influenza virus (10-15%) and adenovirus (5%) (Palmenberg et al., 2009; Pelczar, 2010; Eccles, 2005). On an average, individuals usually suffer one to three episodes of common cold in an year but the incidence decreases with age, presumably due to resistant to different virus strains (Davidson, 1999; Kumar and Clark, 1998).

Patient develops symptoms of the disease usually within one to two days of contact to a peak of the symptoms on second to fourth day of infection. Symptoms resolve within a period of 7-10 days. Patients may present with some

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or all of the following symptoms like Sore throat, Hoarseness of voice, Sneezing, Nasal discharge/ Nasal blockage, Headache, Cough, Malaise, Flushing of face and Low grade fever (Pelczar, 2010 and Eccles, 2005).

According to literature of Unani Medicine, common cold has been defined as a condition in which flow of catarrhal fluids from the anterior ventricles of brain towards nose and throat is increased. Some physicians have differentiated them by saying that the flow of these fluids towards nose is known as *Zukam* while the flow towards throat is known as *Nazla*.

The causes of *Nazla-o-Zukam* have been divided broadly into two main groups.

1. Predominance of *Hararat*, either intrinsic or extrinsic
2. Predominance of *Burudat*, either intrinsic or extrinsic

Accordingly, the disease has been classified into two types i.e. *Har* and *Barid*.

Nazla-e-Har: In this condition, symptoms of the disease are usually higher in intensity and include symptoms of predominance of heat like running nose with pricking/ burning sensation, thin watery nasal discharge, flushing of face, watering eyes, increased body temperature and excessive thrust (Ibn Sina, 1998; Jurjani, 1996; Qamari, 2008; Kabiruddin, 1925; Kabiruddin, 2003; Khan, ynm).

A detailed treatment of *Nazla-e-Har* (common cold) has been given by physicians of the system including its line of treatment according to the causative factors. Certain *Mufrad* (single) as well as *Murakkab* (compound) drugs along with some regimenal therapies, have been used extensively by these physicians. *Habb-e-Shifa* is one of such compound preparation used widely to relieve symptoms of *Nazla-e-Har* (common cold) quickly with a promising response. During this study, the cases of *Nazla-e-Har* were included only and the validation of drug *Habb-e-Shifa* was carried out in such cases (Ibn Sina,1998; Khan, ynm).

Objectives of the Study

- To assess the safety of Unani Pharmacopoeial formulation *Habb-e-Shifa* for symptomatic relief in the patients of *Nazla-e-Har* (common cold).
- To assess the efficacy of Unani Pharmacopoeial formulation *Habb-e-Shifa* for symptomatic relief in the patients of *Nazla-e-Har* (common cold).

Material and Methods

The study drug *Habb-e-Shifa* was procured from the CRIUM, Hyderabad. Composition of *Habb-e-Shifa* is given in table-1.

Table 1: Formulation of *Habb-e-Shifa* given in NFUM part 1st page no. 31

Sr.No.	Ingredients	Scientific names	Parts used	Quantity
1	Tukhm-e-Jauzmasil	*Datura stramonium* Linn.	Seed	6 parts
2	Rewand chini	*Rheum emodi* Wall.	Root	4 parts
3	Zanjabeel	*Zingiber officinale* Rosc.	Rhizomes	2 parts
4	Samagh-e-arabi	*Acacia nilotica* (L.) Willd. ex Del.	Gum	2 parts

Dosage and administration

All the patients were selected as per inclusion and exclusion criteria of *Nazla-e-Har* (common cold). Unani Pharmacopoeial Drug *Habb-e-Shifa* (pill) was given orally with water one pill BD up to 50kg of b.w. and 2 pills BD above 50kg b.w. for seven days. No concomitant treatment was given.

Place of study

The present open level study was carried out after obtaining the approval of Institutional Ethics Committee of RRIUM, Patna in the patients attending the GOPD at Regional Research Institute of Unani Medicine, Patna.

Selection of patients

The patients were selected on the basis of inclusion and exclusion criteria given below:

Inclusion criteria

1. The patients of either sex in the age group of 18-65.
2. Patients with recent onset of any of the following symptoms.
   - Khushuna al-Halaq (sore throat)
   - Buhha-al-Sawt (hoarseness of voice)
   - Utas (sneezing)
   - Suda (headache)
   - Sual (cough)
   - Runny nose
   - Iya (malaise)
   - Flushing of face
   - low grade fever (<102 ^{0}F)

Exclusion criteria

1. Patients of acute or chronic lower respiratory tract infection like Pneumonia, Bronchitis, Asthma and Bronchiectasis
2. Fever (>102^{0}F)
3. Known case of any other acute illness
4. Pregnant and lactating women
5. Known case of renal/Hepatic/Cardiac impairment or any disease requiring long term therapy

Safety assessment

The safety was monitored on the basis of the laboratory investigations CBC (Hb%, TLC, DLC, ESR), LFT (S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase), KFT (S. Urea, S. Creatinine, Uric acid) and Urine R/M done at baseline and at the end of the study. The safety of the drug was also assessed clinically on the basis of adverse events as reported by the patients or observed clinically on the follow up. No adverse effects of the Unani Pharmacopoeial drug *Habb-e-Shifa,* were observed during the course of study and at the end of the study, the drug was found safe in the patients of *Nazla-e-Har*.

Efficacy assessment

The patients were assessed clinically on 3rd and 7th day of the treatment and the efficacy of the Unani Pharmacopoeial drug *Habb-e-Shifa* was evaluated on the basis of reduction in the sign and symptoms as per mentioned in the CRF. The severity of symptoms were recorded in numbers as per the Visual Analogue Scale (VAS).

Statistical analysis

Clinical subjective parameters, pathological and biochemical parameters were statistically analyzed using student's ANOVA with Dunnett's Test and paired 't' test. The results were expressed as the Mean ± SEM. $P<0.05$ has been considered as statistically significant and $p<0.001$ has been considered as statistically highly significant.

Results and Discussion

In the present study, the maximum number of patients belonged to age group 18-29 years (48.28%). It was also found that maximum no. of patients were male 32 (55.17%) patients while 26(44.83%) patients were female (Table 2).

Table 2: Distribution of patients according to age and sex

Age Group (Years)	Number & Percentage of Males	Number & Percentage of Females	Total (Percentage)
18-29	18 (31.04)	10 (17.24)	28 (48.28)
30-39	5 (8.62)	4 (6.90)	9 (15.52)
40-49	3 (5.17)	8 (13.79)	11 (18.97)
50-59	6 (10.34)	4 (6.90)	10 (17.24)
60-65	-	-	-
Total (Percentage)	32(55.17)	26(44.83)	58(100)
Mean±S.E.M	32.9±2.17	34.34±2.36	33.59±1.58

In the study the maximum no. of patients observed possess Balghami mizaj(65.52%), followed by Damvi(25.86%) and Safrawi (8.62%). No patient of Saudawi mizaj was enrolled in the study (Table 3).

In the present study 25.86% of the patients showed very good response and 50% showed good response, while 24.14% patients showed poor response of the drug (Table 4).

In the present study, the efficacy of *Habb-e-Shifa* was evaluated over a period of seven days on the basis of symptom wise improvement. There was significant improvement reported in sore throat (35.22%,), hoarseness of voice (31.11%), sneezing (55.41%), running nose (48.46%), headache (51.94%), malaise

Table 3: Distribution of patients according to temperament

Temperament	Number of Cases	Percentage (%)
Damvi (Sanguine)	15	25.86
Balghami (Phlegmatic	38	65.52
Safravi (Bilious)	5	8.62
Saudavi (Melancholic)	-	-
Total	58	100

Table 4: General therapeutic response of *Habbe Shifa*

	Total	Excellent (90-100%)	Very Good (60-89%)	Good (30-59%)	Poor (< 30%)
No. of Patients	58	-	15	29	14
Percentage (%)	100	-	25.86	50	24.14

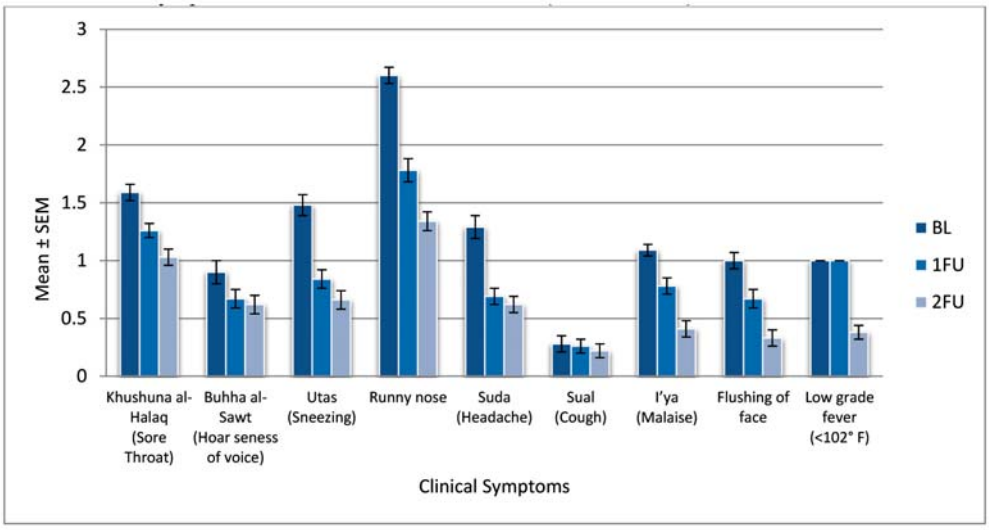
(62.93%), flushing of face (67.00%) and mild fever (<102°F) (62.00%) (Table 5 and Figure 1 & 2).

Response of *Habb-e-Shifa* by reducing the symptoms associated with common cold, can be attributed to its ingredients.

Table 5: Effect of Unani pharmacopoeial formulation, *Habb-e-Shifa* on different symptoms associated with *Nazla-e-Har* (common cold)

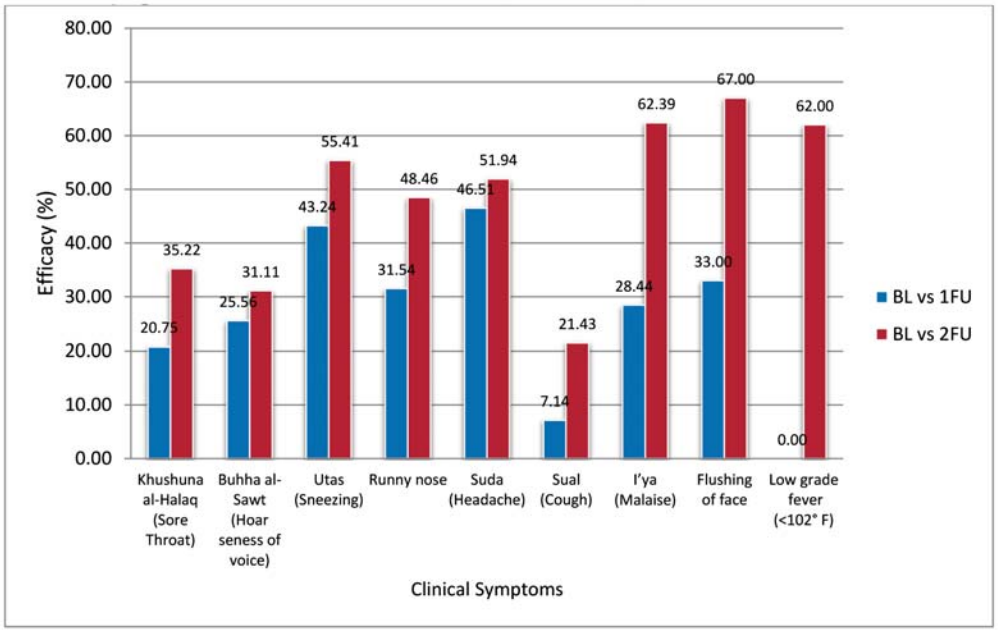
Clinical Symptoms	Base Line	1st Follow up		2nd Follow up	
	Mean±S.E.M	Mean±S.E.M	Efficacy (%)	Mean±S.E.M	Efficacy (%)
Khushuna al-Halaq (Sore Throat)	1.59 ± 0.07	1.26±0.06**	20.75	1.03±0.07***	35.22
Buhha al-Sawt (Hoarseness of voice)	0.9±0.1	0.67±0.08^{ns}	25.56	0.62±0.08*	31.11
Utas (Sneezing)	1.48±0.09	0.84±0.08***	43.24	0.66±0.08***	55.41
Runny nose	2.6±0.07	1.78±0.1***	31.54	1.34±0.08***	48.46
Suda (Headache)	1.29±0.1	0.69±0.07***	46.51	0.62±0.07***	51.94
Sual (Cough)	0.28±0.07	0.26±0.06^{ns}	7.14	0.22±0.06^{ns}	21.43
I'ya (Malaise)	1.09±0.05	0.78±0.07**	28.44	0.41±0.07***	62.39
Flushing of face	1±0.07	0.67±0.08**	33.00	0.33±0.07***	67.00
Low grade fever (<102^{o} F)	1±0	1±0^{ns}	0.00	0.38±0.06***	62.00

***p<0.001, **p<0.01,*p<0.05, ns=non significant when compare to the baseline.



BL =Base Line, 1FU=1st Follow up, 2FU=2nd Follow up

Figure 1: Effect of Unani pharmacopoeial formulation, *Habb-e-Shifa* on different symptoms associated with *Nazla-e-Har* (common cold)



BL =Base Line, 1FU=1st Follow up, 2FU=2nd Follow up

Figure 2: Efficacy of Unani pharmacopoeial formulation, *Habb-e-Shifa* on different symptoms associated with *Nazla-e-Har* (common cold)

Habb-e-Shifa has rewand chini (*Rheum emodi* Wall.) in its ingredients which is proven as anti-allergic. Some recent studies reported that rewand chini has *emodin* which exhibited the anti-allergic activities via increasing the stability of the cell membrane and inhibiting extracellular Ca^{+} influx, which might have helped the trial drug in reducing the subjective parameters of the patients (Wang *et al*., 2012; Rehman *et al*., 2014)

Rewand Chini may also help in boosting the immune system and reducing the sign & symptoms and also in keeping the kidney function and liver functions normal in this study, as it has already been reported to have hepato-protective, nephro-protective, anti-microbial, anti-oxidant, antiulcer, anticancer, antifungal, and immune-enhancing properties (Kaur *et al*., 2015).

Habb-e-Shifa also contains Zanjabeel (*Zingiber officinale* Rosc.), it has gingerols and shogaol which are most active constituents of ginger and they are reported to possess anti pyretic, analgesic, antiemetic, anti-asthamatic and anti inflammatory activities. Results of this study are also showing some of the similar results like highly significant reduction in the fever, malaise, headache and sore throat (Mishra *et al*., 2012).

The ginger also has antimicrobial, antioxidant, anti inflammatory, hepato-protective, neuro-protective, and cardio-protective properties and some of these

properties may helped the trial drug in demonstrating the significant results in this study (Ghosh *et al.*, 2011; Islam *et al.*, 2014).

Samagh-e-Arabi *(Acacia nilotica* (L.) Willd. ex Del.*)* is also an ingredient of *Habb-e-Shifa* which is used as emollients, astringent, and demulcent on irritated mucous membranes (Bhatnagar et al., 2013). These properties may have helped in the improvement of some symptoms of the common cold. *Acacia nilotica* (L.) Willd. ex Del. is a haemostatic which may remain helpful in controlling the running nose in the present study. *Acacia nilotica* (L.) Willd. ex Del. is used in irritation, dysentery, diarrhoea, and ulcers of the stomach, these properties may prevent the patients of common cold from the complications of the disease (Jahan *et al.*, 2008).

The main constituent of *Habb-e-Shifa* is Tukhm-e-Jauzmasil (*Datura stramonium* Linn.). It contains biologically active substances like alkaloids, atropine, scopolamine, tannin, carbohydrate and pretrens and is traditionally used in fever, skin disorder, ear pain, cough, asthma, body pains and it may have played an important role in the results of this study (Sayyed and Shah, 2014).

It is a natural source of antioxidant and phytochemicals having antimicrobial activities. The secondary metabolites of *Datura stramonium* Linn. are highly effective against different types of diseases such as anti diabetic and antiviral etc. This study is also supporting that *Datura stramonium* Linn. cures the fever and may have antiviral activity as it is main ingredient of *Habb-e-Shifa* because *Nazla-e-Har* is a viral induced upper respiratory tract infection (Sayyed and Shah, 2014).

The present study is also in agreement with a study of Tajuddin M, who has reported that *Habb-e-Shifa* has significant analgesic and antipyretic effect (Tajuddin *et al.,* 2007).

As no adverse results were reported in the pathological and biochemical parameters done at the baseline and at the end of the study. The drug was found safe at the given dosage schedule. This is also in the consonance with recent study that this Unani pharmacopoeial drug is safe at normal therapeutic dose as well as at higher doses (Tarannum *et al.*, 2014).

Conclusion

On the basis of above observations, it can be concluded that Unani pharmacopoeial formulation '*Habb-e-Shifa'* is effective in the management of *Nazla-e-Har* (common cold). Moreover, the drug is cheaper, easily available and well tolerated by the patients without having any side effect.

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Contribution of Lifestyle Changes in the Development of Type 2 Diabetes Mellitus: A Cross Sectional Study

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Abstract

The main objective of this study is to find out association of lifestyle changes with occurrence of Type 2 DM. This was a hospital based cross sectional study that enrolled 166 patients (95 males and 71 females) using convenient sampling. A detailed semi structured schedule was used, having necessary information regarding important demographics and lifestyle related risk factors of Type 2 DM such as dietary habits, socioeconomic status, basal metabolic index, physical and mental stress, exercise profile, alcohol consumption, tea / coffee consumption, smoking and tobacco chewing, and the nature of work. Among the studied population, maximum number of patients was in the age group of 35-44 years, the male and female diabetic patients were found to be 57.23% and 42.77%, respectively. In the selected subjects most of the candidates were belonging to 4th or upper lower socioeconomic class. As per BMI status, 40.96% patients were found normal, 42.78% were overweight and 16.26% were obese. Among them 63.86% were having history of physical or mental stress, 32.54% were doing regular exercise, 7.83% were irregular and 59.63% were not doing any exercise. 146 patients were non alcoholic, 12 were alcoholic, while 8 were ex-alcoholic. 83.74% patients were found current user of tea or coffee or both, 21.68% patients were found current users, 10.86% were ex-users and remaining 67.46% were non-users of smokes and tobacco, 65 (39.16%) were sedentary type of workers, 82 (49.40%) were moderate workers and only 19 (11.44%) were strenuous workers. It was concluded that rising prevalence of Type 2 DM is clearly associated with changes in lifestyle and dietary habits.

Keyword: Type 2 DM, Life style changes, Risk Factors, BMI.

Introduction

Currently, the health scenario is riddled with the burden of non-communicable diseases (NCDs), such as cancer, cardiovascular disease and diabetes. Diabetes is not a new disease, rather, its clinical features and complications were known to ancient physicians though its aetio-pathology was not clearly known. During last few decades it has broken all the restriction of age, socioeconomic status and lifestyle diversities etc and has widespread prevalence. In the past, it was considered a disease of affluent class, but now no one is safe from its risk as it is considered a leading cause of death and disability worldwide (Lozano *et al*., 2012). World Health Organisation has recently declared India as the capital of diabetes. About 80 million diabetics is the projected number up to 2030 for India (Anonymous, 2012; Gupta *et* al., 2015), while at present about 60 million cases are residing in the country (Gupta *et* al., 2015). Diabetes is a silent killer because

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of its cardio cerebro renal complications and a major cause of morbidity and disability. Fairly significant amount of wealth of the country is consumed for the care of diabetic patients. With the passage of time aetiology of diabetes was explored precisely and the management was revolutionized however no specific agent, responsible for diabetes, has yet been identified. Diabetes mellitus has a long evolution regarding the aetiology, but scientists ultimately concluded that â-cell dysfunction and qualitative as well as quantitative abnormalities of insulin are causative factors for diabetes. But why this occurs in some people is not clear. It has been argued that various host and environmental factors that lead to lifestyle changes are associated with diabetes.

Therefore, the scientists are trying to explore the aetiological determinants so as to put a check on them in order to arrest or slow down the spread of diabetes. Among the various factors responsible to contribute the development of diabetes, lifestyle changes are considered to be the most important. The present study is designed to determine the role of changes in lifestyle in giving rise to diabetes. With the growing population and rapid industrialization changes in lifestyle, routine works, habits and even in cultural ethos are taking place. These changes are somehow responsible to contribute to a number of diseases including the diabetes mellitus. The sorting of the associated lifestyle factors is the focus of the present study. The study will attempt to determine the relationship if any, between the various attributes of lifestyle changes and Type 2 DM. It is an observational, cross sectional hospital based survey undertaken in outdoor patients of Type 2 DM, visiting NIUM Hospital, Bangalore, especially its health promotion unit (HPU).

Materials and Methods

The study was conducted for six months between 20th, August 2008 and 20th, February 2009. Total 166 diagnosed cases of Type 2 DM fulfilling the criteria of inclusion were selected for the study.

A detailed semi structured schedule was used, having necessary information regarding the study. It included the information regarding demographic profile such as age, sex, religion and lifestyle related risk factors of Type 2 DM like dietary habits, socioeconomic status, Basal Metabolic Index, physical and mental stress, exercise profile, alcohol consumption, tea / coffee consumption, smoking and tobacco chewing and nature of work.

Results and Discussion

In the present study it was found that 3.62% patients were in age group of 25-34 years, 24.70% in 35-44 years, 26.51% in 45-54 years, 25.30% in 55-64 years

and 19.87 were in the age group of 65 years and above. Majority of the patients (26.51%) was from the age group of 45-54 years whereas only 3.62% patients were from the age group of 25-34 years. It indicated that DM is more common in the age group of 40 and above. Almost similar findings have been reported by Ramchandaran *et al*. (2001).

The study revealed that 57.23% and 42.77% of the patients were male and female, respectively. This higher percentage of male patients than females may be because of the higher prevalence of Type 2 DM in male population. It has been reported in a study that prevalence of DM among men and women in India is 12.5% and 11.9%, respectively. Similarly, 2.6% prevalence in males and 1.6% in females in Tamil Nadu has been reported (Ramchandra et *al*., 2001). A report from Andhra Pradesh also showed higher prevalence of Type 2 DM in male (Gupta & Mishra, 2007). A national level study conducted at 10 big centres of India showed 11.2% prevalence in men and 8.2% in women (Reddy *et al*., 2006). Thus our findings which are in consonance of other studies, clearly demonstrated that prevalence of diabetes is higher in male than the female population.

Table 1: Demographics

Contents	No. of patients	Percentage
Age:		
25-34	6	3.62%
35-44	41	24.70%
45-54	44	26.51%
55-64	42	25.30%
≥65	33	19.87%
Sex:		
Male	95	57.23%
Female	71	42.77%
Religion:		
Muslim	104	62.65%
Hindu	57	34.34%
Christian	5	3.01%

The prevalence of DM in people of different religions i.e. Muslim, Hindu and Christian was found to be 62.65%, 34.34% and 3.01%, respectively. A bit different findings have been reported in a study conducted at the same centre (Saquib, 2007). However, these reports cannot be said to be conclusive because the data

do not appear to be community representative, as the majority of the patients (62.65%) belonged to Muslim community, while the population of this community in the country is only about 15%. This difference may be attributed to higher attendance of Muslim patients in NIUM hospital (Saquib, 2007). Therefore, a multicentre study over a larger number of patients is warranted to arrive at a definite conclusion.

As far as the dietary habit is concerned, it was categorized simply into vegetarian and non-vegetarian. The findings revealed that 90.37% patients of Type 2 DM were non-vegetarian or having mixed diet. But any conclusive inference from this finding cannot be drawn in favour of its prevalence in non-vegetarian because the study was conducted in small group of patients attending NIUM hospital, and the study sample too small to be considered the representative of the community. Further, different components of food such as complex carbohydrate, fat and proteins etc should ideally be taken into account while dealing with the dietary habits.

Table 2: Distribution of patients according to dietary habits

Type of diet	Number	Percentage
Vegetarian	16	9.63%
Non-veg./Mixed	150	90.37%
Total	166	100%

Socio-economic status (SES) influences the nutrition, lifestyle and exercise habit of the community, thus it is directly related to prevalence of Type 2 DM. The present study revealed the maximum prevalence of Type 2 DM (57.23%) in class IV or lower socioeconomic class. This finding was contrary to reported one wherein higher prevalence has been attributed to higher socioeconomic group. Certain other studies also revealed the higher prevalence of DM in lower socioeconomic classes, but such studies are mostly from abroad. Connolly *et al*., (2000) reported high prevalence of Type 2 DM in most deprived area with low socioeconomic status. According to their study diabetes prevalence among men, in the least deprived quintile was 13.4 per thousand as compared to 17.22 per thousand in most deprived. In a study from USA it has been reported that low income was associated with higher prevalence of diabetes. A population based cross sectional study from New Castle revealed higher prevalence of diabetes in lower socioeconomic class (Connolly *et al*., 2000). Low level of income and education, and thereby low socioeconomic status has been associated with increased prevalence of Type 2 DM in many other studies (Hamman *et al*., 1983). A similar trend as shown in many foreign studies which is otherwise unusual in Indian context was observed in present study. This

unusual trend of prevalence may be attributed to metropolitan status of Bangalore city that may have affected the community in the same way as in developed countries.

Our findings revealed an inverse relation between the prevalence of Type 2 DM and socioeconomic status. It appears that low level of education and income are more important risk factors of Type 2 DM than the plenty of food and sedentary mode of life, which are considered as major risk factors for Type 2 DM in high socioeconomic class. One important reason for conventional inverse relationship between low socioeconomic status and DM may be attributed at least partially to poor accessibility of health facilities and related investigations in a country like India. An opinion is emerging that DM affect the people irrespective of their socioeconomic status.

Table 3: Distribution of patients according to SES

SES	Number	Percentage
I	2	1.20%
II	34	20.48%
III	32	19.28%
IV	95	57.23%
V	3	1.81%
Total	166	100%

No doubt obesity predisposes Type 2 DM and most of the obese develop it sooner or later. In the present study 42.78% patients were found overweight and another 40.96% were at border line, while 16.26 % were obese. The finding clearly indicated the contributory role of weight gain in the development of Type 2 DM. Although 40.86% of the patients were not categorized to be overweight the majority was at border line. Several studies have revealed obesity as a significant and independent risk factor for Type 2 DM (Anonymous, 2004). Obesity was found to increase the risk of Type 2 DM by 28 times as compared

Table 4: Distribution of patients according to BMI

BMI Status	Number	Percentage
Underweight	0	0%
Normal	68	40.96%
Overweight	71	42.78%
Obese	27	16.26%
Total	166	100%

to non-obese individuals (Dutt *et al*., 2004). These reports are in consonance of the finding of the present study.

63.86% diabetic patients were found to be affected with mental or physical stress or both. Stress has been considered a risk factor for hormonal imbalance including insulin. It has also been documented that stress interferes with â-cell functions (Benjamin *et al*., 2000). Thus, stress was found to be directly associated with the development of diabetes.

It is not easy to obtain the precise history of stress because patients mostly refuse to admit that they have any stress related problem though they have it. The present study revealed the higher prevalence of Type 2 DM in stress afflicted patients. This stress may be of diverse origin i.e. physical, mental or psychological etc. Irrespective of the type of stress, patients were categorized dichotomously in two groups. It has been reported in a study that stress, history of trauma and history of surgery were found to increase the risk of Type 2 DM. It has been further reported that chronic to moderate stress leads to development of Type 2 DM (Dutt *et al*., 2004).

Table 5: Distribution of patients according to physical / mental stress

State of Stress	Number	Percentage
Positive	106	63.86%
Negative	60	36.14%
Total	166	100%

Exercise plays an inverse role in the development of diabetes. This fact is consistently reported from almost all studies conducted till date. In present study it was found that the diabetes was highly prevalent (59.63%) in patients with history of nil exercise, 32.54% patients were regular to exercise and 7.83% were irregular. Exercise not only regulates insulin secretion but also enhance the glucose utilization. Moreover, exercise burns the excess of fat, a major contributory factor for insulin resistance, and rectifies the impaired glucose tolerance. Unani physicians have emphasized that *Riyazat* (exercise) dissolves

Table 6: Distribution of patients according to exercise profile

Exercise Profile	Number	Percentage
Regular	54	32.54%
Irregular	13	7.83%
Nil Exercise	99	59.63%
Total	166	100%

and disperses the waste and helps maintain the *Mizaji* (temperamental) normalcy- an important attribute responsible for the maintenance of health.

Alcohol intake was not found related to Type 2 DM in any way, because in present study 87.96% patients were found to be non-alcoholic, while only 7.23% were alcohol and 4.23% were ex-users of alcohol. So it seems reasonable to conclude that there is no direct relationship between alcohol intake and Type 2 DM.

Table 7: Distribution of patients according to alcohol consumption

Status	Number	Percentage
Non-alcoholic	146	87.96%
Ex-user	8	4.81%
Current Alcoholic	12	7.23%
Total	166	100%

The present study surprisingly revealed the higher (90.97%) prevalence of Type 2 DM in tea/coffee lovers. Several studies revealed inverse association between consumption of green/black tea or coffee and Type 2 DM (Tuomilehto *et* al., 2004). One thing which is worth mentioning here is that such tea and coffee are usually taken without sweetener (sugar) in western countries, but in India it is customary to drink sweet tea which is neither green nor black. So the contradictory finding may be attributed to the use of sugar in tea, not to tea itself. Every time when the tea is taken some amount of sugar is consumed. This has a very high hyperglycaemic index that may contribute to exhaustion of â-cells along certain metabolic effect. In Indian scenario tea consumption is included in the risk factors of DM possibly for the first time, the contemporary data, therefore, could not be traced in this regard.

Table 8: Distribution of patients according to tea/coffee consumption

Status	Number	Percentage
Current user	139	83.74%
Ex-user	12	7.23%
Non-user	15	9.03%
Total	166	100%

Regarding the smoking and tobacco chewing habits, the present study showed that the prevalence of Type 2 DM was 21.68% in current smokers or tobacco chewers, 10.86% in ex-user and 67.46% in non smokers/ tobacco chewers. The combined prevalence of Type 2 DM in current and ex-user was 32.54%. The present findings were supported by the finding of Gupta *et al* (2003). They

reported 37.10% prevalence in men and 18.80% in women smokers (Gupta *et al.,* 2003). In a study smoker had been shown to have higher level of insulin and lower level of sex hormone binding globulin, suggesting that cigarette smoking exacerbates the insulin resistance, a characteristic feature of Type 2 DM (Bloomgarden, 1998). In a case control study it was found that out of 75 diabetics 39 were smokers (Dutt *et al*., 2004). This clearly indicates higher risk of Type 2 DM in smokers.

Table 9: Distribution of patients according to smoking and tobacco chewing habits

Status	Number	Percentage
Current users	36	21.68%
Ex-users	18	10.86%
Non-users	112	67.46%
Total	166	100%

It was found that Type 2 DM was maximally prevalent (49.40%) in moderate workers. This finding was contradictory to the results of previously conducted studies wherein it is reported that the diabetes is strongly associated to sedentary mode of life (Park, 2007; Ramchandaran *et al*., 2002). Several ecological studies suggested that Type 2 DM prevalence is consistently lower in population with higher level of physical activity (Harris, 1991). Studies from different parts of the country also revealed that sedentary life is a significant risk factor for diabetes (Dutt *et al*., 2004). The discrepancy may be attributed to the small sample size. However, it is also possible that the disease has started affecting the non conventional population. It was found prevalent in 59.63% patients who gave a history of nil exercise. This finding is consistent with the sedentary mode of life. In the present study, lifestyle was classified on the basis of nature of work of the patients whereas history of exercise was taken from the patients. Discrepancy between history of exercise and mode of lifestyle may be attributed to the way of classifying the mode of lifestyle, because it seems reasonable that professional workers may be doing moderate exercise but may have denied seeing it a routine work. Because of this contradiction in history of exercise and profession,

Table 10: Distribution of patients according to nature of work

Nature of Work	Number	Percentage
Sedentary	65	39.16%
Moderate	82	49.40%
Strenuous	19	11.44%
Total	166	100%

erroneous data may have been obtained from which no precise inferences can be drawn.

Conclusion

The rising prevalence of Type 2 DM is clearly associated with age, sex, weight, socioeconomic status, stress, exercise and smocking/tobacco chewing etc. These attributes of life are changing because of the rapid industrialization and socio-economic development. Therefore, the chances of prevalence of DM are increasing rapidly. It was also observed that DM has started affecting the population that was hitherto considered as non-diabetic bastion, for example, in non-obese and poor class of population. The study demonstrated that lifestyle changes contribute significantly to the development of Type 2 DM. Therefore, it is warranted that suitable modification in lifestyle should be made to averse the process of development of DM and people should be made aware of it.

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Clinical Study to Validate the Safety and Efficacy of Unani Pharmacopoeial Formulations in Bawāsīr Dāmiya (Bleeding Piles): A Preliminary Study

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Abstract

A clinical study was conducted to scientifically validate the safety and efficacy of Unani pharmacopoeial formulations, *Habb-e-Rasaut*, *Habb-e-Muqil*, *Majoon Muqil* and *Marham Saeeda Chob Neem Wala* in patients with *Bawāsīr Dāmiya* (Bleeding Piles) at Regional Research Institute of Unani Medicine (RRIUM), Bhadrak (Odisha) during 2013-2014. Out of all the cases registered for the study, seventy nine patients completed the trial. After 42 days of treatment, the symptoms of the disease, including rectal bleeding, rectal pain and pruritus ani were found decreased by 50%, 50% and 62.5% respectively as compared to baseline. The variations in the values of liver function tests and kidney function tests before and after treatment were found within normal limits. The studied drugs were found well tolerated and no adverse effects were observed during the study. The study presents the preliminary results and is affirmative of the safety and efficacy of Unani pharmacopoeial formulations in the treatment of *Bawāsīr Dāmiya* (bleeding piles).

Keywords: *Bawāsīr Dāmiya,* Bleeding Piles, Unani pharmacopoeial formulation, *Habb-e-Rasaut*, *Marham Saeeda Chob Neem Wala*

Introduction

Bawāsīr (Piles) affects about 5% of the general population. They are extremely common in adults and may develop for the first time during pregnancy. Except for pregnant women, they are rarely encountered in persons under age 30 (Boon *et al.,* 2006; Kumar *et al.,* 2006). Symptomatic haemorrhoids affect >1 million individuals in Western civilization per year. The prevalence of haemorrhoids is not selective for age or sex. However, age is known to have a deleterious effect on the anal canal. The prevalence of haemorrhoids is less in underdeveloped countries. The typical low-fiber, high-fat Western diet is associated with constipation and straining, and the development of symptomatic haemorrhoids (Kasper *et al.,* 2005). Most women of European stock and probably all those who have a baby develop haemorrhoids at some time; those with a family history of haemorrhoids and varicose veins suffer most. Haemorrhoids develop as a part of the pelvic congestion of pregnancy and are probably encouraged by atony of the vessel walls (Jeffcoate, 1982).

The symptoms and signs of *Bawāsīr Dāmiya* (Bleeding Piles) are rectal bleeding, mucosal prolapse, mucoid perianal discharge, pruritus ani, and

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nonspecific discomfort. Bright red, painless rectal bleeding after defecation, as the name haemorrhoids implies, is the principal and earliest symptom. Rectal and anal pain occurs on prolapse. A dull ache may be due to engorgement of the haemorrhoidal tissue. Severe pain may indicate a thrombosed haemorrhoid. Haemorrhoids that bleed but do not prolapse are called *first-degree haemorrhoids*. Haemorrhoids that prolapse on defecation but reduce spontaneously are called *second-degree haemorrhoids*. Haemorrhoids that prolapse on defecation but reduce manually after bowel movements and then stay reduced are called *third-degree haemorrhoids*. Haemorrhoids that are permanently prolapsed are called *fourth-degree haemorrhoids* (Kabīruddīn, 1916; Russel *et al.*, 2004)

The word "haemorrhoid" is derived from Greek words *haima* meaning blood and *rhoos* meaning flowing, and was originally used by a Great Greek physician Buqrāt (Hippocrates) (460-377 BC) to describe the flow of blood from the veins of the anus (Leff E, 1987). Haemorrhoids are commonly known as Piles (Latin: *pila* = a ball) and they are known as *Bawāsīr* in *Unani* system of medicine. "*Bawāsīr*" (singular: *Bāsūr*) is an Arabic word meaning *Sūlūl* (wart), which is used to describe the haemorrhoidal disease in Unani system of Medicine (Kabīruddīn, 1916; Khayat, 1983). Hippocrates defines haemorrhoids as vascular tumours *(Sal'a'Urūqī)* of mucous membrane *(Ghishā' Mukhātī)* in the lower part of *Mi'ā' Mustaqīm* (rectum). According to Samarqandi, haemorrhoid is a type of extra growth on the terminals of haemorrhoidal veins produced by accumulation of thick melancholic *(Ghalīz Sawdāwī)* blood, which resembles flesh *(Dishbiz)* (Kabīruddīn, 1916). Nafīsibn 'Iwaz Kirmānī defines haemorrhoids as extra growths located on the haemorrhoidal veins, which look like flesh or cartilage (Kirmānī, 1908). Haemorrhoids or piles are dilated veins of the anal canal (Russel *et al.*, 2004)."*Bawāsīr*" or "Piles" (Haemorrhoids) are mentioned in medical writings of every culture including Babylonian, Egyptian and Greek.

Abū Bakr Muhammad ibn Zakariyya Rāzī in his famous book, *Kitāb al-Hāwī fi'l Tibb* has described haemorrhoids in detail. According to Rāzī (Rhazes), the basic cause of haemorrhoids is the accumulation of melancholic (*Sawdāwī*) blood in the varicosed veins around the *Maq'ad* (anus) (Rāzī, 1962). Hakīm Muhammad Akbar Arzānī in his book, *Tibb-i-Akbar* mentioned that *Bawāsīr-e-Khūni* is caused by thick melancholic *(Ghalīz Sawdāwī)* blood (Arzānī, 1924). Abu'l Hasan Ahmad ibn Muhammad Tabarī in his book, *Mu'ālajāt al-Buqrātiyya* mentioned that *Bawāsīr* is a melancholic (*Sawdāwī*) disease which is caused by accumulation of abnormal thick blood in the terminal part of anal blood vessels. This blood becomes abnormal within the liver due to excessive heat and dryness or due to intake of such foods, which

produce melancholic *(Sawdāwī)* blood (Tabarī, 1997). Ibn Sīnā in his famous book, *Al-Qānūn fi'l Tibb* says that haemorrhoids are caused by accumulation of black bile *(Sawdā')* or melancholic *(Sawdāwī)* blood. Less commonly they may be developed due to accumulation of phlegm *(Balgham)* (Kintūrī, 1906). Hakīm Ajmal Khān in his book, *Hāziq* described the aetiology of haemorrhoids, including excessive heat, excessive use of hot foods, e.g., red chilies and meat, and hot climatic conditions, which lead to burning of blood and production of thick *(Ghalīz)* blood (Khān, 1987).

Hakīm Kabīruddīn says that haemorrhoids are the vascular tumours of mucous membrane of the lower rectum. In haemorrhoids, thick melancholic *(Ghalīz Sawdāwī)* blood due to presence of excessive earthy particles is accumulated in the terminal part of anal blood vessels. Three morphological categories of haemorrhoids are described as *Sūlūlī, 'Inabiyya,* and *Tūtī. Bawāsīr Sūlūlī* (wart-like pile masses) are lentil or gram like pile masses which resemble small hard warts and produced by black bile *(Sawdā')*. *Bawāsīr 'Inabiyya* (grapes-like pile masses) are round shaped pile masses which resemble grapes and produced by such matter that falls between melancholic *(Sawdāwī)* and sanguineous *(Damwī)*. *Bawāsīr Tūtī* (mulberry-like pile masses) are loose pile masses which resemble mulberry and produced by sanguineous *(Damwī)* matter (Kabīruddīn, 1916; Anonymous, 2012).

Materials and Methods

The present study was multi-centric study running simultaneously in three centers including Bhadrak. Other two centers were RRIUM, New Delhi and RRIUM, Kolkata (West Bengal). The said data belongs to RRIUM, Bhadrak only. Final study with complete sample size may be published later on by the Council.

The study was conducted at Regional Research Institute of Unani Medicine, Bhadrak (Odisha) on 79 patients of *Bawāsīr Dāmiya* (Bleeding Piles). The patients were selected from the OPD of the institute during 2013-2014. The patients of either sex in the age group of 18 to 65 years were included in the study. Inclusion criteria were rectal bleeding, rectal and anal pain, pruritus ani, and first and second degree haemorrhoids. The patients below 18 years and above 65 years of age, patients with third and fourth degree haemorrhoids, patients with anal fissures, patients with other long-term diseases, malnourished patients (BMI of <18.5kg/m^2 and haemoglobin<12g/dL), patients with inflammatory bowel disease (ulcerative colitis and Crohn's disease), pregnant women and lactating mothers were excluded from the study.

The clinical study protocol was approved by the Institutional Ethics Committee (IEC) of the institute on 15.03.2013 and the trial has been registered with CTRI and the registration number is CTRI/2013/10/004069. After obtaining written informed consent, patients were enrolled for the study and they were subjected to the haematological and biochemical investigations. haematological investigations included haemogram [haemoglobin (Hb), erythrocyte sedimentation rate (ESR), red blood cell (RBC) count, total leukocyte count (TLC), differential leukocyte count (DLC: neutrophils, eosinophils, basophils, lymphocytes, monocytes) and Platelet counts], urine examination (routine &microscopic), stool examination (routine &microscopic) and stool for occult blood. Biochemical investigations included liver function tests (LFTs) comprising serum bilirubin, serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT) and alkaline phosphatase (ALP) and kidney function tests (KFTs) comprising serum creatinine, blood urea, and serum uric acid.

The parameters for assessment of efficacy of the formulations were rectal bleeding, rectal pain and pruritus ani. These parameters were graded accordingly, in case of rectal bleeding as no bleeding = 0, occasional bleeding = 1, moderate bleeding = 2 and profuse bleeding = 3; in case of rectal pain as no pain = 0, mild discomfort = 1, moderate pain = 2 and severe pain = 3; and in case of pruritus ani as no itching = 0, occasional itching = 1, moderate itching with skin lesions = 2 and severe itching with exudates from the skin lesions = 3.

For overall assessment of efficacy, relief in symptoms and signs were calculated and patients were divided into four groups on the basis of relief they have got. If a patient gets 95-100% relief in symptoms and signs, he/she was placed as cured, if gets 70-94% relief in symptoms and signs then he/she was labelled as relived, if gets 35-69% relief in symptoms and signs then marked as partial relived and if patient gets less than 35 percent relief he/she was placed as not relieved.

The clinical follow-up of all the cases were carried out at regular interval of two weeks up to six weeks. The haematological and biochemical investigations were conducted at baseline and at the end of the study. The safety of trial drugs was evaluated by biochemical investigations and clinically by monitoring adverse effects which were carefully sought at each follow-up. *Mizāj* (temperament) of the patients was assessed as per the parameters described in Unani classical literature. The clinical and laboratory findings observed in every case were recorded on a separate case record form (CRF) designed especially for clinical study on *Bawāsīr Dāmiya* (Bleeding Piles). The duration of treatment was 6 weeks. No concomitant treatment was

allowed during the study. Baseline and follow-up values of haematological and biochemical investigations were statistically analyzed using Student's paired 't' test. The significance level of P <0.05 was used in this study.

Study Drugs, Dosage Schedule, and Mode of Administration

The following Unani Pharmacopoeial formulations used in the study were obtained from Central Research Institute of Unani Medicine (CRIUM), Hyderabad.

1. *Habb-e-Rasaut* was given in the dose of 1 pill orally twice daily with water.
2. *Habb-e-Muqil* was given in the dose of 1 pill orally twice daily with water.
3. *Majoon Muqil* was given in the dose of 5g orally once daily with water
4. *Marham Saeeda Chob Neem Wala* (ointment) was advised to apply locally before and after each defaecation.

Composition of Study Drugs

Habb-e-Rasaut contained five ingredients (Table 1), *Habb-e-Muqil* contained nine ingredients (Table 2), *Majoon Muqil* contained 14 ingredients (Table 3) and *Marham Saeeda Chob Neem Wala* contained 10 ingredients (Table 4).

Results

After completion of 42 days of treatment, the combination of Unani Pharmacopoeial Formulations exhibited significant improvement in symptoms and signs of *Bawāsīr Dāmiya* (Bleeding Piles). Rectal bleeding, rectal pain and pruritus ani were decreased by 50%, 50% and 62.5% respectively as compared to baseline (Figure1).

Table 1: Composition of *Habb-e-Rasaut*

S.No.	Unani Name	Scientific Name	Quantity
1	Rasaut	*Berberis aristata* D.C	50 gm
2	Kateera	*Astragalus gummifera* Labill.	20 gm
3	Mazu	*Quercus infectoria* Olivier	10 gm
4	Sang-e-Jarahat	Silicate of Magnesia	10 gm
5	Geru	Bolus Armenia Rubra	10 gm

(Anonymous, 2006)

Table 2: Composition of *Habb-e-Muqil*

S.No.	Unani Name	Scientific Name	Quantity
1	Muqil	*Commiphora mukul* Hook ex Stocks	85 g
2	Post-e-Halela Zard	*Terminalia chebula* Retz.	60 g
3	Post-e-Halela Kabli	*Terminalia chebula* Retz.	60 g
4	Halela Siyah	*Terminalia chebula* Retz.	60 g
5	Aamla Khusk	*Emblica officinalis* Gaertn.	60 g
6	Sakbeenaj	*Ferula persica* Willd.	20 g
7	Khardal	*Brassica nigra* Linn.	10 g
8	Roughan-e-Badam	*Prunus amygdalus* Batsch	20 ml
9	Aab-e-Gandana	*Allium ascalonicum* Linn.	100 ml

(Anonymous, 2006)

Table 3: Composition of *Majoon Muqil*

S.No.	Unani Name	Scientific Name	Quantity
1	Post-e-Halela Kabli	*Terminalia chebula* Retz.	10 g
2	Post-e-Balela	*Terminalia belerica* Roxb.	10 g
3	Aamla	*Emblica officinalis* Gaertn.	10 g
4	Dana Heel Khurd	*Elettaria cardamomum* Maton.	10 g
5	Badiyan	*Foeniculum vulgare* Mill.	10 g
6	Nankhwah	*Trachyspermum ammi* Linn.	5 gm
7	Sazaj Hindi	*Cinnamomum tamala* Nees.	5 gm
8	Narmushk	*Mesua ferrea* Linn.	5 gm
9	Zanjabeel	*Zingiber officinale* Rosc.	5 gm
10	Satar Farsi	*Zataria multiflora* Boiss.	5 gm
11	Waj-e-Turki	*Acorus calamus* Linn.	5 gm
12	Filfil Daraz	*Piper longum* Linn.	5 gm
13	Muqil	*Commiphora mukul* Hook ex Stocks	85 gm
14	Asal	Honey	350 gm

(Anonymous, 2006)

Table 4: Composition of *Marham Saeeda Chob Neem Wala*

S.No.	Unani Name	Scientific Name	Quantity
1	Post Neem	*Azadirachta indica* A. Juss.	10 gm
2	Maghaz Neem	*Azadirachta indica* A. Juss.	10 gm
3	Post Bakayin	*Melia azedarach* Linn.	10 gm
4	Maghaz Bakayin	*Melia azedarach* Linn.	10 gm
5	Rasaut Musaffa	*Berberis aristata* D.C	10 gm
6	Safaida Kashghari	White Lead	10 gm
7	Gugal	*Commiphora mukul* Hook ex Stocks	10 gm
8	Kafoor	*Cinnamomum camphora* Nees & Eberm.	10 gm
9	Mom Zard	Honey Bee Wax	30 gm
10	Raughan Kunjud	*Sesamum indicum* Linn.	120 ml

(Anonymous, 2008)

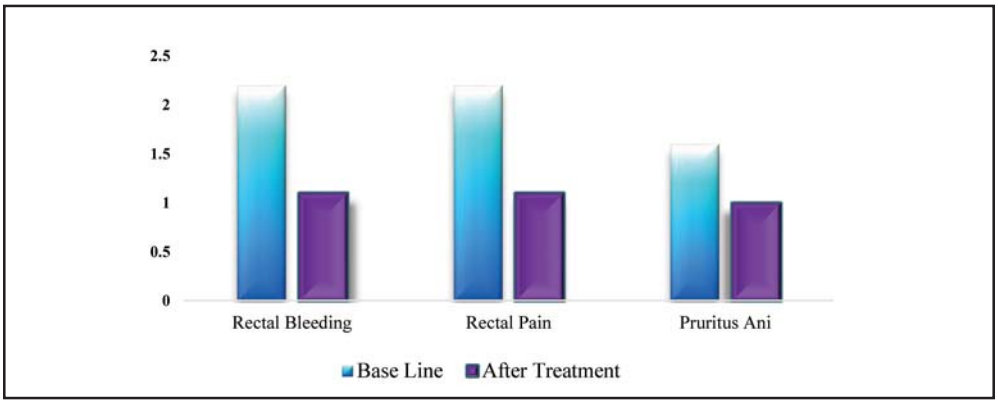

Figure 1: Mean values of clinical parameters at baseline and after treatment

Out of 79 patients of *Bawāsīr Dāmiya* (Bleeding Piles) who have completed the study, 26 (32.9%) patients were cured (95-100% relief in symptoms & sign), 35 (44.3%) patients were relieved (70-94% relief in symptoms & sign) and 17 (21.5%) patients were partially relieved (35-69% relief in symptoms & sign) whereas only one (1.26%) patient was not relieved (0-34% relief in symptoms & sign) (Figure2).

The mean values of haematological and biochemical parameters at baseline and after 42 days of treatment are shown in Table 5 and Table 6 respectively. The variations in the values of liver function tests (LFTs) and kidney function tests (KFTs) before and after treatment were found within normal limits revealing the safety of study drugs. The study drugs were found well-tolerated and no adverse effects were observed.

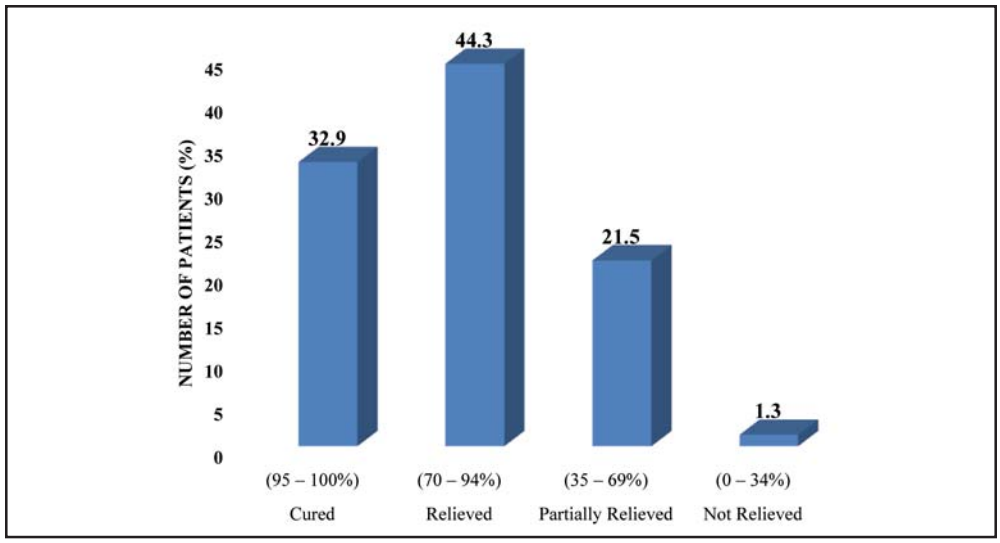

Figure 2: General therapeutic response

Table 5: Mean values of haematological investigations at baseline and After Treatment

Haematological Investigations		Period	Mean ± SD	P value
Haemoglobin (gm%)		BT	12.54±0.14	<0.05
		AT	12.37±0.13	
ESR (mm/hr)	1st Hour	BT	17.23±1.65	>0.05
		AT	17.97±1.60	
	2nd Hour	BT	35.79±2.81	>0.05
		AT	36.72±2.75	
Total Leucocytes Count (cmm)		BT	6811.39±136.93	>0.05
		AT	7114.56±137.22	
Red Blood Cells (mill/cmm)		BT	3.37±0.07	<0.05
		AT	3.55±0.07	
Platelet Count (cmm)		BT	2.56±0.02	>0.05
		AT	2.54±0.01	
DLC	Neutrophils	BT	61.51±0.67	>0.05
		AT	62.14±0.57	
	Lymphocytes	BT	29.43±0.55	>0.05
		AT	28.65±0.54	
	Monocytes	BT	8.48±0.33	>0.05
		AT	8.52±0.25	
	Eosinophils	BT	0.58±0.08	>0.05
		AT	0.70±0.09	

BT= Before Treatment; AT= After Treatment

Table 6: Mean values of biochemical investigations at baseline and after Treatment

Biochemical Investigations	Period	Mean ± SD	P value
SGOT (Units/ml)	BT	29.58±1.51	< 0.05
	AT	29.65±1.78	
SGPT (Units/ml)	BT	29.86±1.78	< 0.05
	AT	25.79±1.47	
ALP (K&A Units/100ml)	BT	111.90±8.04	> 0.05
	AT	111.82±8.72	
Serum Bilirubin (mg %)	BT	0.58±0.02	> 0.05
	AT	0.56±0.02	
Serum Creatinine (mg %)	BT	1.20±0.03	< 0.05
	AT	1.11±0.03	
Serum Urea (mg %)	BT	20.66±0.66	> 0.05
	AT	19.61±0.68	

BT= Before Treatment; AT= After Treatment

Discussion

Unani pharmacopoeial formulations used in this study were found effective in the treatment of *Bawāsīr Dāmiya* (Bleeding Piles). The signs and symptoms of *Bawāsīr Dāmiya* (Bleeding Piles) were significantly reduced. After 42 days of treatment, the improvement recorded were 50% for rectal bleeding, 50% for rectal pain and 62.5% for pruritus ani. These drugs were found well-tolerated and no any adverse effects were observed during the study. The values of LFTs and KFTs after treatment showed the safety of study drugs. The study is affirmative of the safety and efficacy of Unani pharmacopoeial formulations in the treatment of *Bawāsīr Dāmiya* (bleeding piles).

Conclusion

On the basis of above findings, it can be concluded that Unani pharmacopoeial formulations – *Habb-e-Rasaut, Habb-e-Muqil, Majoon Muqil* and *Marham Saeeda Chob Neem Wala* are safe and effective in the treatment of *Bawāsīr Dāmiya* (bleeding piles).

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Clinical Study of Qurse Kushta Khabs al-Hadeed and Habbe Marwareed in the Management of Sayalan al-Rahim (Leucorrhoea)

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Abstract

Sayalan al-Rahim (Leucorrhoea), simply means a white flow- a white discharge, sometimes described as the excessive amount of normal vaginal discharge, is encountered as a major problem in gynaecological practice. It is a symptom of certain underlying pelvic pathology that represents through the symptoms like low backache, itching and burning sensation of vulva, poor appetite, discomfort; general weakness and pain in both legs etc. In Unani medicine its pathology, signs and symptoms and management have been described with necessary details. Two important pharmacopoepial compound drugs viz *Qurse Kushta Khabs al-Hadeed* and *Habbe Marwareed* have been described to be effective and are used successfully in the management of *Sayalan al-Rahim* since long by Unani physicians. Therefore an open label study was designed to evaluate the safety and efficacy of two Unani Pharmacopoeial formulations namely *Qurse Kushta Khabs al-Hadeed* and *Habbe Marwareed* in cases of *Sayalan al-Rahim.*

A total of 58 cases of fertile age group patients (13-45 years) diagnosed to be afflicted with *Sayalan al-Rahim* were studied. It was found that out of 58 cases 36 were relieved, 17 were partially relieved, while no response was recorded in 05 cases. The drugs were found safe on biochemical and haematological parameters. The study demonstrated that the test drugs are safe and effective in the management of *Sayalan al-Rahim*.

Keywords: *Sayalān al-Rahim,* Leucorrhoea, *Qurse Kushta Khabs al-Hadeed* and *Habbe Marwareed,* Unani Medicine

Introduction

Sayalan al-Rahim (Leucorrhoea) is a common symptom among females of reproductive age group (Devi, 2013; Padma *et al*., 2013). The word "Leucorrhoea" simply means a white flow-a white discharge (Williams, 1942) however, the term is restricted to mean an excessive amount of the normal vaginal discharge (Kumar and Malhotra, 2008). It is non hemorrhagic in nature, and is often associated with irritation. The discharge may be white, yellow or greenish in colour (Tabbussum *et al*., 2014). It is a symptom of certain underlying pelvic pathology (Tewiri *et al.,* 2001), but its etiology is complex and not well understood (Daneshfard and Tafazoli, 2015). It produces many associated problems like low backache, itching and burning sensation of vulva, poor appetite, discomfort, general weakness, pain in both legs etc. Prevalence of vaginal discharge in India has been reported to be about 30 per cent however the women in rural areas and those of underprivileged class suffer most (Thulkar *et al*., 2010).

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According to Ibn Sina (ynm) and Jurjani (2010) the disease is caused by weakness of *quwwat-e-hazima* (digestive faculty) of uterine vessels, while Khan (2011) and Arzani (ynm) have mentioned the poor *quwwat-e-ghazia* of uterus as the causative factor. Some physicians say that the disease results due to weak *quwwat-e-jaziba* (Majoosi, 2010) whereas few added infection of morbid humours in uterine vessels to the list. However, almost all the scholars are of the opinion that general debility is one of the most important predisposing factors of *Sayalan al-Rahim* and the related symptoms (Khan, 2011). Thus, according to Unani medicine the weakness of some of the faculty (*Quwa*) of the reproductive organs particularly uterus along with the general weakness and compromised immunity is responsible to give rise to *Sayalan al-Rahim*. Therefore, strengthening the reproductive organs, improving the general health and augmenting the immunity have been described to be the treatment guideline of *Sayalan al-Rahim*, certainly along with symptomatic management.

There are a number of single Unani drugs as well as compound formulations which have been described to be safe and effective in the treatment of *Sayalan al-Rahim* (Leucorrhoea). *Qurse Kushta Khabs al-Hadeed* (QH) and *Habbe Marwareed* (HM) are two important Unani pharmacopoeial formulations containing ingredients which improve the general health and the health of reproductive organs and thereby improve the *Sayalan al-Rahim*. Although these formulations are being used successfully since long, in the management of many diseases attributed to develop because of general weakness including *Sayalan al-Rahim* but the scientific data on their safety and efficacy are lacking. Therefore, this study was undertaken to validate the safety and efficacy of QH and HM in the treatment of *Sayalan al-Rahim.*

Materials and Methods

The study was carried out in the OPD of Regional Research Institute of Unani Medicine, Aligarh, after the approval of Institutional Ethics Committee. The patients were subjected to the trial after obtaining their written informed consent. The two test drugs i.e. QH and HM were obtained from Central Research Institute of Unani Medicine, Hyderabad. Female patients in the age group of 13-45 years having excessive white discharge with or without backache, general weakness and anaemia (8-10 mg %) were included in the study. While patients acute/acute on chronic/Chronic PIDs, or those having any abnormal condition on p/s examination (in case of married females), taking hormonal therapy; patients on long-term medication, on oral contraceptives/IUDs, pregnant and lactating women were excluded from the study. Duration of study was 2 years. The total duration of treatment was 4 weeks and the patients were evaluated fortnightly. QH (100 mg) and HM (250 mg) were given orally after meals along with water in the form of 1

tab twice daily. Seventy four subjects out of the patients visited the out-patient department of RRIUM, Aligarh, during the period from August 2014 to September 2015 were selected for the study on the basis of inclusion and exclusion criteria. However, only 58 subjects completed the study, while 16 patients dropped it out. Each case was investigated for Complete Blood Test (CBC), Urine Examination (Routine & Microscopic), VDRL (at the time of screening) and biochemical investigations (Random Blood Glucose (at the time of screening only), LFT, KFT before starting and at the end of treatment. The efficacy of the study drugs was assessed on the basis of improvement in the symptoms on a 10-point Visual Analogue Scale (VAS). For the assessment of efficacy of the test drug, the results were interpreted in terms of percentage efficacy. Percentage efficacy was calculated by reduction in VAS score from baseline findings which was calculated by the following formula:

$$\text{Percentage efficacy} = \frac{\text{Maximum score} - \text{Minimum score} \times 100}{\text{Maximum score}}$$

Assessment was done in following manner:

0-10%	not relieved
11-60%	partially relieved
61-100%	relieved

Data obtained from haematological and biochemical parameters were analyzed statistically by one-way Analysis of Variance (ANOVA) followed by Dennett's test. The values were considered significant when the p value was found less than 0.05 ($p<0.05$).

Observation and Results

Table 1: Demographic data

S.No.	Demographic data	Mean± SD	
1.	Age (in years)	26.034±8.24	
2.	Duration of disease (in months)	51.03±53.98	
3.	Mizaj	Damvi (sanguine)	6(10.34%)
		Balghami (phlegmatic)	37(63.79%)
		Saudavi (melancholic)	0
		Safrawi (choleric)	15(25.86%)
4.	Marital status	Married	33 (56.90%)
		Unmarried	25 (43.10%)

Table 2: Effect of the treatment

Response			
No. of Cases	**Relieved (61-100%)**	**Partial Relieved (11-60%)**	**Not Relieved (0-10%)**
	36 (62.06%)	17 (29.31%)	05 (8.62%)

n=58

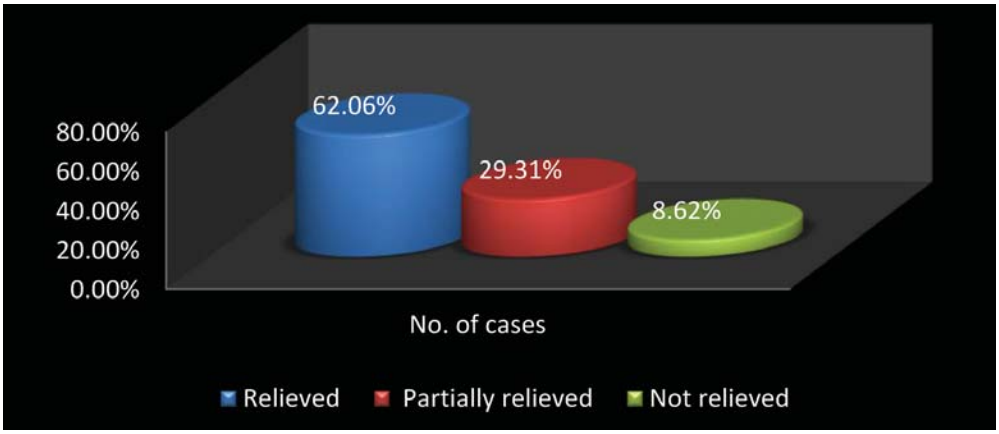

Figure 1: Effect of the treatment

Table 3: Effect of QH and HM on CBC

Parameter → Group ↓	Haemo-globin (gm %)	R.B.C. (10^6 /mm^3)	T.L.C. (10^3/ mm^3)	E.S.R.(mm /hr)		Poly-morphs (%)	Lympho-cyte (%)	Eosino-phil (%)
				1 Hour	2 Hour			
First day of treatment	11.36 ±0.20	3.91 ±0.07	7.57 ±0.25	40.0 ±1.17	50.0 ±1.03	61.0 ±0.91	34.0 ±0.91	05 ±0.25
Last day of treatment	11.38 ±0.20▪	3.93 ±0.07▪	7.7 ±0.22▪	41.0 ±1.54▪	50.0 ±1.08▪	62.0 ±1.03▪	33.0 ±1.04▪	05 ±0.27▪

n = Total no. of 58 patients, ▪ P is not being significant

Table 4: Effect of QH and HM on liver and kidney function

Parameter → Group ↓	SGPT (IU/L)	SGOT (IU/L)	Serum Alkaline Phosphatase (IU/L)	Blood Urea (mg %)	Serum Creatinine (mg %)	Serum Uric Acid (mg %)
First day of treatment	20.82 ±1.61	24.71 ±1.32	81.07 ±6.97	19.81 ±0.75	0.85 ±0.01	4.09 ±0.13
Last day of treatment (28^{th}-days)	18.35 ±1.18▪	20.97 ±0.98▪	77.76 ±6.99▪	20.1 ±0.68▪	0.86 ±0.01▪	4.05 ±0.14▪

n= 58 patients

Discussion

The study demonstrated that QH and HM produced significant effect to help ameliorate the symptoms of *Sayalan al-Rahim*. It was found safe as none of the patients complained any unwanted response. It was observed that the mean age of the patients was 26.034±8.24 years. It was also observed that 63.79% of the patients were of *Balghami mizaj* (phlegmatic temperament), 25.86% of *Safrawi mizaj* (choleric temperament) and 10.34% % patients were of Damvi mizaj (sanguine temperament), while none of the cases was found of *Saudavi mizaj* (melancholic temperament). It indicated that the diseases is common in relatively younger age group of reproductive life and that women with *Balghami* temperament are more prone to be afflicted with the diseases. The mean duration of disease was found to be 51.03±53.98 months. It bespeaks that either the disease prevails over a long period of time or the patients remain reluctant to consult a physicians for quite some times. They visit a hospital or a practitioner only when the symptoms become intolerable. It was noted leucorrhoea was more prevalent among the married women (56.90%) as compared to the unmarried women (Table 1). This may be because most of the unmarried women may have shied away to visit a hospital rather they have preferred to visit private practitioners because in Indian society particularly among the lower middle social class women are always reluctant to visit a hospital for gynaecological problems. Since our study was confined to an institutional hospital therefore a limited turnout of unmarried women may be a possibility. But in another study a high prevalence of vaginal discharge among married women has also been reported (Chaudhary et al., 2012), which is in consonance with the findings of our study. It means both the possibilities cannot be ruled out, one that the disease is more common in married women and second the unmarried women frequently hesitate to visit a hospital.

For the assessment of efficacy of the trial drug the result was interpreted in terms of percentage of efficacy. Thirty six patients (62.06%) were relieved, 17 (29.31%) were partially relieved whereas no improvement was seen in 5 (8.62%) of the patients (Table 2). Apart from the improvement in sign and symptoms, a marginal increase in Hemoglobin percentage was also observed in 31 subjects ($p<0.05$) (Table 3). As Unani physicians have stated anaemia (*Qillat wa riqqate khoon)* and general weakness (*Zoafe aam*) as important causes of *Sayalan al-Rahim* and mentioned iron preparations (*Murakkabate Faulad*) and *Habbe Marwareed* as the treatment (Nafis 2009, and Khan 1987), so our study by demonstrating the haemoglobin increasing effect has validated the Unani practice with the drugs that have tonic and blood procreator activity in the management of *Sayalan al-Rahim*. The two test drugs have been described to possess *muqawwi, muharrik*, blood procreator and related activities and are used in a number of conditions

consistent with general debility, weakness, perilous immunity etc. Since, the etiology of *Sayalan al-Rahim* has been associated mainly with poor health and hygiene, weakness and low immunity therefore improvement in its sign and symptoms proves to be the testament of the efficacy of test drugs in cases of *Sayalan al-Rahim*.

No adverse effect was noted on haematological and biochemical parameters including the kidney and liver function tests conducted before and after the study (Table 4). It indicated that the drugs are safe. It is important in the context that these two drugs are commonly prescribed by the physicians in pathological conditions requiring relatively larger period of treatment. The safety profile provides a liberty to the physicians and the patients to use this drug for a longer period.

Conclusions

It may be concluded that oral administration of two important pharmacopoeal drugs i.e. *Qurse Kushta Khabs al-Hadeed* and *Habbe Marwareed* is safe and effective in the management of *Sayalan al-Rahim* (leucorrhoea).

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Therapeutic Evaluation of a Polyherbal Formulation Leuco-Cure in Trichomoniasis

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Abstract

Trichomoniasis is a common public health problem in women worldwide and accounts for almost half of all curable infections. This infection is found in approximately 50% of the patients who complain of vaginal discharge and over 200 million people worldwide become infected every year with it. In the present study a proprietary Unani preparation namely Leuco-Cure capsule (Dehlvi Remedies), has been studied in patients of trichomoniasis to determine its efficacy and safety. The patients were treated with Leuco-Cure (2 capsules), twice a day for 14 days, by oral route along with a cup of milk. After two weeks of treatment patients showed 80% reduction in important clinical features such as abnormal vaginal discharge, pruritus vulva and trichomonas in wet mount examination. The findings suggested that Leuco-Cure is effective in the treatment of trichomoniasis.

Keywords: Unani drug Leuco-Cure, Vaginal discharge, Trichomoniasis, *Sailanur Rahem*

Introduction

Trichomoniasis is the most common vaginal infection in women of child bearing age. It is caused by an ovoid / pear shaped, actively motile, flagellated parasite i.e. *Trichomonas vaginalis* that is a protozoon, slightly larger than a leucocyte and is anaerobic (Dutta, 2001; Dawn, 2001). Unani medicine postulates that it occurs following the change in the quality or/and quantity of Phlegm (*Balgham*) in the body especially in the pelvic region; *Balgham* serves as a good medium for infection (Zeenat & Hasan, 2016). Trichomoniasis in Unani literature has also been described to be a type of *Sailanur Rahem* (leucorrhoea) characterized by excessive uterine discharge. *Ufunat* (infection) in the uterus leads to weaken different faculties of reproductive organs that in turn disturb the local homeostasis of pelvic region leading to excessive discharge (Ibn Sina, 2007; Majoosi, 1889)

Trichomoniasis occurs at any age from birth onwards but most often in the young adults and is found in approximately 50% of the patients who complain of vaginal discharge (Kumar & Malhotra, 2008). The World Health Organization has estimated that this infection accounts for almost half of all curable infections worldwide (Schwebke & Burgess, 2004). Scientific reports show highly divergent prevalence of trichomonas in different countries and even in different geographical regions (Say & Jacyntho, 2005). The complications associated with trichomoniasis in women include various inflammatory conditions, cervical erosion, cervical cancer and infertility. Premature rupture of the placental membranes, contributing to premature labour, and low weight babies at birth, is known perinatal complications.

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Increased risk of HIV infection due to trichomoniasis has been reported in both sexes (Cudmore *et al*., 2004). The disease is usually treated with Metronidazole, a 5-nitroimidazole drug derived from the antibiotic azomycin. Common adverse reactions of Metronidazole are usually mild, although some patients do have reactions severe enough to necessitate halting Metronidazole therapy (Cudmore *et al*., 2004). Such a situation warrants some alternative arrangement for the treatment of trichomoniasis. There are a number of safe and effective drugs in Unani system of medicine that have been described to be effective in trichomoniasis, vaginitis and *Sailanur Rahem* etc. Many non pharmacopoeal drugs in recent years have been shown to demonstrate interesting therapeutic response in many pathological conditions. Leuco-Cure (capsule), a proprietary Unani preparation, is also one such drug effective in gynaecological problems including the trichomniasis. Therefore, present study was designed to evaluate the efficacy of Leuco-Cure in the management of trichomoniasis.

Materials and Methods

Leuco-Cure capsule prepared by Dehlvi Remedies, New Delhi, was procured from its local agency at Malegaon. The ingredients of Leuco-Cure are given in Table 1.

The patients who visited the OPD of Department of Ilmul Qabalat wa Amraz-e-Niswan, Mohammadia Tibbia College and Assayer Hospital, Mansoora, Malegaon during 2013-14, were screened for the presence of *Trichomonas vaginalis* on the basis of clinical signs and symptoms. The diagnosis of screened patients was however confirmed after pathological investigation.

Table 1: Ingredients of Leuco-Cure (Each 500 mg capsule contains)

S.No.	Name of Ingredients	Scientific Name	Quantity
1	Mochras	*Bombax malabaricum*	100 mg
2	Kamarkas	*Butea frondosa* gum	75 mg
3	Mayeen Kalan	*Tamarix galllica*	75 mg
4	Marwareed Saaida	*Mytilus margaritiferus*	50 mg
5	Lodh Pathani	*Symplocos racemosa*	50 mg
6	Mazu Sokhta	*Quercus infectoria*	50 mg
7	Gule Dhawa	*Anogeissus latifolia*	50 mg
8	Kushta Sadaf	Cyprae moneta (Calcined)	25 mg
9	Mastagi	*Pistacia lentiscus*	25 mg

After taking the informed consent, 60 diagnosed patients of 18-45 years were included in the study. They were informed about the disease, examination to be performed and type of treatment. The patients suffering from candidiasis, chlamydial vaginitis, diphtheritic vaginitis, granular vaginitis, bacterial vaginitis, senile vaginitis, emphysematous vaginitis, vaginitis adhaesiva, neoplasm of cervix or vagina or any other systemic disease were excluded from the study. The permission of Institutional Ethics Committee (IEC) was taken prior to the commencement of the clinical study. The patients were divided into two groups of 30 patients each with the help of computer randomized tables/ numbers. The patients in group I, were treated with Metronidazole in a dose of 400 mg, twice a day for one week, orally, while the patients in group II, were treated with Leuco-Cure in a dose of two capsules, twice a day for two weeks, by oral route.

Before and after the treatment, specific investigations such as 'vaginal pH determination', 'amine (whiff) test' and 'saline wet mount examination of vaginal discharge' were done to confirm the diagnosis and to use as important objective parameters for the assessment of the efficacy of the treatment. The pH was measured (Khan, 2007) by using a Ranbaxy pH indicator paper with a range of 4.5 to 7 with distinct colour keys to 4.5, 5, 5.5, 6, 6.5 and 7. The paper was applied to the anterior vaginal fornix to avoid contamination with cervical mucous. The colour developed on the moistened paper was matched with the colour scale provided with the kit. The amine test (Egan & Lipsky, 2000) was performed by adding 2 to 3 drop of 10% KOH directly to swab or to the discharge on the speculum; release of fishy or amine odour was recorded as positive Amine or Whiff test. Differentiation between bacterial vaginosis and trichomoniasis depends on microscopic evaluation of material recovered from the vagina. The most useful approach for evaluation in the clinical setting is the wet mount. A drop of vaginal discharge was collected by a pipette or swab from the posterior vaginal fornix and placed on a clean warm glass slide. Two drops of normal saline were added and mixed with the vaginal discharge. A glass cover slip was placed over it. The wet film was immediately examined (hpf 45^{x}). The *Trichomonas vaginalis* were recognized by their shape, size and their nozing and rotatory movements. The presence of large numbers of polymorphonuclear leucocytes (PMNs) supports the diagnosis of trichomoniasis (Rein & Liang, 1999). The presence of parasite was recorded in the Case Record Form. The clinical features were graded on point scales and the changes were noted in CRF on every follow up.

The patients were advised for weekly follow up. They were also advised abstinence and not to use concomitant therapy during the treatment. At each visit the patients were examined carefully to assess the different parameters. Each patient underwent per vaginal examination in lithotomy position after general and systemic examination. Tenderness of vaginal wall and straw berry appearance of vagina and cervix was recorded by per speculum examination. Scoring system for overall

evaluation of each patient was done. The vaginal discharge was graded (Mirza *et al*., 2011) as none (-) for no discharge, mild (+) for normal moistness of vagina without staining or moistening the underclothes, moderate (++) for undeniably soiled the underclothes that require frequent changing and washing and severe (+++) that requires the use of absorbent pad. Pruritus (Akhyani *et al*., 2005), burning micturition and dysuria (Marickar & Salim, 2009) were classified as none (-), mild (+), moderate (++) and severe (+++). Dyspareunia, backache and lower abdominal pain were assessed by visual analogue scale (Lin *et al*., 2005) as none (-), mild (+), moderate (++) and severe (+++). Tenderness and congestion of vaginal wall and straw-berry appearance of vagina and cervix were also graded as none (-), mild (+), moderate (++) and severe (+++). The percentage decrease in scores was determined by comparing the baseline and post treatment scores. Finally, recorded findings were statistically analyzed using Chi square test to determine the significance.

Results and Discussion

The test drug was studied for its efficacy in the management of trichomoniasis by observing clinical features and the findings of laboratory investigations. The subjective (Table 2) and objective (Table 3) findings were tabulated, analyzed and compared with the standard drug.

On the day of registration abnormal vaginal discharge was found in all (100%) the patients included in the study, while after treatment it remained only in 16.66%,

Table 2: Effect of standard and test drugs on subjective parameters

Symptoms (Subjective Parameters)	Group I (Standard Control)						Group II (Test)					
	Baseline		Post treatment		Improve-ment		Baseline		Post treatment		Improve-ment	
	No	%	No	%	No	%	No	%	No	%	No	%
Abnormal vaginal discharge	30	100	05	16.66	25	83.33	30	100	06	20	24	80
Malodour	28	93.33	04	14.28	24	85.71	27	90	05	18.51	22	81.48
Pruritus vulva	30	100	05	16.66	25	83.33	30	100	06	20	24	80
Dyspareunia	23	76.66	03	13.04	20	86.95	24	80	04	16.66	21	87.5
Low backache	18	60	02	11.11	16	88.88	17	56.66	03	17.64	14	82.35
Pain in lower abdomen	16	53.33	02	12.5	14	87.5	15	50	02	13.33	13	86.66
Burning micturition & Dysuria	21	70	03	14.28	18	85.71	19	63.33	03	15.78	16	84.21

and 20% of the patients indicating an improvement of 83.33% and 80% of the cases in group I and II, respectively. Malodour on day zero was found in 93.33% and 90% of the cases in group I and II, respectively, whereas after treatment it reduced and was found only in 14.28% and 18.51% of the cases indicating an improvement of 85.71% and 81.48%. Pruritus vulva on day zero was found in 100% of the patients in each group. It reduced significantly as only 16.66% and 20% of the patients were found to have this problem after the treatment, respectively. On day zero, dyspareunia was found in 76.66% and 80% of the cases in group I and II, respectively, whereas it was found absent in 86.95% and 87.5% of the cases, respectively after the treatment. Prior to the treatment low backache was found in 60% and 56.66% of the patients in group I and II, respectively, which was found reduced significantly as only 11.11% and 17.64% patients in group I and II, respectively reported this problem after receiving the treatment and 88.88% and 82.35% of the patients got complete relief. Lower abdomen which was complained by 53.33% and 50% of the patients was improved as after treatment, it continued only in 12.5% and 13.33% patients in group I and II, respectively. Prior to the treatment burning micturition and dysuria were found in 70% and 63.33% of the cases in group I and II, respectively which reduced significantly after treatment and was found in 14.28% and 15.78% of the patients only, thus showing an improvement of 85.71% and 84.21%, respectively.

On examination, tenderness of vaginal wall was found in 76.66% and 80% of the patients in group I and II, respectively prior to treatment, which reduced significantly after treatment and was found in 13.04% and 16.66% of the cases only. Improvement was observed in 66.66% and 83.33% of the patients, respectively.

Table 3: Effect of standard and test drugs on objective parameters

Signs (Objective Parameters)	Group I (Standard Control)						Group II (Test)					
	Baseline		Post treatment		Improvement		Baseline		Post treatment		Improvement	
	No	%	No	%	No	%	No	%	No	%	No	%
Tenderness of Vagina	23	76.66	3	13.04	20	66.66	24	80	4	16.66	20	83.33
Strawberry appearance	08	26.66	Nil	0	08	100	09	30	Nil	0	09	100
pH > 4.5	30	100	6	20	24	80	30	100	7	23.33	23	76.66
Positive Amine Test	30	100	3	10	27	90	30	100	5	16.66	25	83.33
Trichomonas in slide	30	100	5	16.66	25	83.33	30	100	6	20	24	80

On day zero straw berry appearance of cervix and vagina was found in 26.66% and 30% of the patients in two groups, respectively. While after treatment it disappeared totally, showing 100% improvement in each group. A pH of more than 4.5 was found in all the patients in the investigation conducted before the treatment but after treatment it was found reduced in 80% and 76.66% of the cases, respectively. On day zero, amine test was found positive in all the patients, while after treatment it was found negative in 90% and 83.33% of the cases in group I, II, respectively. Prior to the treatment, trichomonas in slide was found in 100% of the patients in each group, however after treatment it reduced and was found only in 16.66% and 20% of the patients.

Relief in clinical symptoms along with reduction in microbiological count was considered as the criteria of improvement. The patients who got relief from abnormal vaginal discharge along with absence of trichomonas in slide after treatment were rated as cured. While the patients having no relief in abnormal vaginal discharge and trichomonas were found in their slides after treatment, were rated as not cured. Complete cure was observed in 83.33% patients in group I and 80% cases in group II (Table 4).

The finding of present study in respect of subjective and objective parameters indicated that there was no statistical difference between the two groups suggesting that both the drugs produced almost equal degree of response.

As per the Unani literature the diseases occur due to irregular and disproportional distribution of the *Akhlat* (Humours). The *Akhlat* are classified in to four categories with four primary qualities. According to this *Dam* (Blood) is hot and moist, *Balgham* (Phlegm) is cold and moist, and *Safra* (Yellow Bile) is hot and dry, while *Sauda* (Black Bile) is cold and dry. The mucous fluid secreted from the vagina is a kind of *Balghami Khilt* (Ahmad, 1980). This disease occurs due to change in the quality or quantity of *Balgham* (Majoosi, 2005). Thus, either the temperament (Kaifiyat) of *Balgham* is altered or some other normal or abnormal *khilt* is mixed with *Balgham* to the extent of altering its temperament. Its dominance as such is also the cause of many diseases including excessive vaginal discharge and related symptoms. The qualitative/quantitative changes in *Balgham* can be either identified with various signs and symptoms associated with it or by the chemical and physical examination of various samples of *Balgham* (Ahmad, 1980). *Balgham* is mainly

Table 4: Response to treatment

Response	Group I (Standard Control)		Group II (Test)	
	No.	%	No.	%
Cured	25	83.33	24	80
Not cured	5	16.66	6	20

synthesized in liver and used by different organs for certain physiological function (Hamdani, 1980). When it becomes abnormal, *Quwate Maska* of the body (retentive power) does not absorb it. The retention of morbid matters thus caused, leads to the causation of vaginitis; it also invites various organisms to grow. It is one of the facts that wherever is the focus of infection in the body, the culture media for it is provided by Phlegm. In the other words *Balgham* is the first to catch infection (Ahmad, 1980). The temperament of *Balgham* has been described to be *barid ratab* (cold, moist) therefore the signs and symptoms of *Balghami* diseases are also manifested with *burudat* and *rutubat* (cold and moisture). Most of the ingredients of Leuco-Cure because of having a temperament opposite to the temperament of *Balgham* appear to be effective in improving the signs and symptoms of trichomoniasis and vaginal discharge which are supposed to arise because of ascendance of *Balgham*. Most of the ingredients of Leuco-Cure have been described in classical and ethnopharmacological literature to be *Qabiz* (astringent), *Habis*, *Mohallil* (anti-inflammatory), *Mufatteh* (deobstruent), *Mujaffif* (dessicative), *Musakkin* (analgesic). They have also been reported to be antimicrobial and antiseptic (Anonymous, 1976; Anonymous, 1988; Chatterjee & Pakrashi, 2005; Chopra *et al*., 1956; Ghani, YNM; Hakeem, 1999; Khan, 1313H; Kirtikar & Basu, 1991; Nadkarni, 1954). Due to these medicinal properties, Leuco-Cure may have produced *yaboosat* (dryness) that lead to the constriction in the vaginal wall and resolved the discharge and inflammatory condition, and relieved the pain.

The study clearly showed that Leuco-Cure is effective in trichomoniasis, which was evidenced by decrease in amount of abnormal vaginal discharge, pruritus, dyspareunia, backache, pain in lower abdomen, burning micturition and dysuria, tenderness and congestion of vaginal wall, strawberry appearance, pH and absence of trichomonas in slides and also by negative amine test. The efficacy of the test drug may also be attributed to its antiprotozoal activity. No adverse effect of test drug was reported during the entire period of study.

Conclusion

In the light of finding and discussion it can be concluded that Unani polyherbal drug Leuco-Cure possesses significant effect against trichomoniasis. Therefore, it can be used effectively and safely in patients afflicted with it and its associated conditions.

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Therapeutics, Phytochemistry and Pharmacology of *Vitex negundo* Linn: A Review

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Abstract

Vitex negundo Linn is a deciduous, woody, hard, aromatic shrub growing to a small tree and flourishing mainly in the Indian subcontinent. Almost all parts of the plant possess a multitude of phytochemical secondary metabolites which impart an unprecedented variety of medicinal uses to the plant. The plant has been extensively used in treatment of a number of ailments by the healers of traditional medicine and folk medicine, and in recent years scientific evidence has been generated in respect of its pharmacological and therapeutic sues. It is used in all systems of medicine including Ayurveda, Unani, Siddha, Homeopathy, and Allopathy. It is commonly used in folk medicine in India, Bangladesh, China, Philippines, Sri Lanka, and Japan. Keeping in view the medicinal importance of the drug in Unani Medicine and other traditional systems of medicine, an attempt has been made to review the available stock of knowl;edge available in traditional, ethnobotanical and scientific literature on its phytochemical and ethno-pharmacological properties, and therapeutic uses.

Keyword: *Vitex negundo* Sambhalu, Phytochemistry, Pharmacology, Medicinal uses, Unani medicine

Introduction

Vitex negundo, Linn. (Family : Verbenaceae) is a deciduous, woody, hard, aromatic shrub, growing to a small tree and flourishing mainly in the Indian subcontinent (Vishwanathan & Basavaraju, 2010). The seeds of the plant are known as *Tukhm-e-Sambhalu* (Ahuja *et al*., 2015).The word *Vitex* is derived from the Latin word 'vieo' (meaning to tie or bind) because of the flexible nature of its stems and twigs. The plant is known in Sanskrit as Nirgundi that literally means to 'protect the body from diseases'. It is therapeutically used in many traditional systems of medicine including Ayurveda, Unani, Siddha, Homeopathy, and Allopathy. A popular local quote of the Bengalis reiterates that a man cannot die of disease in an area where *Vitex negundo*, *Adhatoda vasica* and *Acorus calamus* are found (Vishwanathan and Basavaraju, 2010). It is one of the common plants used in Indian medicine and almost its all parts are employed (Chatterjee & Pakrashi, 1995; Anonymous, 1976), but the leaves and the roots are more important (Anonymous, 1976). It possesses a multitude of phytochemical secondary metabolites which impart an unprecedented variety of medicinal uses to the plant (Vishwanathan &Basavaraju, 2010). It is commonly used in folk medicine in India, Bangladesh, China, Philippines, Sri Lanka, and Japan. It has multifarious uses in basketry, dyeing, fuel, food, stored-grain protectant, field pesticide, and growth promoter manure (Ahuja *et al*, 2015).

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In Unani system of medicine *Vitex negundo* (Sambhalu) is in use since thousands of years by Unani physicians Dioscoredes and Jalinus. It has quadrangular density whitish tomentose branches up to 4.5 meter high (Hussain, 2004). It is a shrub measuring about 4-10 fit in height and its stem is thick about 1.5 fit in width. It has number of branches (Lubhaya, 1984), each having 5 leaves which appear like a palm with finger like projection (Nabi, 1920). Due to claw like leaves the plant is also called as Panjgasht (Ansari, 2009). It cannot be broken easily (Ibn Baitar, YNM). Leaves of the plant are 1.5- 2 inch long, jagged as that of leaves of *Anar* (*Punica granatum*) and *Arhar*, pointed, long as spear, glabrous, but hoary on dorsal side (Lubhaya, 1984). Leaves are white on one side and blackish on the other (Ghani, 2011). According to Ibn Baitar (ynm), the leaves of the plant are same as that of Zaitoon (*Olea europea*) but comparatively softer than it. Its leaves have also been described to be similar to that of Tulsi (*Ocimum sanctum*) having tip at its end (Ghani, 2011). When the leaves are crushed they smell like *Bisbasa* (*Myristica fragrans*) (Ibn Baitar, YNM). The leaves shed off in autumn weather. Flowers grow in small group of bunches. They are yellowish blue or whitish red in colour (Naseeruddin, 2010). The fruits/ seeds of the plant are small in size like Baobarang (*Embelia ribes*). They are black or white in colour (Ali, 1999; Lubhaya, 1984).They are similar to black pepper but comparatively smaller in size (Nabi, 1920). Wood and bark are thin, smooth and blue in colour (Naseeruddin, 2010). Unani physician Dioscorides stated that according to geographical situations, some plants are spermatophyte and some are non-spermatophyte. Mostly leaves and seeds on account of having hot and dry temperament are used for therapeutic purposes (Ibn Baitar, YNM).

Distribution

Vitex negundo is found throughout the greater part of India, ascending to an altitude of 1500 meters in the outer Himalayas (Ladda and Magdum, 2012). It is also distributed in Ceylon, Afghanistan, tropical Africa, Madagascar, China and Philippinea (Kirtikar & Basu, 1991). It thrives in humid places or along water courses in wastelands and mixed open forests (Vishwanathan & Basavaraju, 2010). It is found in scrub jungles and road-side in the warmer parts of India (Chatterjee &Pakrashi, 1995). It is abundant along the bank of rivers, in moist area, open-waste lands and near the deciduous forests. It is widely planted as a hedge-plant along the roads and between the fields (Anonymous, 1976).

Vernaculars

The plant is known by different names in different languages, areas and traditions: *Aslag, Fanjangasht, Zukhamsate asabea, Zukhamsatilourag* (Arabic); *Nirdundi, Nilanirgundi, Sindhavaara* (Ayurved); *Nishinda, Nigrundi, Samalu, Nisinda*

(Bengal); *Katri, Lingur, Nargunda, Nirgundi, Nirgur, Nisinda, Shiwari* (Bombay); *Kiyowbhanbin, Kiyubanbin* (Burma); *Houang kin, Mu Ching* (Chinese); *Shamalu, Shambali* (Deccan); *Chhatimal, Nishinda, Shimalu, Sumalu* (Dehradun); *Five leaved chaste tree, Indian Privet* (English); *Nagaol, Nagda, Nagoda, Nagodz, Nigod, Nirgari* (Gujrati); *Sambhalu, Mewri, Nengar, Ningori, Nirgandi, Nirgunda, Nisinda, Panikisambhalu, Sambhal, Sanbhalu, Shawali, Shiwali, Shiwari, Sindhuca, Sinduari* (Hindi); *Shiwa, Shiwali, Simali* (Kumaon); *Indrani, Nochi, Vellanochi, Vennochi* (Malayalam); *Lingur, Nirguda, Nirgunda, Nirgundi, Nirgur* (Marathi); *Sewali* (Nepal); *Banjangasht, Panjangusht, Sisban* (Persian); *Agnocasto* (Philippines); *Bankahu, Banna, Binna, Biuna, Marwa, Marwan, Mawa, Maura, Mora, Morann* (Punjab); *Marwandai, Mehrwan, Warmande* (Pushtu); *Indrani, Nilapushpa, Nilanirgundi, Nirgundi, Shephali, Sinduvara, Surasa* (Sanskrit); *Noohi* (Siddha); *Vellai-nochi, Nirochi, nochchi, Nirkkundi, Sinduvaram, Tiriburamerittan, Vennochi* (Tamil); *Sindhuvaruma, Nallavavili, Vavili, Vayali* (Telgu); *Banjan Kusht, Hashishatur Ruhbania* (Unani); *Sambhalu* (Urdu); *Begundia, Indrani* (Uriya) (Anonymous, 1987; Anonymous, 1987; Chatterjee and Pakrashi, 1995; Khare, 2004; Kirtikar and Basu, 1991; Ibn Baitar, YNM).

Mizaj (Temperament)

Unani physicians have unanimously described the *Mizaj* of *Tukhm-e-Sambhalu* (seed) as Hot and Dry. But they differ regarding its degree. Some described as Hot and Dry in second degree (Khan, YNM), while others have described it Hot in second degree and Dry in third degree (Ghani, 2011).

Afa'al (Action)

In classical Unani literature, various actions of *Tukhm-e-Sambhalu* (*Vitex negundo* seed/ fruit) have been described in details such as *mulattif*, *qabiz* (Nabi, 1920); *mohallil*, *musakkin*, *dafe ta'affun* (Hussain, 2004); *qate balgham*, *mukhrij-e-deedan-e-ama'a*, *muqawwie bah*, *dafe surfa*, *moarriq*, *dafe alam*. It cures all menstrual problems (Ghani, 2011). It also possesses *mujaffif*, *musakhkhin*, *mudirr-e-haiz*, *mulaiyan* properties (Ibn Baitar, YNM). It acts as *mufatteh sudad-e-jigar wa dimag*, *muhallil-e-warm-e-dimag* (Nabi, 1920).

Istemal (Uses)

Tukhm-e-Sambhalu has been described to be useful in various diseases such as *usr-e-tams, qillat-e-tams, zofe bah, sua'l, zeequnnafas, dabaila, basoor,, bars, sailan-e-mani, dard-e-dandan, warm-e-lissa*, salivation, *hummiyat khafifa*, *zofe sama'at, wajaulmafasil* (Ghani, 2011); *dog and snake bite* (Nabi, 1920); *istisqa tabali, amraz-e-tihal, qillat-e-laban* (Ibn Baitar, YNM), *warm-e-rahem, warm-e-*

khisiya, warm-e-maq'ad, dard-e-halaq (Naseeruddin, 2010). It heals all types of wounds (Hussain, 2004).

Because of analgesic effect, oral administration of seed powder relieves s*usre tams* (dysmenorrhoea) and regulates the menstruation. Local application of paste on umbilicus or vulva makes the labour easy (Ghani, 2011). Sitz bath of decoction of leaves and fruits relieves uterine pain and resolves pelvic inflammatory disorders. The fruit acts as emmenagogue when taken orally or inhaled or applied locally as suppository with Jangali podina (*Ageratum conyzoides*) (Ibn Baitar, YNM). The decoction of leaves is used as sitz bath to reduce metritis (*warm-e-rahem*), orchitis (*warm-e-khisiya*) and rectitis (*warm-e-maq'ad*). The decoction is also used as sitz bath at the time of delivery to expel out the retained materials in uterus (Naseeruddin, 2010). Use of pillow filled by *Vitex negundo* leaves is very helpful to allay headache (Ghani, 2011), while paste of leaves is applied locally for headache (Khan, YNM). The boiled leaves are applied locally 2-3 times a day to reduce inflammation and pain of joint (Ghani, 2011). Inhalation of vapour of leaves is effective in common cold, gout and fever (Ghani, 2011). The decoction of Sambhalu leaves is useful in tonsillitis as it resolves the inflammation. Instillation of sap of leaves is used to improve eye vision (Naseeruddin, 2010). Oral administration of crude or roasted seeds, leaves and flowers may bring down the libido. (Ibn Baitar, YNM). Khare (2004) on the other hand has described that Unani physicians prescribe powder of Tukhm-e-Sambhalu and dry ginger with milk to increase the libido. Seed's powder is prescribed in a dose of 2-3 gm/day for spermatorrhoea and spermatochesis. To increase sperm count, a combination of Sambhalu seeds and *Kushta-e-Jast* (zinc) is commonly prescribed.

Botanical description

Vitex negundo is a large shrub or sometimes a small slender tree, it has branchlets, and underside of leaves is inflorescence hoary, with short grey pubescence. Plant bark is thin, grayish in colour, branchlets, quadrangular in texture, whitish with a fine tomentum (Kirtikar & Basu, 1991). Leaves are 3-5 foliolate, having lanceolate leaflets, entire or crenate, glabrate, dark-green above, pale greenish-tomentse beneath, larger central leaflets (Chatterjee & Pakrashi, 1995), terminal leaflets 5-6 × 1.6- 2.3 cm, lateral ones smaller (Anonymous, 1987), with a very short petiolule, all nearly glabrous above, covered with a fine with tomentum beneath, base acute, common petioles are 2.5- 3.8 cm long. Flowers are small, in lateral cymes, forming an elongated, terminal thyrsus, often compound at the base, bluish purple in colour (Chatterjee & Pakrashi, 1995), but black when ripe and 0.5-0.6 cm in diameter (Hussain, 2004). It has 3 mm long calyx having white tomentus, teeth triangular 0.8- 1 mm long (Kirtikar Basu, 1991; (Chatterjee & Pakrashi, 1995), and persistent calyx (Hussain, 2004). Corolla is 1 cm long, bluish purple coloured, tomentose

outside, hairy inside at the insertion of the stamens, upper lip 2 mm long, divided to the base into 2 obtuse lobes, 5 mm long lower lip, , with 2 short oblong obtuse lateral lobes 1.5 mm deep and a large 4 mm long broadly obovate crenulated terminal lobe. Filaments are hairy at the very base. Its ovary is glabrous in nature with glabrous style. Stigma is forked type. Fruits are drupaceous and black when ripe having size of less than 6 mm in diameter. Dried fruits are much valued medicinally in china (Anonymous, 1976). The roots are cylindrical, hard and tough, and break with an irregular fracture, somewhat tortuous pieces, with very few attached rootlets, some of the pieces measures 0.25-5.0 cm in diameter (Anonymous, 1976). Outer bark is grayish brown and exhibits longitudinal cracks. The wood and powdered root is pale yellow in colour (Anonymous, 1976). Bark is obtained after monsoon (Anonymous, 1987).

Figure 1: *Vitex negundo* L. Plant with flowers

Figure 2 : *Vitex negundo* L. Seed/ Fruit

Pharmacological actions (As described in ethnobotanical and traditional literature)

Vitex negundo has been described in detail in ethnobotanical and scientific literature and various pharmacological actions have been attributed to it. Some of the pharmacological actions and therapeutic uses are as follows:

The whole plants of *Vitex negundo* is anthelmintic, heating, astringent, cephalic, stomachic, demulcent, deobstruent and expectorant. It also has tranquillizing effect. The fruit acts as emmenagogue, nerve tonic, vermifuge, cephalic and the dried fruits are vermifuge. Aqueous extract of fruit has analgesic effects but the fruit itself has cooling effect. The flowers of plant exhibit astringent, cardio tonic and cooling effects. Leaves are vermifuge, antiparasitic, anti-inflammatory, antirheumatic, but act as anodyne when used externally. Root is considered anodyne, diuretic, expectorant, febrifuge, tonic and anthelmintic (Anonymous, 1976; Chatterjee and Pakrashi, 1995; Anonymous, 1987; Kirtikar and Basu, 1991).

Therapeutic uses

The *Vitex negundo* seeds have been described to be effective in skin diseases, pruritus, colic, heart diseases and cough; especially useful in rheumatism (Chatterjee & Pakrashi, 1995). The whole plant is used in many diseases including asthma, bronchitis, convulsion, eye diseases, inflammation, leukoderma and splenomegaly etc. It promotes hair growth, biliousness and painful dentition in children (Kirtikar & Basu, 1991). The fruits (seeds) of the plant are used to relieve headache, catarrh, coryza (Khare, 2004). They produce good effect on diseases of cutaneous tissue and leprosy. In Unani medicine, the seed acts as diuretic and deobstruent, and is administered orally with sikanjabeen (a compound of sugar and vinegar) to resolve hard swelling, especially that of spleen. Powdered seeds (2-3g/day) are prescribed in spermatorrhoea and spermatochesis (Khare, 2004). Flowers of the plant are useful in cholera, diarrhea, fever and liver complains (Chatterjee & Pakrashi, 1995). They reduce the swelling of joints and testes and allay headache (Anonymous, 1984). Leaves are alternative, effective in gonorrhea, epididymitis, orchitis, catarrh and headache (Chatterjee & Pakrashi, 1995), rheumatic swelling of joints and sprains (Anonymous, 1976). Juice of leaves is used for cleaning ulcers, sinuses, sores (Anonymous, 1984). A preparation of oil with juice of leaves is useful for scrofulous sores and sinuses. Decoction of its leaves is used to treat rheumatic disease. Its juice is externally used for foetid discharge and maggots in ulcer (Chatterjee & Pakrashi, 1995). Paste of leaves is applied to temporal region during headache (Khare, 2004). The expressed juice of leaves is poured into nostrils in stupor and coma (Kirtikar & Basu, 1991). An ointment made from the juice is applied locally as a hair tonic (Anonymous, 1976). Decoction of leaves and the vapours are employed in bath for the treatment of febrile, catarrhal and rheumatic affections (Anonymous, 1976). A decoction of its leaves is given along with the long pepper (*Piper longum*) in catarrhal fever with heaviness of head and dullness of hearing, and used as sitz bath in the puerperal stage of women (Kirtikar & Basu, 1991). Leaves of *Vitex negundo* and leaves of *Calotropis gigantea* are made into paste. The paste is applied to cure joint pain. Fresh leaves extraction of *Vitex negundo* is applied for healing of cuts/ wounds. Fresh leaves are boiled in water till vaporization and the vapour are inhaled to get relief from cold and cough (Devi *et al*., 2016). Root of plant helps to relieves diseases like colic, dyspepsia, leprosy (Chatterjee & Pakrashi, 1995), rheumatism, boil, dysentery, piles (Anonymous, 1976). Ash of plant is a source of potassium carbonate or pear-ash, and is reported to be used as an alkali in dyeing (Anonymous, 1976).

Phytochemistry

Very little phytochemical work has been carried out on *Vitex negundo* Linn. It has organic and inorganic constituents such as alkaloids, glycosides, tannins,

reducing sugars, steroids and sodium potassium, calcium, magnesium, iron respectively (Anonymous, 1987). Seeds of *Vitex negundo* gave various hydrocarbons; n-Tritriacontane, n-hentriacontanol, nhentricontane, n-pentatricontane, n-nonacosane, β-sitosterol, phydroxybenzoic acid and 5-oxyisophthalic acid; 3, 4- dihydroxybenzoic acid etc (Singh *et al.,* YNM). Other constituents of seeds are beta-sitosterol, p-hydroxybenzoic acid and 5-oxyisophthalic acid (Khare, 2004). The seed also has linoleic acid, oleic acid, palmitic and stearic acid; also contain *n*-hentriacontane, *n*-pentatriacontane, *n*-nonacosane, *n*-tritriacontane; 3β-acetoxyolean-12-en-27-oic, 2α, 3α-dihydroxyolean-5, 12-din-28-oic, 2β, 3α-diaacetoxyolean-5, 12-dien-28-oic and 2β, 3α-diacetoxyolean-5, 12-dien-28-oic and 2α, 3β-diacetoxy-18-hydroxyolean-5, 12-dien-28-oic acids; 5,7,3'-trihydroxy-6,8,4'-trimethoxy flavone and a flavonoid-artematin; 6-hydroxy-4-(4-hydroxy-3-methoxyphenyl)-3-hydroxymethyl-7-methoxy-3, 4- dihydro-2-naphthaldehyde; 5β- hydro-8, 11 (Chatterjee & Pakrashi, 1995). Leaves yielded an alkaloid, nishindine, the flavonoids 5-dydroxy-3,6,7,32 ,42 -pentamethoxyflavone and casticin, the irridoid glycosides angusid, and 22 -p-hydroxybenzoyl mussaenosidic acid, and an essential oil (Khare, 2004). Other constituents of leaves are carotene, vitamin-C, gluco-nonitol, *p*-hydroxybenzoic acid, 5-oxyisophthalic acid and β-Sitosterol also found in leaves (Chatterjee & Pakrashi, 1995). Stem bark contains two leucoanthocyanidines. Bark contains fatty acid, beta sitosterol, vanillic acids, p-hydroxybenzoic acid, luteolin and flavonoid C-glycoside (Khare, 2004). Stem has p-hydroxybenzoic and vanillic acids; luteolin; 6, 8-d-O-methyl-leucodelphinidin and 3',4'-di-O-methyl-leucocyanidin-7-O-rhamnoglucosides. 3-formyl-4, 5-dimethyl-8-oxo-5H-6, 7-dihydronaphtho (2, 3-b) furan; acetyl oleanic acid are derived from root (Chatterjee & Pakrashi, 1995).

Pharmacological studies

A number of studies have been carried out on *Vitex negundo* Linn in recent years showing that it possesses different pharmacological effects. Some of the important pharmacological effects are as follows:

Analgesic

The extract of *Vitex negundo* produces significant analgesic effect alone and also potentiates the analgesic effect of morphine and pethidine in mice, because the extract has central effect and alters the threshold to pain sensation and produce prominent analgesic effect (Gupta *et al*., 1997). Analgesic effect of aqueous extract of its fruits was evaluated in rats using analgesiometer. The finding demonstrated good analgesic effect (Anonymous, 1976).

Antiarthritic

The decoction of leaves of *Vitex negundo* was found to prevent the swelling of joints in experimental arthritis induced by formaldehyde injection in adult albino rats (Anonymous, 1976).

Antinociceptive

In a study it has been reported that ethanol extract of leaves of *Vitex negundo* possesses both central and peripheral analgesic activity. It may be useful in relieving both the visceral and integumental pain and as adjuvant therapy along with standard analgesic drug (Tandon & Gupta, 2004).

Anticancer

The findings of a study revealed that extract of *Vitex negundo* leaves possesses anti-cancer activity against Ehrlich ascites tumour cells (Anonymous, 1976).

Antidiabetic

A study was carried out to evaluate the antidiabetic activity of aqueous and ethanol extract of *Vitex negundo* leaves. Both the extracts were found to exhibit a significant hypoglycemic activity in alloxan induced diabetic rats. Aqueous extract was found more effective than ethanol extract (Prasanna *et al*., 2012).

Antiepileptic

The ethanol extract of leaves of *Vitex negundo* reduced the number and duration of tonic convulsions in rats subjected to maximal electroshock seizure (MES) in albino rats. The result revealed that it is useful as an adjuvant therapy along with standard anticonvulsants. The extract showed a maximum inhibition (80% mortality) against MES-induced seizures (Jayasree *et al.,* 2012). Petroleum ether extract from dried leaves showed anticonvulsant activity against strychnine and leptazole at high dose levels in Swiss albino mice (Gupta *et al*., 1997). Its methanol extract exhibited anticonvulsant activity and protected animals from maximal electroshock seizure (MES) either by blocking sodium channels or by enhancing GABA receptor mediated inhibitory transmission due to the presence of flavanoids (Kumar *et al.,* 2011). Cold aqueous infusion and chloroform extract of the root of *Vitex negundo* were found to inhibit tremors induced by oxytremorine in mice (Khare, 2004).

Antifungal

Ethanol extract of fruit seeds of *Vitex-negundo* showed significant activity (90%) against *Fusarium solani* and moderate response (60%) against *Microsporum canis*

with no effect on *Candida albicans*, *Candida glabrata*, while *Asperillus flavus* strains were found insensitive against the extract (Mahmud *et al*., 2009). Extract of leaves and twigs of the plant showed significant antifungal activity against *Trichoderma viridiae* and *Fusarium helminthosporium* (Khare, 2004).

Antiinflammatory

Seeds of *Vitex negundo* exhibited significant anti-inflammatory effect and markedly suppressed early and delayed inflammatory changes (Khare, 2004). Ethyl acetate extract of leaves produced significant anti-inflammatory activity against carrageenin, bradykinin and 5-HT-induced hind paw oedema (Khare, 2004).

Antimicrobial

Various extracts of *Vitex negundo* have been shown to possess prominent antimicrobial activity against *Bacillus subtilis*, *Bacillus megaterium*, *Salmonella typhi* and *Vibro mimicus.* The LC_{50} (50% mortality) value of 12.5ìg/ml, 1.55ìg/ml and 1.56ìg/ml for methanolic crude extract, pet. ether and carbon tetrachloride fractions respectively was reported when compared with Kanamycin, 30ìg.disc (Chowdhury *et al*, 2009). The extracts of leaves and twigs also showed significant antibacterial activity against *Micrococcus pyognes* var. aureus and *Escherichia coli* (Anonymous, 1976).

Antioxidant

Vitex negundo is a potential source of natural antioxidants. Methanol extracts of different parts of *Vitex negundo* showed significant antioxidant activity. The leaves and stem showed maximum antioxidant property (Sharma *et al*., 2010). The leaf of *Vitex negundo* has protective action on the brain, which could be attributed to its antioxidant potential and fractions of leaf prevent the enzymatic leakage and elevation of serum uric acid, triglycerides and lipoprotein levels. All the fractions (except the residual fraction) prevented the rise in lipid peroxidation and enhanced the antioxidant enzymes in ethanol-induced cerebral oxidative stress in rats (Umamaheswari *et al.,* 2012).

Antifilarial

Ethyl acetate extract of *Vitex negundo* leaves was found effective against cattle filarial adult worm *S. cervi*. The treated worms were completely immobilized due to the lethal effect of the plant extract at lower concentration in a dose dependent manner (Sahare & Singh, 2013).

Antitumor

Aqueous and ethanol extracts of leaves of *Vitex negundo* Linn have been found to exhibit anti tumor property. Ethanol extract reduced the cancer cell count to 0.92 ± 0.38 X 106 cells in the treated mice and aqueous extract reduces cancer cell count to 1.02 ± 0.18x 106 cell in the treated mice and both extracts increased the RBC count significantly to 3.7 ±0.19 million/cumm 3.61 ± 0.15 million/cumm, respectively. Similarly both extracts restored the WBC value to11.5 ±714.36cells/ml x 103, 11.49 ±699.83 cells/ml x 103, respectively, and restored the HB % and platelet count (Dewade *et al.,* 2010).

Anxiolytic

The anxiolytic activity of ethanol extract of *Vitex negundo* was evaluated clinically. The findings demonstrated that the extract is effective in relieving anxiety and is useful in primary medical care (Adnaik *et al*., 2009).

Central nervous system

In a study it was concluded that the petroleum ether extract of *Vitex negundo* itself does not have any sedative hypnotic action but it potentiates the sedative-hypnotic action of other drugs such as diazepam and phenobarbitone (Gupta *et al*., 1997).

Cytotoxic activity

The petroleum ether and carbon tetrachloride fraction extract of *Vitex negundo* showed significant cytotoxic activity against brine shrimp nauplii (Choudhury *et al*., 2009).

Hepatoprotective

An experimental study showed strong preliminary evidence that alcohol extract of *Vitex negundo* has hepatoprotective effects against liver toxicity by induced by thioacetamide in *Sprague Dawley* rats as proven by macroscopical, microscopical, and biochemical analyses (Kadir *et al*., 2013).

Insecticidal

The leaves of *Vitex negundo* are reported to possess insecticidal properties. For this purpose they are laid over stored grain to ward off insects (Anonymous, 1976).

Laxative

In an experimental study the leave extract of *Vitex negundo* exhibited significant laxative activity in rats (Adnaik *et al*., 2008).

Spermatogenic and ovulatory

In a clinical study it has been demonstrated that dry powder of *Vitex negundo* leaf with cold water for 120 days, raised the sperm count by 3-5 times and the ratio of live and dead sperm also increased to optimum level from 1:1 to 1:4. While on withdrawal it again came down to base level within another 120 days (Khare, 2004).

The flavonoid-rich fraction of seeds caused disruption of the latter stages of spermatogenesis in dogs (Bhargava, 1989) and interfered with the male reproductive function in rats (Das *et al*., 2004).

Conclusion

Vitex negundo Linn. (Sambhalu) has been in use since times immemorial to treat many diseases. Various traditional medicines are successfully using this drug to manage different pathological conditions. Phytochemical, experimental and clinical investigations have verified many claims of traditional medicine in respect of its pharmacological and therapeutic effects. Experimental studies have demonstrated its analgesic, antiarthritic, antinociceptive, anticancer, antidiabetic, anti-epileptic, antifungal, anti-inflammatory, antileprotic, antimicrobial, antioxidant, antifilarial, antitumor, anxiolytic, cytotoxic, hepatoprotective, insecticidal, laxative and spermatogenic and ovulatory effect activities. However, extensive clinical research is required to explore its full therapeutic potential.

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Standardization and Evaluation of Antibacterial and Antifungal Activity of Root Bark of Dar-e-Hald *(Berberis aristata)*

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Abstract

Due to unsystematic use of many antibiotics and antifungal drugs even at higher doses at medical centers to get early medical and commercial benefits causes many problems to human health. Microorganisms developed resistance against many antimicrobial drugs and uses of these synthetic medicines are also associated with severe adverse effects. Therefore, there is an urgent and constant need to develop new, safe and effective therapeutic agents for the treatment of infections. Dar-e-Hald (*Berberis aristata*) is a medicinal plant used in Unani System of Medicine since long time either as single drug or in compound formulations to treat infectious diseases. In this study Dar-e-Hald was screened for its antibacterial and antifungal activity against different gram positive and gram negative bacterial strains such as *Bacillus sp, Staphylococcus aureus, Streptococcus pyogenes, Vibrio cholera, E. coli and Proteus sp.etc.* and different fungal strains like *Aspergillus flavus, Aspergillus fumigates, Aspergillus nigur, Candida albicans, Candida keyfr, Candida parapsilosis.* The Aqueous and alcoholic extract and powder of the test drug was used to determine antibacterial and antifungal activity by disc-agar diffusion technique at three concentration levels (50, 25 and 12.5µg/disc) and compared with standard drugs. Ciprofloxacin (5 µg/disc) taken as standard for antibacterial potential and for antifungal activity Fluconazole (10 µg/disc), Nystatin (100 µg/disc) and Amphotericin (100 µg/disc) were used. Zone of Inhibition was taken as the parameter for the assessment of antimicrobial activity. Minimum inhibitory concentration for alcoholic extract of *Berberis aristata* against bacterial and fungal strains was also determined. Dar-e-Hald shows significant activity against most of the bacterial and fungal strains used for the study. Furthermore, before testing these drugs for antimicrobial activity, the samples of the drugs were also checked for authenticity based on certain Physico-chemical parameters.

Keywords: *Berberis aristata,* Antibacterial, Antifungal, Physico-chemical

Introduction

Infectious diseases shares high percentage of the health problems in the developing countries, hence it is the need of today to find quick, effective and safe remedies for these health problems. The simple medicaments but also the polypharmaceutical preparations of Unani System of Medicine have great significance in the treatment of many diseased conditions (Rahman *et al.,* 2011). Natural products in current use possess nearly every conceivable type of biological activity. World Health Organization (WHO) estimates that 4-billion people from all over the world use herbal medicines. The discovery of a vegetable extract of

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medicinal benefit leads to the isolation of active principle and its subsequent chemical characterization (Shetty *et al.,* 2008). Despite the potential of plants to provide us with useful pharmaceutical agents, the field is still having wide area to be studied. Only an estimated 5–10% of the approximately 3lacs–5lacs plant species worldwide have been screened for one or more bioactivities (Mpala *et al.,* 2010). Plants which are widely used as medicines constitute a major source of natural organic compounds (Prabuseenivasan *et al.,* 2006). During the recent past due to resistant microbes, side effects and complications of synthetic drugs, interest grows in traditional and alternative systems of medicine and therefore, greater attention has been given to the plants and their products for use in treatment. 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). In India nature has given us a very rich botanical wealth and a large number of diverse types of medicinal plants grow in different parts of the country (Malik *et al.,* 2016).

Microbiological stimulus is one of the major causes of many infectious diseases, inflammation and pyexia. The allopathic management of microbial diseases and their signs and symptoms is limited to the use of antibacterial, anti-inflammatory and antipyretic drugs in single forms or in combinations whose administration is associated with several adverse effects on patients, which include hypersensitivity, depletion of beneficial gut mucosal flora, immune-suppression and allergic reactions etc. (Ahmad *et al.,* 1998). Because of the side effects and the resistance that pathogenic microorganisms builds due to indiscriminate use of many antibiotics, creating an immense clinical problem in the treatment of infectious diseases. Thus much attention has been given to extracts and biologically active compounds isolated from plant species used in herbal medicine (Essawi and Srour, 2000, Davis 1994). Therefore, there is an urgent and constant need to develop new and effective therapeutic agents for the treatment of infectious diseases (Khan and Jain, 2003, Monroe and Polk, 2000, Bhavnani and Ballow, 2000). Plant-derived products are slowly emerging as a viable alternative because they are cheap, abundantly available and relatively less toxic (Sarkar, *et. al.,* 2005).

Several screening studies have been carried out in different parts of the world 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). There are several reports on the antimicrobial and other medicinal activities of different herbal extracts in different regions of the world (Chung *et al*., 2004, Nair and Chanda, 2004, De Boer *et al.,* 2005, Nair *et al.,* 2005). Plant-based medicines

represent a vast untapped source of treatment and have enormous therapeutic potential. They are effective in the treatment of infectious diseases as well as their complications while simultaneously mitigating many of the side effects that are often associated with synthetic drugs (Iwu *et al.,* 1999).Unani System of medicine, mainly based on herbal preparations also offers a number of single and compound drugs that are used successfully in the management of various infectious diseases (Rahman *et al.,* 2013).

Therefore, present study was undertaken during 2004 at the department of Ilmul Advia, A.K. Tibbiya College, A.M.U., Aligarh to evaluate the antimicrobial activity of root bark of Dar-e-Hald (*Berberis aristata* DC). This Unani medicinal plants was selected on the basis of their actions mentioned in classical as well as modern medico-ethno-botanical literatures as antiseptic, anti-microbial, anti-fungal, anti-inflammatory, antipyretic or as anti- infective and blood purifier, or are in clinical practices of Unani physicians for treatment of various infectious diseases.

Since the efficacy, safety and global acceptance of medicinal plants depends upon its authenticity and quality. Therefore, standardization of these drugs is mandatory to make it less controversial and more efficacious to use (Rahman *et al.,* 2013). So, Dar-e-Hald was also tested for their originality based on certain Physico-chemical parameters before evaluating for pharmacological activity.

Materials and Methods

Collection of plants

Dar-e-Hald was procured from Dawakhana Tibbiya College, Aligarh Muslim University, Aligarh. The sample was authenticated in Pharmacognosy section of the Department of Ilmul Advia and found within the range of standards (Anonymous, 2007, Khory and Katrak, 1985). Dar-e-Hald was dried in shade and then powdered for study.

Physicochemical parameters

It includes ash values (total ash, acid insoluble ash, water soluble ash), moisture content, loss of weight on drying, pH (1% and 10% solution) and water and alcohol soluble contents in the test drugs (Anonymous, 1968, Jenkins *et al.,*1967, Anonymous, 1987).

Anti-microbial studies

Extracts preparation

Alcoholic and aqueous extract alongwith powder dissolved in distilled water of Dar-e-Hald were used for the anti-bacterial studies. Alcoholic extract of the coarsely

powdered drug was prepared by the method of Ibrahim and Osman (1995) with some modifications. Coarse powdered drugs were extracted using a Soxhlet's apparatus with 95% ethanol as solvent, at 55°C for 06 hours or until the extracting return in the Siphon was colorless. The resultant extract was then concentrated in a water bath, at 40°C. The, stock solutions were prepared in 95% ethanol. Strict aseptic precautions were followed throughout the process and the heat wherever needed was kept as low as possible to prevent the thermolabile substances present in the drugs from destruction. Same procedure, as mentioned above, was carried out to prepare aqueous extracts using distilled water as solvent at 60°C and concentrated at 50°C.

Bacterial and fungal strains used in the study

Various Gram positive and Gram negative bacterial and fungal strains were used for detection of the anti-microbial activity of the extracts (Table 1). Standard and clinical strains were obtained from the Department of Microbiology, Jawaharlal Nehru Medical College and Hospital, Aligarh.

Antibacterial and antifungal susceptibility screening

Serial dilutions of the alcoholic extracts were prepared in ethyl alcohol so that 01 ml contained 100 times the amount of the extracts required per disc. Aliquots (01

Table 1: Bacterial and fungal strains used for the detection of antimicrobial activity of the drug

Gram Positive bacterial strains	Gram Negative bacterial strains	Fungal Strains
Bacillus sp.	*Citrobacter sp.*	*Aspergillus flavus*
Staphylococcus aureus	*E. Coli*	*Aspergillus fumigatus*
Streptococcus pyogenes	*Klebsiella sp*	*Aspergillus fumigates ATCC204305*
	Proteus sp.	*Aspergillus nigur*
	Pseudomonas aerugenosa	*Candida albicans*
	Salmonella typhimurium	*Candida keyfr*
	Shigella sp.	*Candida krusei ATCC6258*
	Vibrio cholerae	*Candida parapsilosis*
		Candida parapsilosis ATCC22019
		Candida tropicalis

ml) of these dilutions were transferred to bottles containing batches of 100 discs (06mm in diameter) of filter paper (Whatmann No.1, Whatmann, England). Bottles were placed in a water bath at 50°C with occasional shaking to allow an even distribution of the extracts between discs until complete evaporation of the alcohol had been achieved (Malik *et al.,* 2016).

Antibacterial activity was determined using the disc-agar diffusion technique according to the method described by Finegold and Martin, 1982. Similarly the antifungal activity was also determined by same technique, at 25^0C for 24 to 72 hours depending upon the growth of fungi. The whole experiment was performed in triplicate and diameters of zones of inhibition were recorded.

Determination of Minimum Inhibitory Concentration (MIC)

Broth micro-dilution testing was performed according to the method defined by National Committee for Clinical Laboratory standards (NCCLS) (Anonymous, 1993 and 1997) with minor modifications, to determine the Minimum inhibitory Concentrations. A doubling dilution of the extracts was prepared using RPMI-1640 (HiMedia Lab. Ltd., India) broth supplemented with 0.3gm/L L-glutamine (HiMedia Lab. Ltd., India), 0.165M MOPS buffer (Hi Media Lab. Ltd., India) (35.54gm/L) and 0.01% DMSO (Qualigens Fine Chemicals, India). Extracts were diluted in 100% DMSO, and further diluted 01: 5 0 in RPMI-1640 medium, and their resultant solution was used for doubling dilution series. Micro-titre plates were prepared containing 100µL of dilution of extracts with final concentrations ranging from 25mg/ml to 9.5 x 10^{-5} mg/ml. 100µL of the standardized inoculums of each bacterial and fungal species was added in their respective dilution wells. For each test there was a sterility control well containing RPMI only, two sets of control wells, one containing RPMI broth alone and the other containing RPMI broth with DMSO, and an extract control. The whole experiment was performed in duplicate.

The concentration levels of Dar-e-Hald used to determine anti-microbial activity of test drug were 50, 25 and 12.5µg/disc. Furthermore, results were analyzed statistically by Student's 't' test and P value d" 0.05 were considered statistically significant. Standard drug taken for antibacterial potential was Ciprofloxacin (5 µg/disc) and for antifungal activity Fluconazole (10 µg/disc), Nystatin (100 µg/disc) and Amphotericin (100 µg/disc) were used.

Results

Physicochemical parameters

The analytical values of different physicochemical parameters such as Solubility, Moisture content, Loss of weight on drying, Ash values and pH values of the Dar-e-Hald was determined and are depicted in table 2.

Table 2: Physico-chemical values of the Dar-e-Hald

Physico-chemical parameters	Results (Mean±SE)
Water soluble contents (1% solution)	3.06±0.03
Water soluble contents (10% solution)	1.38±0.01
Alcohol soluble contents (1% solution)	3.07±0.01
Alcohol soluble contents (10% solution)	1.42±0.02
Moisture content (%)	10.66±0.14
Loss on drying at 105^0C (%)	12.60±0.21
Total Ash (%)	3.01±0.05
Acid Insoluble Ash (%)	1.27±0.03
Water Soluble Ash (%)	1.14±0.02
pH (1% solution)	1.10±0.03
pH (10% solution)	1.20±0.00

Anti-microbial studies

Aqueous and alcoholic extract of Dar-e-Hald alongwith powder of the test drug which was dissolved in distilled water (dw) was screened against Gram positive and Gram negative bacterial strains and fungal strains. The activity of the Dar-e-Hald was recorded and shown in table 3 and 4.

Table 3: Antibacterial potential of Dar-e-Hald *(Berberis aristata)* (P value d" 0.05 was considered statistically significant)

Bacterial Strains	Test Drug Concentration (µg/disc)	Zone of inhibition (ZOI) in mm (Mean ± S.E.)			
		Alcoholic extract	Aqueous extract	Powder dissolved in dw	Ciprofloxacin (5µg/disc)
Staphylococcus aureus	50	12.33±0.02 p<0.001	14.13±0.11 p<0.001	No Effect	25.16±0.02
	25	08.26±0.02 p<0.001	No Effect	No Effect	
	12.50	07.40±0.11 p<0.001	Not Tested	Not Tested	
Streptococcus pyogenes	50	12.16±0.12p <0.001	12.13±0.02p <0.001	No Effect	10.13±0.01
	25	11.26±0.02 p<0.003	No Effect	No Effect	
	12.50	10.30±0.04 p<0.013	Not Tested	Not Tested	

Bacterial Strains	Test Drug Concentration (µg/disc)	Zone of inhibition (ZOI) in mm (Mean ± S.E.)			
		Alcoholic extract	Aqueous extract	Powder dissolved in dw	Ciprofloxacin (5µg/disc)
E. coli	50	10.23±0.12 p<0.001	No Effect	No Effect	19.10±0.00
	25	07.30±0.15 p<0.001	No Effect	No Effect	
	12.50	06.06±0.02 p<0.001	Not Tested	Not Tested	
Klebsiella sp	50	No Effect	No Effect	No Effect	25.03±0.08
	25	No Effect	No Effect	No Effect	
	12.50	Not Tested	Not Tested	Not Tested	
Pseudomonas aerugenosa	50	No Effect	No Effect	No Effect	23.16±0.17
	25	No Effect	No Effect	No Effect	
	12.50	Not Tested	Not Tested	Not Tested	
Proteus sp.	50	No Effect	No Effect	No Effect	13.16±0.02
	25	No Effect	No Effect	No Effect	
	12.50	Not Tested	Not Tested	Not Tested	
Bacillus sp.	50	13.30±0.15 p<0.002	16.10±0.11 p<0.001	No Effect	17.10±0.01
	25	08.36±0.18 p<0.001	08.23±0.14 p<0.01	No Effect	
	12.50	06.30±0.02 p<0.001	No Effect	Not Tested	
Salmonella typhimurium	50	No Effect	No Effect	No Effect	10.13±0.02
	25	No Effect	No Effect	No Effect	
	12.50	Not Tested	Not Tested	Not Tested	
Shigella sp	50	No Effect	07.30±0.10 p<0.001	No Effect	16.10±0.01
	25	No Effect	No Effect	No Effect	
	12.50	Not Tested	Not Tested	Not Tested	
Citrobacter sp.	50	No Effect	No Effect	No Effect	22.00±0.00
	25	No Effect	No Effect	No Effect	
	12.50	Not Tested	Not Tested	Not Tested	
Vibrio cholerae	50	32.13±0.02 p<0.001	14.10±0.04 p<0.001	14.00±0.00 p<0.001	16.10±0.01
	25	26.13±0.11 p<0.001	10.22±0.01 p<0.001	09.13±0.07 p<0.01	
	12.50	20.16±0.03 p<0.001	09.02±0.01 p<0.01	No Effect	

Table 4: Antifungal activity of Dar-e-Hald *(Berberis aristata*) (P value d" 0.05 was considered statistically significant)

Fungal Strains	Test Drug Concentration (µg/disc)	Zone of inhibition (ZOI) in mm (Mean ± S.E.)				Nystatin (100µg/disc)	Amphotericin B (100µg/disc)
		Alcoholic extract	Aqueous extract	Powder dissolved in dw	Fluconazole (10µg/disc)		
Aspergillus flavus	50	18.10±0.26 p<0.013	No Effect	18.33±0.05 p<0.001	_____	20.20±0.10	16.10 ±0.03
	25	12.40±0.13 p<0.001	No Effect	11.40±0.09 p<0.001			
	12.50	07.36±0.12 p<0.001	Not Tested	07.60±0.04 p<0.001			
Aspergillus fumigatus	50	36.10±0.11 p<0.001	No Effect	19.46±0.07 p<0.001	_____	24.20±0.11	18.10±0.04
	25	26.20±0.11 p<0.001	13.90±0.01 p<0.001	14.20±0.04 p<0.001			
	12.50	14.15±0.30 p<0.001	10.10±0.04 p<0.001	08.16±0.07 p<0.001			
Aspergillus fumigatus ATCC204305	50	36.10±0.02 p<0.001	No Effect	26.03±0.02 p<0.001	18.10±0.01	26.10±0.02	22.10±0.10
	25	28.20±0.15 p<0.001	No Effect	16.46±0.07 p<0.001			
	12.50	16.10±0.04 p<0.001	Not Tested	12.36±0.07 p<0.001			

Fungal Strains	Test Drug Concentration (µg/disc)	Zone of inhibition (ZOI) in mm (Mean ± S.E.)				Nystatin (100µg/disc)	Amphotericin B (100µg/disc)
		Alcoholic extract	Aqueous extract	Powder dissolved in dw	Fluconazole (10µg/disc)		
Aspergillus nigur	50	21.20±0.02 p<0.05	No Effect	20.16±0.03 p<0.001	_____	21.10±0.15	16.20±0.14
	25	14.50±0.18 p<0.001	No Effect	17.33±0.09 p<0.001			
	12.50	08.80±0.02 p<0.001	Not Tested	12.40±0.05 p<0.001			
Candida albicans	50	38.26±0.17 p<0.001	26.00±0.00 p<0.001	31.16±0.08 p<0.001	_____	26.10±0.11	24.00±0.00
	25	28.16±0.15 p<0.001	18.00±0.00 p<0.001	22.30±0.05 p<0.001			
	12.50	18.20±0.23 p<0.001	12.20±0.05 p<0.001	14.40±0.05 p<0.001			
Candida keyfr	50	40.30±0.26 p<0.07	26.20±0.10 p<0.001	29.10±0.12 p<0.001	38.20±0.02	26.20±0.01	24.00±0.00
	25	32.20±0.10 p<0.07	12.00±0.00 p<0.001	15.90±0.03 p<0.001			
	12.50	21.09±0.14 p<0.001	10.10±0.20 p<0.001	14.16±0.14 p<0.001			
Candida krusei ATCC6258	50	38.10±0.12 p<0.001	30.10±0.15 p<0.001	32.46±0.11 p<0.001	32.10±0.11	28.20±0.11	26.20±0.10
	25	26.10±0.10 p<0.002	18.16±0.07 p<0.001	18.16±0.07 p<0.001			
	12.50	16.20±0.01 p<0.001	12.20±0.12 p<0.001	11.30±0.05 p<0.001			

Fungal Strains	Test Drug Concentration (µg/disc)	Zone of inhibition (ZOI) in mm (Mean ± S.E.)				Nystatin (100µg/disc)	Amphotericin B (100µg/disc)
		Alcoholic extract	Aqueous extract	Powder dissolved in dw	Fluconazole (10µg/disc)		
Candida parapsilosis	50	36.20±0.14 p<0.001	20.10±0.00 p<0.001	22.40±0.09 p<0.001	22.10±0.12	22.00±0.00	24.20±0.11
	25	22.50±0.16 p<0.009	12.36±0.07 p<0.001	14.40±0.05 p<0.001			
	12.50	14.20±0.16 p<0.001	08.14±0.06 p<0.001	12.36±0.07 p<0.001			
Candida parapsilosis ATCC22019	50	36.10±0.02 p<0.001	26.10±0.01 p<0.001	29.30±0.05 p<0.001	22.20±0.11	28.10±0.02	32.10±0.02
	25	24.10±0.17 p<0.002	14.40±0.04 p<0.001	14.30±0.05 p<0.001			
	12.50	14.16±0.08 p<0.001	08.11±0.06 p<0.001	09.30±0.18 p<0.001			
Candida tropicalis	50	38.33±0.12 p<0.001	27.20±0.14 p<0.001	29.46±0.07 p<0.001	32.10±0.12	26.16±0.12	20.20±0.01
	25	26.20±0.12 p<0.001	15.50±0.04 p<0.001	24.30±0.05 p<0.001			
	12.50	16.10±0.07 p<0.001	10.20±0.02 p<0.001	16.30±0.05 p<0.001			

Minimum Inhibitory Concentration (MIC)

MIC for alcoholic extract of *Berberis aristata* was also determined especially against those bacterial and fungal strains for which it shows significant effect. The results are depicted in table 5.

Table 5: MIC for alcoholic extract of Dar-e-Hald (*Berberis aristata*)

Bacterial Strains tested	MIC values (mg/ml)	Fungal strains tested	MIC values (mg/ml)
Staphylococcus aureus	07.60 x 10^{-4}	*Aspergillus flavus*	03.00 x 10^{-3}
Streptococcus pyogenes	03.80 x 10^{-4}	*Aspergillus fumigatus*	03.00 x 10^{-3}
E. Coli	06.10 x 10^{-3}	*Aspergillus nigur*	03.00 x 10^{-3}
Shigella Sp.	30.00 x 10^{-3}	*Candida albicans*	01.50 x 10^{-3}
Vibrio cholera	07.60 x 10^{-4}	*Candida keyfr*	03.80 x 10^{-4}
		Candida parapsilosis	07.60 x 10^{-4}
		Candida tropicalis	01.50 x 10^{-3}

Discussion and Conclusion

Standardization of the test drugs

Nature is the source of many modern drugs and on the basis of their uses in traditional medicine, many of these have been isolated (Rahman *et al.,* 2011). About 80% of the world population depends on natural source of medicine for their wellness and this herb based medicine plays a vital role in human health care (Doughari, *et al.,* 2008). Therefore, with the ever-increasing use of herbal medicines worldwide and the rapid extension of the global market for these products, the safety and quality of medicinal plant materials and finished products have become a major concern for health authorities and pharmaceutical industries. A disease cannot be managed comprehensively until the delivery of genuine samples of drug is ensured (Jahan *et al.,* 2008).

These physico-chemical parameters are considered as tools of checking quality, identity and purity of the Unani drugs. The water and alcohol soluble content of the drug is used as an index of purity for formulations. The amount of the extract that the drug yields in a solvent is often an approximate measure of the amount of certain constituents that the drug contains. Therefore, for establishing the standards of any drug these extractive values and solubility play an important role, as the adulterated or exhausted drug material will give different values rather than the extractive percentage of the genuine one (Jenkins *et al.,*1967). The Moisture content of the test drug determines the release of their active ingredients as well

as their chemical, physical, microbial, shelf-life properties and adulterations (Jacob *et al*., 2006). Loss in weight on drying at 105^0C also indicates towards the loss of volatile substances along with water. pH value of the drug determines whether the drug absorb in stomach or intestine because the drugs in the opposite pH are unionized and absorbed rapidly from stomach or intestine. The pH of the drug was found to be acidic therefore, test drug gets ionized in stomach and absorbs somewhere in intestine. Adulteration of herbal drugs with unwanted materials like earthy matters resulting in higher ash percentage. Therefore, Estimation of Ash values are important parameter for judging impurities along with identity and quality of the drugs (Jenkins *et al.,*1967).

Antimicrobial studies

The antibiotics in modern therapeutic system have tremendous effect in controlling the infectious diseases (Finland, M. 1978). However, the advent of escape mechanism (drug resistance) adopted by most of the pathogens certainly needs a suitable replacement of the presently available antibiotics (Conly *et al.,* 1992; Threlfall *et al.,* 1996). Plants are important source of potentially useful structures for the development of new chemotherapeutic agents. The first step towards this goal is the *in vitro* antibacterial activity assay (Tona *et al.,* 1996). Many reports are available on the antiviral, antibacterial, antifungal, anthelmintic, antimolluscal and anti-inflammatory properties of plants. Some of these observations have helped in identifying the active principle responsible for such activities and in the developing drugs for the therapeutic use in human beings (Palombo and Semple, 2001, Govindarajan *et al.,* 2006, Mahesh and Satish, 2008). 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 (Rahman *et al.,* 2013). In the present study antimicrobial (antibacterial and antifungal) activity of the alcoholic and aqueous extracts and powder of Dar-e-Hald dissolved in distilled water was quantitatively assessed and found to be significant against most of the microbes tested. Alcoholic extract of Dar-e-Hald exhibit significant effect against *Staphylococcus aureus, Streptococcus pyogenes, E. coli, Bacillus sp.*and *Vibrio cholerae* bacterial strains at all the doses. while aqueous extract of the test drug shows significant inhibition against *Staphylococcus aureus, Streptococcus pyogenes* and shigella sp. at the dose of 50 µg/disc, against Bacillus sp. at the doses of 25 and 50 µg/disc and against *Vibrio cholera* at all the doses of the drug used for the test. Distilled water dissolved powder of Dare-e-Hald doesn't show any activity against any bacterial strains except *Vibrio cholerae* at the dose of 25 and 50 µg/disc. As there is upsurge in the immunocompromised patients succumbing to resistant fungal infections, therefore, it is need of the day to search new and natural antifungal drugs. Dar-e-Hald found to have good antibacterial activity so it was also analyzed for its

antifungal effect. Dar-e-Hald shows significant antifungal activity against all the fungal strains at all the doses used in all the three forms except the aqueous extract of the test drug which doesn't shows any effect against *Aspergillus flavus, Aspergillus fumigates ATCC204305 and Aspergillus nigur.* Minimum Inhibitory Concentration is also an important parameter to determine antimicrobial activity. It indicates lowest concentration of antimicrobials or test drug that will inhibit the visible growth of microorganism after overnight incubation. It is considered as 'gold standard' for determining the susceptibility of organism to antimicrobials (Andrews, 2001).

There are many documented, scientifically proved and globally accepted Unani drugs having striking and significant antimicrobial effects. But the present study has partially revealed the activity of test drug to control antibiotic and antifungal resistant microorganism, which are a major threat to human health. Our study has revealed the broad spectrum activity of the crude extract. This may be due to the presence of an active alkaloid "Berberine" which has been studied against a number of microorganisms and was found to be significantly effective and/or may be due to other alkaloids and active constituents present in the drug. Therefore, further evaluation of the active constituents other than berberine is required to ascertain the antimicrobial activity of the test drug. However, the alcoholic and aqueous extract of *Dare-e-Hald* could be a possible source to obtain new and effective herbal medicines to treat infections specially caused by multi-drug resistant strains. Furthermore, it is also necessary to determine the toxicity of the test drugs, their side effects and pharmaco-kinetic properties.

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Ethnomedicines in Kalsi Forests of Dehradun District, Uttarakhand

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Abstract

An ethnobotanical survey conducted durings November-December 2012 and February-March 2013 in the Kalsi Soil Conservation forest division of Dehradun district in Garhwal region of Uttarakhand has provided useful information on folk medicinal claims prevalent among the tribal and other rural people. In the course of fieldwork, a number of wild plants were found to be commonly used in the area by traditional healers as folk drugs against different ailments of humans as well as livestock. In this report ethnomedicinal uses of 54 plant species belonging to 51 genera and 35 families are described. For each species are given the correct botanical and prevalent local names, part used, claimed medicinal use(s) and mode of administration. The study has revealed many new and interesting phytotherapeutic uses from this part of Uttarakhand. Need for their scientific investigations to validate the claims has been re-stressed.

Keywords: Ethnobotanical survey, Ethnomedicines, Kalsi, Dehradun, Garhwal.

Introduction

The district of Dehradun forms a part of Garhwal region in the state of Uttarakhand. A number of cultural and ethnic groups; each with its own distinct way of life, beliefs, social customs, cultural heritage and history made it their homes. It has vast forest area and varied flora (Babu, 1977; Gupta, 1928, 1967; Kanjilal, 1911; Raizada and Saxena, 1978). Traditional phytotherapy exists in every cultural area of this district. This was the reason that ethnobotanical explorations undertaken by the researchers have yielded useful information regarding the folk medicinal uses of diverse native floras as evident from published reports (Chantia, 2003; Bhatt and Negi, 2006; Bisht and Bhatt, 2012; Bist and Pundir, 2008; Deoli *et al.*, 2014; Dobhal *et al.*, 2007; Gairola *et al.*, 2013; Jain and Puri, 1984; Maheshwari and Singh, 1992; Negi *et al.*, 1992; Rana and Datt, 1997; Sharma *et al.* 1979; Sharma and Painuli, 2011; Singh and Pundir, 2004; Singh, 1997; Singh *et al.*, 2008; 1989, 1984; Upadhyaya, 2014). Hence, the survey team of the Regional Research Institute of Unani Medicine, Aligarh selected the forests of this district for an extensive ethnobotanical survey of medicinal plants. The main objective of this field study, besides recording folk medicinal claims prevalent among the indigenous communities, was to prepare a data base of existing medicinal plants especially those used in Unani medicine (Fig. 2-11). Ethnomedicinal uses of plants collected from Mussoorie Forest Division, Dehradun have already been published by us (Ali *et al.*, 2015). The present study concerns the area of Kalsi Soil Conservation forest division of Dehradun and enriches our existing traditional knowledge on herbal pharmacopoeia of this Himalayan valley.

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The Study Area

The area from which data were derived is situated between 30° 19´ - 30° 322 N latitude and 77° 342 -78° 02 E longitude in the Vikasnagar tehsil of Dehradun district, Uttarakhand. There are three territorial ranges viz. Timli, Choharpur and Langha (Fig.1). This division is one of the important parts of Doon Valley in the foothills of the Himalayas. It is rich in vegetation which has both tropical and sub-temperate elements. The area is predominantly inhabited by various tribal communities such as Boxa, Jaunsari and Gujjar. The age-old practice of traditional phytotherapy is still prevalent amongst these people.

Fig. 1: Map of Dehradun district showing the study area

Methodology

Fieldwork was carried out during November-December 2012 and February-March 2013. Information on folk medicinal uses of local plants was obtained through interviews with local medicine men and other knowledgeable village elders. Data on common name of the plant or the crude drug, medicinal use(s), part used, other ingredients added (if any), method of drug preparation and mode of administration were recorded for each folk medicinal claim. Specimens of all the

plants along with relevant information were collected. These were later identified with the help of related floras (Babu, 1977; Duthie, 1903-1929; Gupta, 1928). In some cases botanical identity was finally confirmed by matching them in the herbarium of FRI, Dehradun (DD). All the botanical names were updated following the work of Uniyal *et al.* (2007). 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 for future reference and study.

Results

In the following listing each entry gives botanical name, family in parentheses, local name, locality and voucher specimen number, followed by claimed medicinal use(s), in sequence.

Achyranthes aspera L. (Amaranthaceae), 'Ulktakura', Timli (ZAA 9433, 9646). Patients of jaundice are advised to apply little slaked lime on their palms and then aqueous decoction of stem bits is used as herbal hand wash. Fresh root is chewed on empty stomach in the morning for displacement of navel.

Acorus calamus L. (Araceae), 'Bach', Jharba (ZAA 9325, 9625). For treatment of worm infestation, paste of the rhizome is given orally. In some cases, a piece of dried rhizome is tied as an amulet in the neck of children.

Ageratum conyzoides (L.) L. (Asteraceae), 'Podina jari', Baarwala (ZAA 9549). Fresh leaves are crushed and squeezed to obtain juice. It is applied on sharp cut and wounds to check the bleeding.

Aloe vera (L.) Burm. f. (Liliaceae), 'Gheekawar' 'Ghiratkumari', Jharba (ZAA 9634). Pulp is obtained from the fresh leaf and lightly massaged on the head for vertigo and dandruff.

Asparagus adscendens Roxb. (Liliaceae), 'Satawar', 'Sharaoni' Langha (ZAA 9458, 9654). Fresh roots are added to the feed of milk cow for deficient lactation. Roots were also claimed effective for treating flatulence in cattle.

Barleria cristata L. (Acanthaceae), 'Kalabansa', Timli (ZAA 9558). Ash of flowers mixed with little honey is given three times a day for three weeks in whooping cough.

Bauhinia purpurea L. (Caesalpiniaceae), 'Guiral', Langha (ZAA 9643). Equal quantities of stem bark of 'guiral', 'chandna' (*Litsea glutinosa* (Lour.) C.B. Rob.)), 'sandan' (*Ougeinia oojeinensis* (Roxb.) Hochr.) and 'padam' (*Prunus cerasoides* D. Don) are mixed and ground to make a fine paste. This is used as plaster around the fractured limb after setting the bones right.

Beberis aristata DC. (Berberidaceae),'Kashmoi', Langha (ZAA 586). Root infusion is given once daily to control diabetes.

Bombax ceiba L. (Bombacaceae), 'Semal', Timli (ZAA 5373). Tap root of the young plant is collected, cut into small pieces, dried and ground to make a powder. This is mixed with milk and given once daily for sexual weakness.

Butea monosperma (Lam.) Taub. (Fabaceae), 'Dhak', Vikasnagar (ZAA 9747). The ruby-coloured gum obtained from the tree is used to treat spermatorrhoea: for this about 5g of the gum in the form of powder are given with water two times a day for one month.

Calotropis gigantea (L.) Dryand.(Asclepiadaceae), 'Safed Akh', Baarwala (ZAA 9633). Latex of the plant is mixed with butter and put on abaxial side of the leaf. This is applied on one side of the mouth of cattle for treating flatulence.

Calotropis procera (Aiton) Dryand. (Asclepiadaceae), 'Akh', Mednipur (ZAA 9578). The latex obtained from the leaf is applied locally to soften the tissues and draw out spine from the skin. A garland of stem-bits is prepared and tied around the neck of the patient suffering from jaundice.

Casearia tomentosa Roxb. (Flacourtiaceae), 'Chilla', Horawala (ZAA 9752). Root paste is applied on ringworm.

Cassia fistula L. (Caesalpiniaceae), 'Amaltas'; 'Karnua', Langha (ZAA 9663). One spoonful ash of the dried fruit pulp is given in the morning for constipation.

Centella asiatica (L.) Urb. (Apiaceae), 'Barmi', Baarwala (ZAA 9680). In summer season, paste of the aerial parts is given as cooling agent. Leaf paste is administered orally for vertigo.

Ceriscoides turgida (Roxb.) Tirveng. (Rubiaceae), 'Thaner', Timli (ZAA 9501). Fresh paste of the fruit is applied locally to treat mastitis (inflammation of mammary glands) of cows.

Cheilanthes farinosa (Forssk.) Kaulf. (Cheilanthaceae), 'Chhapa ghans', Horawala (ZAA 9467). Fronds are dried and ground to make a fine powder. It is sprinkled on prolapsed uterus in cases of buffaloes and cows.

Cissampelos pareira L. (Menispermaceae), 'Pari', Sahaspur (ZAA 9683). Leaf juice is given twice daily for one month in spermatorrhoea.

Clerodendrum cordatum D. Don (Verbenaceae), 'Karu', Baarwala (ZAA 9428). Leaves are boiled in water. The liquid is strained. A pinch of common salt is mixed in this decoction. One cup of this preparation is given once daily to control diabetes. It is also claimed effective in flatulence. Leaf paste mixed with little crude sugar is given to goats for common fever.

Datura fastuosa L. (Solanaceae), 'Kala Dhatura', Timli (ZAA 9748). For treating dysentery of horses, half part of the unripe capsule is given with 'gur' (solidified sugarcane juice).

Dicliptera chinensis (L.) Juss. (Acanthaceae), 'Kalabansa', Timli (ZAA 9644). Ash of the aerial parts mixed with honey is given to treat bronchitis.

Diospyros montana Roxb. (Ebenaceae), 'Panchhi', Mednipur (ZAA 9523). Dried pieces of the stem bark of 'panchhi' and 'kura' (*Holarrhena pubescence* Wall. ex G. Don) in equal quantities are boiled in water and the decoction thus prepared is given for flatulence in cases of cattle.

Diplocyclos palmatus (L.) C. Jeffrey (Cucurbitaceae), 'Kappor Kachri', Timli (ZAA 9469). Root of the plant with 'har' (fruits of *Terminalia chebula* Retz.) and 'bahera' (fruits of *Terminalia bellirica* (Gaertn.) Roxb.) is ground to make a powder. About 5g of this powder are given two times a day for three days in the treatment of flatulence.

Euphorbia royleana Boiss. (Euphorbiaceae), 'Suru', Binhar (ZAA 9560). Poultice of phylloclade is applied locally for treating sprain and bruises.

Falconeria insignis Royle (Euphorbiaceae), 'Khirchu', Binhar (ZAA 9563). In cases of bone fractures, stem twigs are used as splints.

Flueggea virosa (Roxb. ex Willd.) Royle (Euphorbiaceae), 'Biswan', Samet (ZAA 9585). Root is rubbed on stone and the paste thus obtained is applied on abscesses to drain off pus.

Helicteres isora L. (Sterculiaceae), 'Kapasi', Timli (ZAA 951). Fruit powder is given with water for few days in dysentery.

Justicia adhatoda L. (Acanthaceae), 'Bansa', Timli (ZAA 9516). In cases of cough, young vegetative buds are dried and burnt to ashes. A little amount of this is mixed with honey and given two times a day till the cure is obtained.

Leucas cephalotes Spreng. (Lamiaceae), 'Guma', Timli (ZAA 9745). Aqueous decoction of dried inflorescences is administered orally to allay fever.

Litsea glutinosa (Lour.) C.B. Rob. (Lauraceae), 'Chandna', Mednipur (ZAA 9431). Inner stem bark is ground with water to make a paste. It is mixed with powdered alum and plastered around the fractured limb after setting the bones right. Splints and bandages are used to hold the bones and plaster in position.

Mallotus philippensis (Lam.) Muell.-Arg. (Euphorbiaceae), 'Reini', Timli (ZAA 9647). An ointment is prepared by mixing the red powder, obtained from the dried fruits, in mustard oil and applied externally on boils for suppuration and healing.

Millettia extensa Benth. ex Baker (Fabaceae), 'Gouj', Timli (ZAA 9679). Lukewarm root decoction is poured over the body of cattle to kill lice.

Mimosa pudica L. (Mimosaceae), 'Chhuimui', Timli (ZAA 9694). Paste of the aerial parts is applied over the prolapsed uterus after delivery in cases of buffaloes and cows.

Nyctanthes arbor-tristis L. (Oleaceae), 'Kurri', Timli (ZAA 9440, 9746). Leaf decoction is mixed with lump of sugar and given two times a day for five days for treating cold with fever. About 10g of the leaf paste with powder of few black peppers is given two times a day for jaundice till the cure is obtained.

Phyllanthus niruri L. (Euphorbiacae), 'Bhuiamla', Timli (ZAA 9462). Fresh juice of aerial parts is given orally two times a day for two weeks in jaundice.

Plumbago zeylanica L. (Plumbaginaceae), 'Chitta', Dharmawala (ZAA 0661). Root bark paste (obtained by grinding in water) is applied on ringworm. Fresh paste of root is applied locally to relieve piles.

Prunus persica (L.) Stokes (Rosaceae), 'Aru', Langha (ZAA 9660). Leaf paste is given orally to children for worm's infestation.

Rauvolfia serpentina (L.) Benth. ex Kurz (Apocynaceae), 'Shuwet Barua', Timli (ZAA 9530). Root powder is given for abdominal pain while the paste mixed with honey is given for cough in children.

Reinwarditia indica Dumort (Linaceae), 'Piuli', Horawala (ZAA 9637). Leaf paste is applied on fungal infection of scalp.

*Roylea cinerea (*D. Don) Baill. (Lamiaceae), 'Jangli Karu', Timli (ZAA 9455). One teaspoonful powder of leaf is given two times a day for controlling diabetes. Leaf paste is given to sheep and goats for fever.

Rumex hastatus D. Don (Polygonaceae), 'Bhilmora', Langha (ZAA 9744). Fresh leaves are rubbed on the palms for healing cracked skin.

Shorea robusta Gaertn. (Dipterocarpaceae), 'Sal', Timli (ZAA 9740). Gum-resin in the form of powder is filled in the vertically half cut banana which is given once daily for 7 consecutive days early in the morning to treat spermatorrhoea.

Sida cordata (Burm. f.) Borss.Waalk. (Malvaceae), 'Kharenti', Timli (ZAA 9722). Leaf paste is applied on boils to speed up suppuration and healing.

Sida cordifolia L. (Malvaceae), 'Kharenti', Baarwala (ZAA 9547). A paste, obtained by crushing the leaves, is applied locally on pustules.

Smilax ovalifolia Roxb. ex D. Don (Smilacaceae), 'Ramdatun', Langha (ZAA 9503). Chopped root is cooked and taken daily as vegetable in general weakness.

Figure 2-11: Some Important Folk Medicinal Plants of the Study Area

Fig. 2: Semal (*Bombax ceiba* L.)

Fig. 3: Dhak (*Butea monosperma* (Lam.) Taub.)

Fig. 4: Amaltas (*Cassia fistula* L.)

Fig. 5: Karu (*Clerodendrum cordatum* D. Don)

Fig. 6: Bansa (*Justicia adhatoda* L.)

Fig. 7: Reini (*Mallotus philippensis* (Lam.) Muell.-Arg.)

Fig. 8: Chitta (*Plumbago zeylanica* L.)

Fig. 9: Shuwet Barua (*Rauvolfia serpentina* (L.) Benth. ex Kurz)

Fig. 10: Piuli (*Reinwardtia indica* Dumort.)

Fig. 11: Bhilmora (*Rumex hastatus* D. Don)

Solanum erianthum D. Don (Solanaceae), 'Sueda', Langha (ZAA 9584). Fresh leaf juice is used as eye drops for pterygium.

Solanum incanum L. (Solanaceae), 'Kantkari', Timli (ZAA 9518). A rosary of dried fruits is strung and worn in neck for jaundice. Seeds are mixed with solidified sugarcane juice and given to buffaloes and cows for inducing conception.

Solanum nigrum L. (Solanaceae), 'Bhamolan', Timli (ZAA 0445). Fresh leaves are given to chew for stomatitis. Cooked leaves as well as vegetative buds are taken as pot herb once daily for pedal oedema. These are also claimed effective in colitis and enteritis.

Syzygium cumini (L.) Skeels (Myrtaceae), 'Jaman', Chirbeli (ZAA 9749). Powder of the stem bark is mixed with curd and given twice daily for few days to treat dysentery and diarrhoea.

Terminalia arjuna (Roxb. ex DC.) Wight & Arn. (Combretaceae), 'Arjun', Vikasnagar (ZAA 9622). Stem bark decoction is given two times a day for cardiac weakness.

Tinospora sinensis (Lour.) Merr. (Menispermaceae), 'Guruj', Timli (ZAA 9670). Decoction of chopped stem is given orally for piles. Stem-bits are added to the feed of cattle to treat general weakness. Stem-bits with young inflorescences of wheat are boiled in water and allowed to cool. Resulting decoction is given orally in oral cancer.

Viola pilosa Blume (Violaceae), 'Banafsa', Langha (ZAA 9655). Flower decoction is drunk for common cold.

Vitex negundo L. (Verbenaceae), 'Mala', Timli (ZAA 9446). For treating paralysis, leaf paste is applied on affected part and bandaged. On crushing fresh leaves emit an aromatic smell which is inhaled in catarrh. Leaf powder is mixed with 'kala namak' (sodium sulphate mixed with sodium chloride) and given to cattle for loss of appetite.

Zanthoxylum armatum DC. (Rutaceae), 'Timur', Langha (ZAA 9606). Stem twig is used once daily in the morning as toothbrush for dental care.

Discussion

This study on Kalsi Soil Conservation Forest Division of Dehradun district has brought to light ethnomedicinal uses of 54 plant species belonging to 51 genera and 35 families. The data are authentic and obtained through direct field interviews of reliable informants who have long been using these herbal drugs in general healthcare. These claims are based on ancestral knowledge and empiric experience. Moreover, many traditional uses of the plants reported herein have not previously been described in the available literature on medicinal and economic plants of the country (Agarwal, 1986; Ambasta, 1986; Anonymous, 2001; Chopra et al., 1956; Jain, 1991; Kirtikar and Basu, 1935; Nadkarni, 1954; Satyvati et al., 1976; 1987). Therefore, scientific screening and evaluation for exploring their therapeutic potential are essential. Documentation of such information will be beneficial from drug discovery point of view since new ethnomedicinal information can serve as drug leads for discovery of novel plant-based pharmaceuticals.

During the present study it was observed that traditional knowledge of folk medicine is usually held only by few elderly people who are the custodians of such information while the younger generation has a poor phytotherapeutic knowledge. Moreover, these traditional healers now represent a disappearing tradition which is not being passed on to the next generation. Similarly there is a threat to many wild species of medicinal importance due to deforestation as a result of expansion of modern tourism, urbanization, excessive grazing, invasion of some foreign weed species, forest fire, over exploitation of natural resources, etc. In this situation the forest land in many places has considerably reduced for wild plants to spread naturally. Furthermore, forests of the area have been degraded into scrub jungles in some localities and savannah in other places. This traditional knowledge, therefore, is in danger of being lost permanently because of rapid cultural changes among the indigenous communities under the influence of increasing developmental activities. Hence, there is a need for properly designed ethnobotanical surveys of other important areas of this region in particular and in other areas of Uttarakhand in general. This could lead to more medicinal plants and their medicinal uses being revealed and utilized for well being of mankind before these useful plants become extinct or their uses forgotten.

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Standardization of a Unani Drug Harsinghar (*Nyctanthes arbor-tristis* Linn.) Leaves

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Abstract

Nyctanthes arbor-tristis L. (Family: Oleaceae) is known as Harsinghar or Siharu Tree in India. The leaves of *N. arbor-tristis* are used in the Traditional Systems of Medicine like Unani, Ayurveda and Sidhha against different diseases such as obstinate sciatica, fever, diabetes and act as cholagogue, diaphoretic and anthelminitic. The major phytochemicals reported in leaves are triterpines and its glycosides, which may be responsible for various pharmacological actions like anti-inflammatory, anti-spasmodic, antibilious, expectorant, laxative, diaphoretic, diuretic and anti-helmintic. Due to various pharmacological actions, commercialization of this drug to meet its increasing demand has resulted in a decline in its quality, because of lack of adequate regulations and scientific protocols. There is, therefore, a need to develop a systematic approach for authentication and develop well-designed methodologies for standardization of this important drug. In the present study, the reported pharmacopoeial parameters to evaluate the raw material and can be used as reference standards for the purpose of quality control/quality assurance of this drug are presented.

Keywords: *Nyctanthes arbor-tristis* L., Pharmacognostical, Phytochemical and TLC/HPTLC

Introduction

Nyctanthes arbor-tristis L. belongs to family Oleaceae and popularly known as 'Night Jasmine' (English) or 'Harsinghar' (Hindi) due to the fact that its flowers produce strong and pleasant fragrance during the whole night (Siddiqui *et al.,* 2006 and Rout *et al.*, 2007). The generic name 'Nyctanthes' has been marked from Greek words 'Nykhta' (Night) and 'anthos' (flower) (Vats *et al.*, 2009 and Meshram *et al.*, 2012). *Nyctanthes arbor-tristis* is a large shrub or small tree widely cultivated in tropical and subtropical regions all over the world. It is native to India and distributed wild in sub-Himalaya region as well as in Indian garden as ornamental plant due to presence of a peculiar and pleasant fragrance. The local people of Andhra Pradesh (India) widely use whole plant for treatment of cancer, root for fever, sciatica, anorexia; Arq as expectorant, leaf for control fever, diabetes and as cholagogue, diaphoretic and anthelminitic (Sah *et al.*, and Kiew *et al.,* 2012). The extracts of various parts of plant have been traditionally used to treat arthritis, malaria, intestinal worm's and constipation. The Juice of the leaves is used as digestives, antidote to reptile venoms, mild bitter tonic, laxative, diaphoretic and diuretic (Chetty *et al.*, 2008). A decoction of the leaves is widely used in

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Ayurvedic medicine to treat arthritis and malaria. The leaves are also used in fungal skin infection, in dry cough and enlargement of spleen. The young leaves are used as female tonic to alleviate gynaecological problems. *Nyctanthes arbor-tristis* was tested against *Encephala myocarditis* Virus (EMCV) and Semliki Forest Virus (SFV). The flowers of *Nyctanthes arbor-tristis* are used in India, Indonesia (Java) and Malaysia to provoke menstruation (Omkar *et al.*, 2006). The hot infusion of flowers is used by some elderly Sri Lankan Buddhist monks as a sedative. The inflorescence is used to treat scabies and other skin diseases. The flower helps in clearing mouth ulcers (Gupta *et al.,* 2005). The flower juice is also used as hair tonic in preventing greying of hair and baldness (Bansal *et al.*, 2013).

The plant is a small tree with grey or greenish rough bark and quadrangular young branches. Leaves opposite decussate, ovate, 10.5 x 6.2 cm, sessile or sub-sessile; bracteates ends in terminal trichotomous cymes; flowers sweet scented; bracts elliptic up to 1.2 cm; calyx ovoid, cylindrical, sub-truncate; corolla with white salver–shaped lobes and orange corolla tubes; stamens 2, inserted on top of corolla tube; filaments short, anthers almost sub – sessile; style cylindrical, shortly, stigma bifid; ovary 2- celled, ovule 1 in each chamber, capsule orbicular, compressed, parallel to partition; seed, orbicular and flattened (Tuntiwachwuttiku *et al.*, 2003).

The plant is very important due the presence of various pharmacological activities viz.; antioxidant, anticancer, anti-inflammatory, CNS depressant, anti-diabetic, hepatoprotective, antimicrobial, antifungal, antimalarial, and antiparasitic (Nazim *et al.*, 2001). The medicinal value of plant is due to the presence of various class of compounds viz., terpenes, steroids, iridoids, glycosides, flavonoids, alkaloids and aliphatic compounds. Some potential phytomolecules like á-pinene, p-cymene, nyctanthin, nyctanthic acid, â-amyrin, oleanolic acid, friedeline, lupeol, astragaline, nymphalin, nyctoside A, arborsides A, B and C, arbortristosides A, B, C, D and E, quercetin, kaemferol and apigenin have been reported from the plant (Rahman *et al.,* 2013; Tandan *et al.,*1991; Paul *et al.,* 1997; Saxena *et al.*, 2005; Ratnasooriya *et al.,* 2005 and; Kumari *et al.,* 2012).

Due to its immense importance as traditional medicine, a simple and reliable method is required for the quality assessment of the leaves of the plant. Quality control of herbal medicines can be assessed through pharmacognosy, physiochemical study and chromatography for moving towards an integrative and comprehensive direction and also to better address the inherent holistic nature of herbal medicines.

Hence, the present research study is an attempts to evaluate the pharmacognostical, physico-chemical parameters and HPTLC profile of the *Nyctanthes arbor-tristis* leaves for identification and check the adulteration of raw material used in the manufacture of traditional medicine.

Materials and Methods

Plant material and chemicals

The leaves of *Nyctanthes arbor-tristis* L. were collected from botanical garden of Pharmacopoeial Laboratory of Medicine, Ghaziabad, India in the presence of phamacognosist for research purpose. After authentication the leaves were washed thoroughly with clean water and dried under a gentle stream of air in the laboratory till no loss in weight (temperature 30 ± 2^0C) and powdered in an electric grinder. Solvents and chemicals used were of analytical grade (E. Merck and SRL).

Pharmacognostical analysis

The dried leaves were subjected to macroscopic studies as per approved format of the Unani Pharmacopoeia of India and evaluated systematically (Jonsan, 1940). Thin transverse sections were taken from leaf (through midrib), stained with safranin and mounted in glycerine by following the micro technique method (Wallis, 1967). Microscopic characters were studied as per standard methods (Trease and Evans, 1972). Microphotography was performed for all portions of the drug. Leaves were studied for their quantitative microscopy using standard procedures (Jonsan, 1940). It includes stomatal number, stomatal index, palisade ratio and vein is-let number.

Phytochemical screening

The phytochemical investigation of the ethanolic extract of *N. arbor-tristis* leaves was carried out. The phytochemical tests were performed on the liquid and dried extract using standard methods (Anonymous, 1999; Khanndelwal, 2007; Harbon, 1998; Rangari, 2002 and Sopan *et al.,* 2012).

Physico-chemical analysis

The dried leaves powder of *N. arbor-tristis* was subjected for the assessment of Pharmacopoeial parameters such as foreign matter, moisture content, total ash, acid insoluble ash, alcohol soluble extractive and water soluble extractive and HPTLC analysis (Khandelwal, 2007 and Verma *et al.* 2013).

Foreign matter determination

Accurately weighed 2g of the leave in a glass dish, Spread it in a thin layer and sort the foreign matter into groups either by visual inspection, using a magnifying lens (6x or 10x), or with the help of a suitable sieve, according to the requirements. Sifted the remainder of the sample passed through a sieve No. 250; dust is

Table 1: Phytochemical screening of ethanolic extract of *N. arbor-tristis* leaves

Phytoconstituents	Results
Phytosterols	++
Triterpenoids	+++
Lactones	-
Flavonoids	+++
Phenolic Compounds	+++
Tannins	+++
Carbohydrates	++
Saponins	++
Saponin Glycosides	++
Cardiac Glycosides	+++
Proteins	-–

+ Weak, ++ Moderate, +++ Strong and – Not present

regarded as mineral admixture. This sorted foreign matter was weighed and calculated the content of foreign matter in grams per 100 g of air-dried sample.

Moisture content (Loss on Drying) determination

Accurately weighed 4g of the leaves powder was taken in a previously weighed Petri dish and heated in a hot air oven at 105°C ± 2°C for 4 hours. It was cooled in desiccators and weighed. The procedure was repeated till constant weight was obtained. The percentage of loss in weight of the sample was calculated. Difference in weight indicated the moisture content of sample.

Total ash determination

Accurately weighed 2.0 g of the leaves powder was taken in a previously weighed Silica dish (crucible). The powder was spread uniformly and ignited in a muffle furnace by gradually increasing the temperature to 600ºC ± 2°C for 3 hrs or until it becomes white, indicated that the sample was free from carbon. The crucible was cooled in desiccators and allowed to stand for 30 minutes and weighed.

Acid insoluble ash determination

To the crucible containing the total ash, added 25 mL of 2M hydrochloric acid (176.83 mL/L of 35% HCl) GR, cover with a watch-glass and gently boiled for 5 minutes. The watch glass was rinsed with 5 ml of hot water and added this liquid to the crucible. Collected the insoluble matter on ash less filter-paper and washed with hot water until the filtrate was neutral to the litmus. Transferred the filter-

paper containing the insoluble matter to the original crucible and it was dried on a hot-plate and ignited for 6 hrs to constant weight. Allowed the residue to cool in a suitable desiccator for 30 minutes and weighed. Calculate the content of acid-insoluble ash in percentage in respect of air-dried material.

Alcohol soluble extractive determination

Accurately weighed 5 g of the air dried coarsely powdered of leaves was macerated with 100 mL of ethanol of specified strength in a closed flask for 24 hrs, shaking frequently during the first 6 hours and allowing standing for 18 hrs. The extract was filtered and 25 mL of the same was taken out in a pre-weighed 100 mL beaker and evaporated to dryness on a water bath. Obtained residue was kept in a hot air oven for 5 hrs at l05°C and cooled in desiccators for half hour and weighed. Till obtaining constant weight the procedure was repeated.

Water soluble extractive determination

Accurately weighed 5 g of the air dried coarsely powdered of leaves was macerated with 100 mL of distilled water in a closed flask for 24 hrs, shaking frequently during the first 6 hours and allowing standing for 18 hrs. The extract was filtered and 25 mL of the same was taken out in a pre-weighed 100 mL beaker and evaporated to dryness on a water bath. Obtained residue was kept in a hot air oven for 5 hrs at l05°C and cooled in desiccators for half hour and weighed. Till obtaining constant weight the procedure was repeated.

Analytical methods

HPTLC Instrumentation

Camag Switzerland HPTLC system equipped with a manual (TLC sample applicator) Linomat-3 fitted with 100 µL syringe (Hamilton, Switzerland), TLC visualize (Reprostar-3), winCATS planar chromatography manager software version1.4.5 and twin trough glass tank (20 x10 cm) was used for the analysis.

Preparation of sample solution

Extract 2 g of sample refluxed with 20 ml of chloroform and 20 ml of alcohol separately on a water bath for 30 min. each. Filtered and concentrated up to 5 ml each and carry out the thin layer chromatography. First, 10µL of chloroform extract was applied on silica gel TLC plate F_{254}. Developed the plate using *Toluene: Ethyl acetate* (8:2) as mobile phase. After development allowed the plate to dry in air and examined under UV 254 nm (Fig 1) and 366 nm (Fig.2). The TLC plate sprayed with vanillin-sulphuric acid reagent followed by heating at 105°C for 1-2

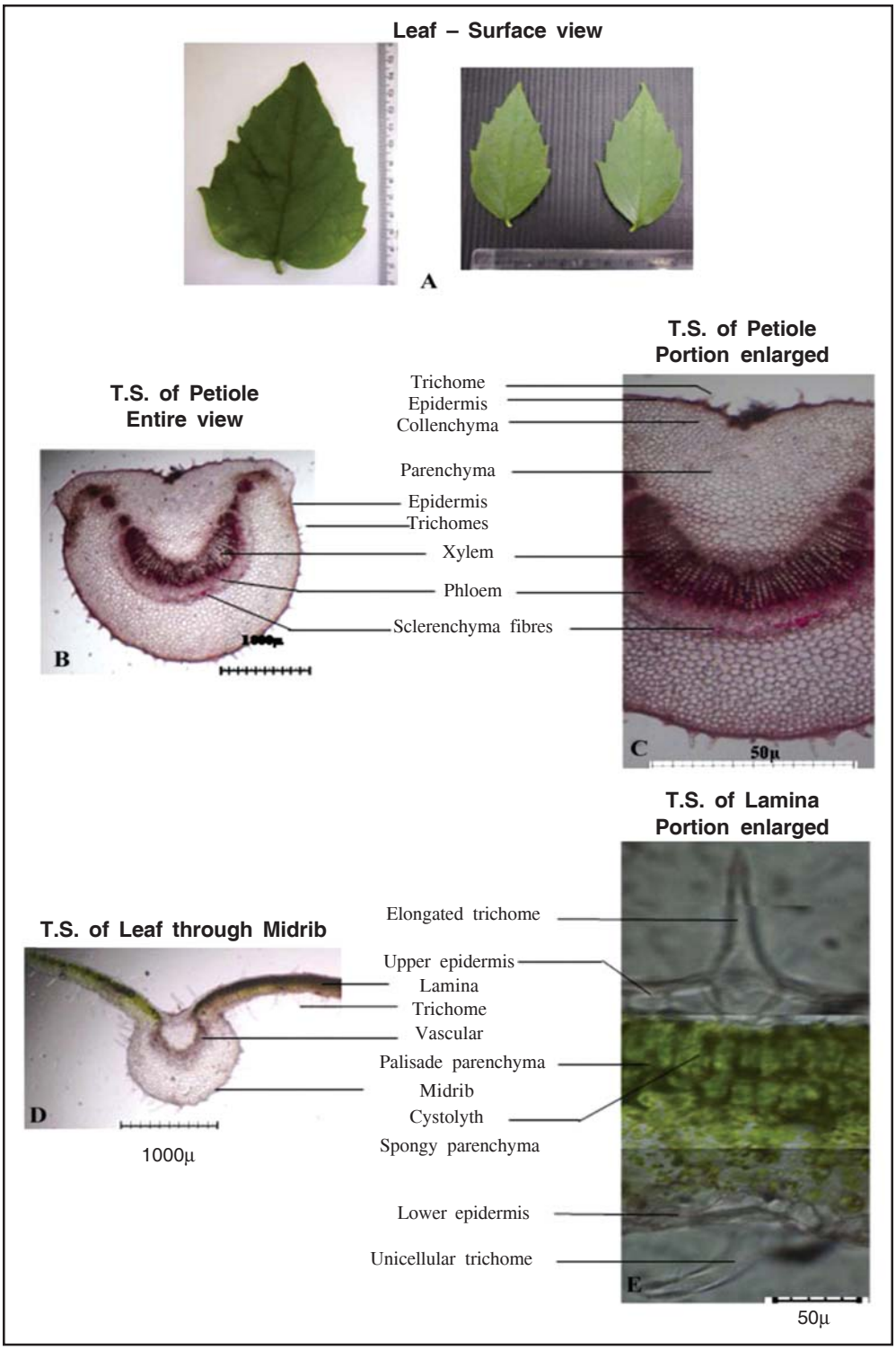

Figure 1: Macroscopic and micrscopic characters of *N. arbor-tristis* leaf

min till the spot appeared and observed under visible light (Fig 3). HPTLC fingerprint profile of chloroform extract of *N. arbor-tristis* leaves at 254 nm are also given (Fig. 4).

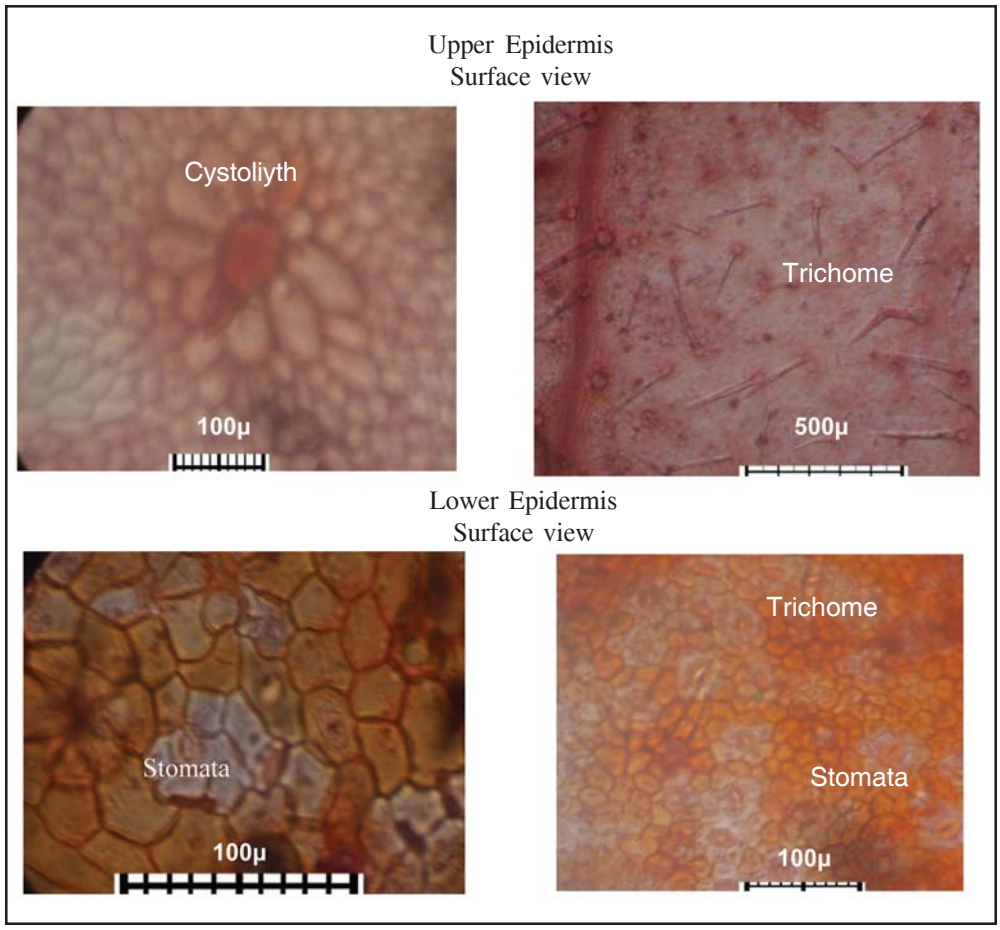

Figure 2: Epidermal characteristics of *N. arbor-tristis* leaf

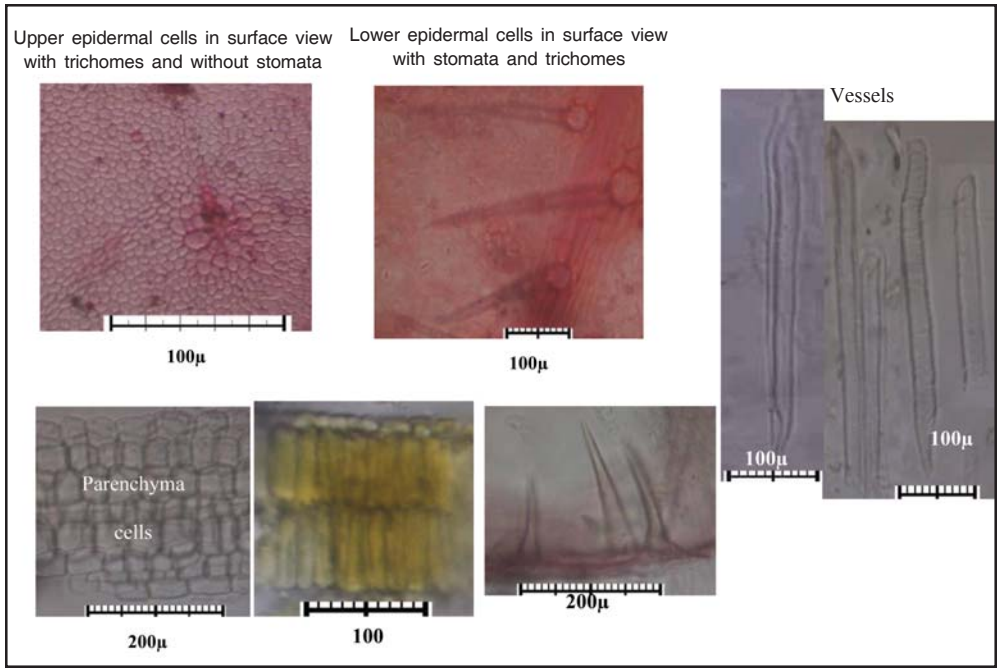

Figure 3: Powder microscopy of *N. arbor-tristis* leaf

Secondly, 10 µL of alcohol extract was applied on silica gel TLC plate F_{254}. The plate was developed using *Toluene: Ethyl acetate* (1:1) as mobile phase. After development the plates they were allowed to dry in air and examined under UV 254 nm (Fig 5) and 366 nm (Fig. 6). The TLC plate sprayed with vanillin-sulphuric acid reagent followed by heating at 105°C for 1-2 min till the spot appeared and observed under visible light (Fig 7). HPTLC fingerprint profiles of alcohol extract of *N. arbor-tristis* leaves at 254 nm are also given (Fig. 8).

Results and Discussion

Macroscopy

Leaves simple, exstipulate, petiolate, petiole very short, 0.5 to 0.7cm; lamina ovate with acute leaf tip, 3 to 12cm in length and 1.5 to 8cm in breadth, margin entire to slightly serrated, venation unicostate reticulate with pinnate incision. Leaves dorsi-ventral, upper surface deep green in colour, slightly rough, hairy with very fine but firm hairs (hirsute) or trichomes, lower surface light green in colour, smooth and soft; odour herbaceous, taste bitter and slightly astringent (Fig. 1 A).

Microscopy

Petiole: T.S. of petiole is heart shaped with prominent notch in the middle of adaxial side; epidermis consisting of single layer of irregular thick walled cells covered with cuticle; trichomes two types and numerous; long, thick walled, with 2-3 basal cells and one tapering cell; some of them are glandular trichomes with multicellular head; cortex consists of few layers of collenchyma, chlorenchyma and parenchyma cells; cortical cells small, polygonal to large, oval in shape loosely arranged towards upper and compact towards lower region; vascular bundles 3 to 7; centrals bundles bigger and lateral bundles comparatively smaller in size; each bundle consists of xylem towards the upper side and phloem towards the lower side of the bundle; a few sclerenchyma fibres present along the lower side of the vascular bundle (Fig. 1 B & C).

Leaf through Midrib: T. S. of leaf shows dorsiventral nature; midrib is highly convex towards the abaxial side; epidermis single layered, consists of thick walled cells with cuticle and numerous trichomes on both upper and lower; trichomes two types: glandular trichomes having unicellular stalk and four celled head and elongated trichomes with thick walls and pointed end; cystolith of calcium carbonate present at base of trichomes; cortex consisting of few layers of collenchyma, chlorenchyma and parenchyma cells; vascular bundle sickle shaped in the centre with xylem towards the upper side and phloem towards the lower side; a few sclerenchyma fibres on the lower side of the vascular bundle (Fig. 1 D).

Lamina: T.S. of lamina shows dorsiventral nature with single layered upper and lower epidermis consisting of thick walled cells with cuticle; trichomes of two types as that of in the midrib region and of variable sizes; cystolith of calcium carbonate present at base of trichomes; mesophyll differentiated into two layers of palisade parenchyma below the upper epidermis and 8 to 9 layers of spongy parenchyma towards the lower side; lower epidermis having numerous scattered stomata (Fig. 1 E); epidermal cells in surface view shows polygonal cells; anisocytic stomata present only in the lower epidermis; stomatal number of the lower epidermis 50 to 55/sq mm and stomatal index is 40±2; palisade ratio 9±2; and vein islet number 14 ±5 (Fig. 2).

Phytochemistry

The physico-chemical parameters are mainly used in judging the purity and quality of the drug. Preliminary phytochemical results showed the presence or absence of certain phytochemical in the drug. Phytochemical test revealed the presence of phytosterols, triterpenoids, flavonoids, phenolic compounds, tannins, saponins, carbohydrates, saponins glycosides and cardiac glycosides results are given in Table 1. Physico-chemical parameters of the leaves of *N. arbortristis* are tabulated in Table 2.

Deterioration time of the plant material depends upon the amount of water present in plant material. If the water content is high, the plant can be easily deteriorated due to fungus. The loss on drying at 105°C was found to be 13.37 %. Total ash is designated to measure the total amount of material produced after complete incarnation of the crude drug. It uses are to detect the contamination and adulteration like sand or earth, unwanted part mixed in crude drug. Leaves showed the total ash content 4.23 %, acid-insoluble /siliceous matter 1.49%, water-soluble extractive 22.44%; is indicating the presence of sugar, acids, saponines, inorganic compounds and other water soluble matter. The amount of alcohol soluble

Table 2: Quality Assessment of *N. arbor-tristis* leaves

S.No.	Parameters	Results
1.	Foreign matter	Nil
2.	Loss on Drying (%)	13.37
3.	Ash content (% w/w)	4.23
4.	Acid Insoluble ash (% w/w)	1.49
5.	Alcohol soluble extractive value(% w/w)	18.96
6.	Water soluble extractive value (% w/w)	22.44

extractive 18.96% shows the presence of polar constituents like phenols, triterpens, steroids, glycosides and flavonoids.

HPTLC analysis

Thin layer chromatographic technique is used to separate the phytoconstituents present in the raw materials. Various solvent systems have been used to separate the maximum number of phytoconstituents in sample of *N. arbortristis* leaves. HPTLC of the chloroform extract solution was developed in the mobile phase of *Toluene: Ethyl acetate* (8:2). TLC plate was derivatized with vanillin sulphuric acid reagent and heated at 105°C till appeared the spots in a hot air oven and TLC plate was visualized under white light (Fig. 1). It showed major spots at R_f0.90, 0.81, 0.63, 0.56, 0.43, 0.31, 0.23 and 0.11 (Green) and under UV 366nm, it showed major spots at R_f0.82, 0.70, 0.64, 0.56, 0.45, 0.32 and 0.12 (Red) (Fig. 2) . After spraying with vanillin-sulphuric acid reagent under visible light it showed

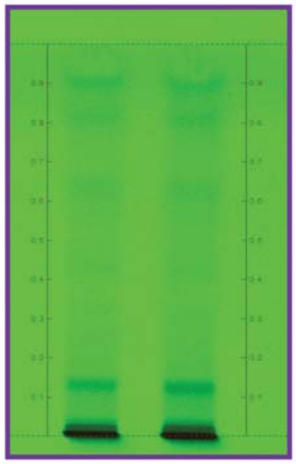

Fig. 1: UV - 254 nm

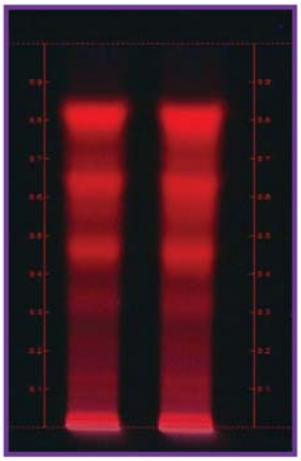

Fig. 2: UV - 366 nm

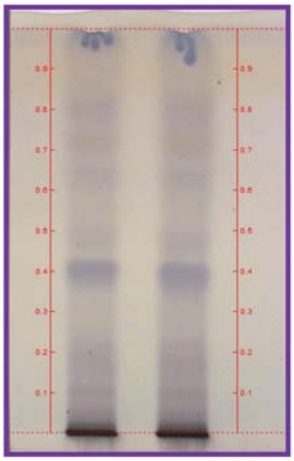

Fig. 3: Visible light

Solvent System : *Toluene: Ethyl acetate* (8:2)

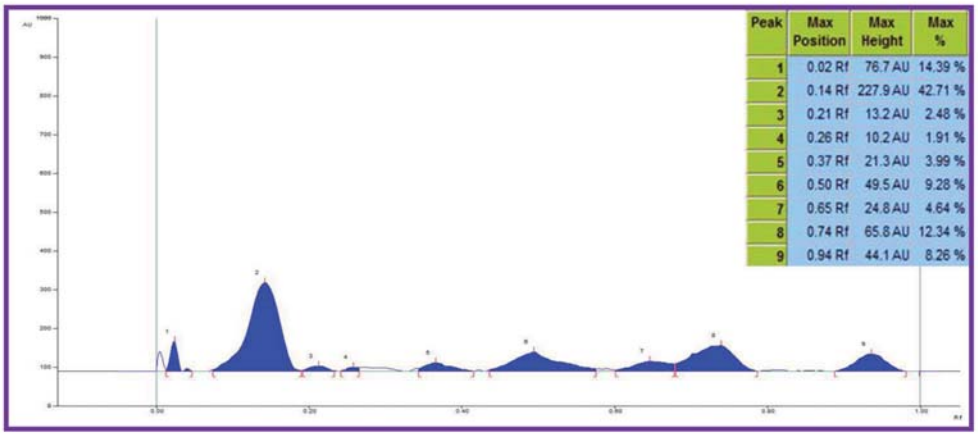

Figure 4: HPTLC fingerprint of chloroform extract of *N. arbor-tristis* leaves at 254 nm

major spots at R_f 0.81, (Violet), 0.72, 0.62, 0.49 (Grey), 0.41 (Violet), 0.22, 0.17 and 0.10 (Grey) (Fig.3). HPTLC fingerprint profile of chloroform extract at 254 nm is shown in (Fig.4).

HPTLC of the alcohol extract solution was developed in the mobile phase of *Toluene: Ethyl acetate* (1:1). TLC plate was derivatized with vanillin sulphuric acid reagent and heated at 105°C till spots appeared in a hot air oven and the plate was visualized under white light. Under UV 254 nm it showed major spots at R_f 0.93, 0.86, 0.49, 0.29, 0.12 and 0.10 (Green), (Fig.5). Under UV 366 nm, it showed major spots at R_f0.94, 0.82, 0.76, 0.49, 0.41, 0.14 and 0.10 (Red) (Fig.6). After spraying with vanillin-sulphuric acid reagent under visible light it showed major spots at R_f 0.95 (Green), 0.73, 0.64 (Violet), 0.50, 0.39, 0.20 and 0.15 (Grey) (Fig.7). HPTLC fingerprint profile of alcohol extract at 254 nm is given (Fig.8).

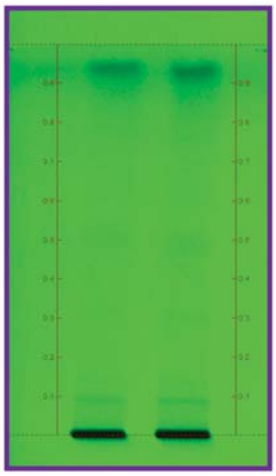

Fig. 5: UV - 254 nm

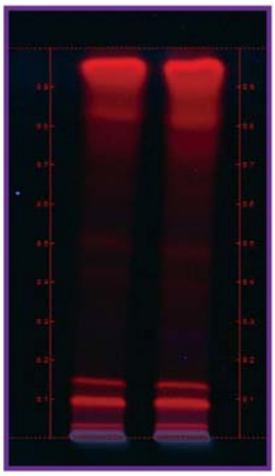

Fig. 6: UV - 366 nm

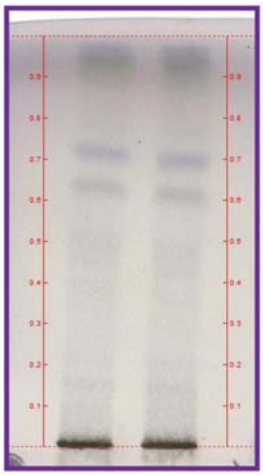

Fig. 7: Visible light

Solvent System : *Toluene: Ethyl acetate* (1:1)

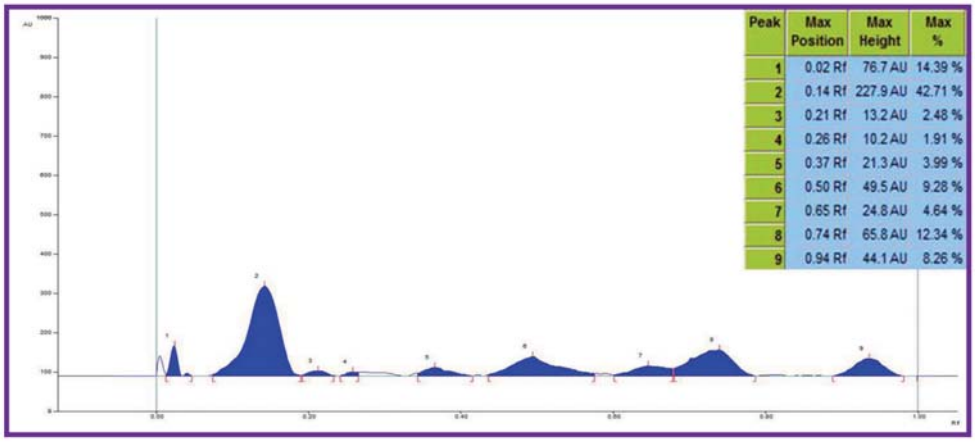

Figure 8: HPTLC fingerprint profile of alcohol extract of *N. arbor-tristis* leaves at 254 nm

Acknowledgements

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Ethnomedicines in Kendrapara District Forests of Odisha, India

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Abstract

Ethnomedicinal information was collected from the tribals and other ethnic people of Kendrapara district forests of Odisha during medicinal plants collection trip to the area in March 2016. Fifty-four folk medicinal plants for treating various human diseases and conditions, are reported. Data presented are first-hand and based on field interviews of local medicine men and material collected in the area surveyed. All folk drug species were collected, identified and voucher specimens prepared. Scientific investigations of all such species in the context of claims reported are suggested to evaluate their medical efficacy and safety. The information provided may also serve as lead material in the discovery of new drugs of plant origin.

Keywords: Kendrapara forests, Ethnomedicine, Odisha, Drug discovery, Lead material.

Introduction

Plant based traditional medicines have remained the most affordable and easily accessible source of treatment in the primary health care system of poor communities (Hosseinzadeh *et al.*, 2015; Payyappallimana, 2010; Yinger and Yewhalaw, 2007). The study of traditional knowledge of medicinal plants by indigenous communities reflects the cultural aspects as well as biodynamic elements that have immense pharmacological potential to cure many diseases (Cox and Balick, 1994; Etkin, 1993; Farnsworth, 1990; Luitel *et al.*, 2014; Minh *et al.*, 2014). Plants based remedies continue to provide a diverse and unique source of new drug discovery process (Gurnani *et al.,* 2014; Lahlou, 2013). It has been proven, time and time again that an impressive number of modern drugs have been isolated from natural sources, mainly based on their use in traditional medicine (Lentini, 2000; Patwardhan *et al.*, 2004 and Rout *et al.*, 2009a). The first step in drug discovery is the documentation of indigenous knowledge, particularly medicinal values of plants species used to treat different ailments. Therefore, the study of ethnobotanical approaches is significant in highlighting locally important plants species, particularly for new drug sources. Documentation of such knowledge may lead to its conservation and facilitate future research on medicinal plants safety and efficacy to validate the medicinal efficacy.

The Study Area

Kendrapara is the east coastal district of Odisha which lies between 20° 21' N to 20° 47' N Latitude and 86° 14 E to 87° 3' E longitude and covers an area of 2644

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sq. km with average elevation of 13 m (2011 Census). Geographically, the district is surrounded Jagatsinghpur district in the south and Jajapur and Bhadrak districts in the north, Cuttack district in the west. Bay of Bengal lies in its eastern side. The district topography has divided the area into two distinct zones: marshy and swampy strips along the coast area and the other one is deltaic plain which is highly fertile. The climate of the district is warm and humid. The district has 1569 villages with a population of 14.40 lakhs and most of its people live in villages (90.94%). Agriculture is the main occupation of the people (2011 Census). The population belong to scheduled tribe, scheduled caste and general. The scheduled tribe population is only 0.52 percent of total population. The major tribal groups are Santal, Shabar and Munda (2011 Census). The other groups are Kandra, Dewar, Dhoba etc. Being a coastal plain area, the Kendrapara district has minimal forest area of 248.05 sq km, which constitutes 9.38% of the total geographical area. The forest products of the district are medicinal plants, timber, firewood, fiber, gum and resin yielding plants, besides edible products. Rural people possess good knowledge on the use of forest products. Up to some extent they use medicinal plants for their day-to-day healthcare needs. They use several medicinally important plant species to cure various diseases. Mostly medicinal plants gain importance in the region where modern medical health facilities are either not available or not easily accessible. Despite the wider acceptance of traditional medicine only few references are available on the studies undertaken in this district (Jena Gouri Sankar and Satapathy, 2015; Panda, 2010; Panda *et al.*, 2016; Pattanaik et al., 2008). However, the indigenous knowledge of the people is not adequately documented. Thus, there is more scope for exploration of rural and tribal dominated area to record more and more information on medicinal uses of plants of this area. The present study was, therefore, undertaken with an aim to document, update and conserve the existing information on the ethnomedicinal plants of the area for future reference and validation.

Material and Methodology

Field survey was conducted in the month of March, 2016 to document ethno botanical information on traditional medicinal plants. The data on folk medicinal uses from rural pockets of Marshaghai, Kendarapara, *Pattamundai, Aul, Rajkanika block of the district* were collected through semi-structured questionnaire from well reputed local herbalists (*Vaidyas*), the elderly rural and tribal people who were familiar with traditional uses of plants particularly for medicinal use. The queries were repeatedly made to increase the reliability of the data. Standard procedures were adopted for collection, preserving and identifying the specimens (Jain and Rao, 1977). Plant specimens were collected, pressed, dried and mounted on herbarium sheets and identified with the help of flora of Odisha (Saxena and

Brahmam, 1996), Botany of Bihar & Orissa (Haines, 1921-25), other regional flora and online literature. The correctly identified specimens were deposited as voucher specimens in the Herbarium of the Survey of Medicinal Plant Unit (SMPU) of Regional Research Institute of Unani Medicine (RRIUM), Bhadrak, Odisha for future reference.

Enumeration

The folk medicinal species are enumerated in alphabetic order. Information on their botanical name, family, local name, Unani name (if any), localities with voucher specimen number, part(s) used, medical efficacy claimed, mode of administration and source are given in sequence:

Aerva lanata (L.) Juss. (Amaranthaceae); Pichhudi Sago; Biseributi; Bachhara-10549; Dysentery and kidney stone.

Root paste prepared with sugar and water is given once daily to cure dysentery.

One tea spoonful powder of whole plant is given daily in the morning to remove kidney stone (SC & other villagers).

Alangium salvifolium (L.f.) Wang (Alangiaceae); Daulan Gachha; Tunapur-10502; Dysentery and joints pain.

Stem bark paste is taken once in a day to cure dysentery.

Root paste is applied locally to cure joints pain (villagers).

Albizzia lebbeck (L.) Benth. (Mimosaceae); Siris; Pentha-10476; Diarrhoea.

Stem bark decoction is taken to cure diarrhoea (villagers).

Amaranthus viridis L. (Amaranthaceae); Nali Khoda/Marish; Chaulai; Bagada-10508; Skin rashes.

Leaf paste is applied on affected part to cure skin rashes (villagers).

Artocarpus lacucha Roxb. *ex* Buch.-Ham. (Moraceae); Jautha; Badhal; Rajkanika-10589; Wounds and headache. Roots paste is used as a poultice on wounds and headache (SC & other villagers).

Bauhinia malabarica Roxb. (Caesalpiniaceae); Kanchan; Tunapur-10501; Stomachache. Bark decoction (10-15 ml) is taken orally for stomachache (villagers).

Bombax ceiba L. (Bombacaceae); Swet Simuli; Semal Sufaid; Kujipur-10583; Cuts/wounds and diabetes.

Root paste is used on cuts and wounds.

Root powder is used to cure diabetes (SC & other villagers).

Butea monosperma (Lam.) Taub. syn. *Butea frondosa* Roxb. (Fabaceae); Palas; Dhak, Tesu; Arua-10526; Skin problem (boils and eczema) and to expel intestinal worms.

Paste of seeds is used to cure skin problems viz., boils and eczema.

Leaf powder is taken to expel intestinal worms (villagers).

Calotropis gigantea R. Br. (Asclepiadaceae); Madar; Aarakh; Tunapur-10505; Skin problem (wound and ringworm).

Latex of plant is applied externally to treat wounds and ringworm (villagers).

Capparis sepiaria L. (Capparaceae); Hadiya Konta; Penthapal-10539; Swellings and rheumatic pain.

Leaf paste is applied locally for swellings.

Root paste is used for rheumatic pain (villagers).

Capparis zeylanica L. (Capparaceae); Kalikunda; Darabachha-10497; Cuts/ wounds.

Root paste is used on cuts and wounds for healing (villagers).

Cassia fistula L. (Caesalpiniaceae); Sunari; Amaltas; Jayanagar-10574; Dysentery and wound healing.

About 15 seeds are grinded into powder and boiled in 1/2 liter of water on slow flame till it remains half. It is strained and cooled.This decoction is give to cure dysentery (villagers). .

Seed paste is used for wound healing (villagers).

Centella asiatica (L.) Urban (Apiaceae); Thalkudi (Brahmi); Nikirei-10520; Stomachache and headache.

Juice of whole plant is taken orally for stomachache (villagers).

Plant paste is applied on forehead to get relief from headache (SC).

Chromolaena odorata (L.) R. M. King & H. Roxb. (Asteraceae); Poksunga; Kapleshwer-10515; Cuts and wounds.

Extract of fresh leaf is used on cuts and wounds for healing (villagers).

Chrozophora rottleri (Geiseler) A. Juss. ex Spreng. (Euphorbiaceae); Nilakanthi; Patkura-10488; Wound healing.

Paste of whole plant is applied on wounds for healing purpose (villagers).

Clerodendrum infortunatum L. syn. *Clerodendrum viscosum* Vent. (Verbenaceae); Bhat; Kapleshwer-10516; Diabetes.

Leaf extract (10 ml) is taken to cure diabetes (villagers).

Coccinia grandis (L.) Voigt (Cucurbitaceae); Ban-kanduri; Balipatra-10552; Skin problem (boils, cuts) and tonsillitis.

Leaf paste is used to cure boils (villagers).

Leaves paste is used for tonsillitis in cattle (villagers).

Cocculus hirsutus (L.) W.Theob. (Menispermaceae); Dahidahia; Tan, Jaljamni; Indupur-10522; Eczema and cough.

Paste of aerial part is used to cure eczema (villagers).

Leaf extract (20 ml) is given to cure cough (villagers).

Coldenia procumbens L. (Boraginaceae); Moinibuta; Narilo-10513; Skin problem (boils and wounds).

Leaf juice is applied externally to cure boils and wounds (villagers).

Crataeva nurvala Buch.- Ham (Capparaceae); Baruno; Rajkanika-10588; Bark; Stomachache (villagers). .

Stem bark powder (one tea spoonful) is taken with water to cure stomachache (villagers).

Crateva religiosa G. Forst. syn. *Crataeva magna* (Lour.) DC (Capparaceae); Varuna, Baruno; Barna; Darabachha-10495; Gall bladder stone.

Stem bark decoction is taken once daily to remove gall bladder stone (villagers).

Crotalaria pallida Aiton DC. syn. *Crotalaria striata* DC. (Fabaceae); Nirmishi; Arua-10527; Skin problem (eczema and skin infections).

Paste of whole plant is used to treat eczema and other skin infections (villagers).

Cuscuta reflexa Roxb. (Cuscutaceae); Nirmula; Kasoos; Bharatpur-10511; Pile and itching. Decoction of whole plant (20 ml) is taken daily to cure piles. (villagers).

Paste of whole plant is applied topically for itching (villagers).

Eclipta prostrata (L.) L. Syn. *Eclipta alba* (L.) Hassk. (Asteraceae); Bhangra (Bhangra); Taradipal-10533; Jaundice and indigestion.

Roots powder is taken once daily to cure jaundice (villagers).

Leaves decoction is used for indigestion (villagers).

Euphorbia tithymaloides L. syn. *Pedilanthus tithymaloides* (L.) Poit. (Euphorbiaceae); Siju; Narilo-10514; Warts and deficient secretion of milk in cattles; Latex, leaf.

Plant latex is applied topically to cure warts (SC).

Leaves are given to cattle (cow) for increase lactation (villagers).

Glycosmis pentaphylla (Retz.) DC (Rutaceae); Mohri, Kukurcheva; Odanga-10485; Leaf, Twig; Diabetes and dental care.

Leaf juice is taken to cure diabetes (villagers).

Twigs are used as tooth brush to strengthen the teeth (villagers).

Gmelina arborea Roxb. (Verbenaceae); Gambhari; Chalunia-10577; Leucorrhoea; Root, Stem bark.

Root decoction (50 ml) daily is taken to cure leucorrhoea (villagers).

Heliotropium indicum L. (Boraginaceae); Hathisund (Hathisunda); Charapada-10521; Skin problem (cuts/wounds and eczema); Leaf.

Leaves paste is applied to cure cuts/wounds and eczema (villagers).

Jatropha curcas L. (Euphorbiaceae); Jhaji; Nuapada-10562; Wound healing and dental care; Latex, twigs.

Latex of plant is applied for wound healing (villagers).

Twigs are used as tooth brush (villagers).

Jatropha gossypifolia L. (Euphorbiaceae); Naliya, Amar Jadi; Nuapada-10561; Dental care (Teeth cleaning and gum swelling); Stem, latex.

Stem is used as tooth brush (villagers).

Latex along with salt is massage for gum swelling (villagers).

Justicia gendarussa Burm.f. (Acanthaceae); Kala basung; Parakula-10493; Skin problem (eczema); Leaf.

Leaf paste is used against eczema (SC & other villagers).

Lawsonia inermis L. (Lythraceae); Benjati; Hena; Indupur-10525; Hair care (hair loss, to control dandruff and to kill lice); Leaf.

Leaves paste is used for hair loss, to control dandruff and to kill lice (villagers).

Lippia javanica (Burm.f.) Spreng. (Verbenaceae); Bhutbari, Gondhyan Gochha; Patkura-10491; Dysentery; Leaf.

Leaves (10-15) are boiled in 100 ml water till left half and this decoction is given to treat dysentery (villagers).

Mallotus nudiflorus (L.) Kulju & Welzev syn. *Trewia nudiflora* L. (Euphorbiaceae); Janda-Khai; Pentha-10480; Wound healing; Fruit.

Fruits pulp is used for wound healing (villagers).

Mimosa pudica L. (Mimosaceae); Lajkoli; Telipatra-10555; Gingivitis; Root.

Roots (20 g) are boiled in 100 ml water and when left half is cooled. It is used for gargle to cure gingivitis (villagers).

Morinda pubescens Sm. syn. *Morinda tinctoria* Roxb. (Rubiaceae); Achhu; Aal; Tunapur-10506; Diarrhoea and dysentery; Leaf.

Extraction of leaf is used to cure diarrhoea and dysentery (villagers).

Mucuna monosperma Wight (Fabaceae); Bidonko; Nuapada-10560; Cold and cough; Seed.

One tea spoonful seed powder is taken daily to cure cold and cough (SC & other villagers).

Murraya koenigii (L.) Spreng. (Rutaceae); Bhursunga (Kariapata); Penthapal-10540; Skin problem (skin eruption, allergy) and piles; Leaf, root.

Leaf paste is used against skin eruption and allergy (villagers).

Root powder is used to cure piles (villagers).

Nicotiana plumbaginifolia Viv. (Solanaceae); Hemraj; Rajkanika-10590; Cuts and wounds; Leaf.

Leaf paste is applied on cuts and wounds for healing (villagers).

Operculina turpethum (L.) Silva-Manso syn. *Ipomoea turpethum* R. Br. (Convolvulaceae); Kalam saga; Turbud; Angarakha-10558; Stomach complaint; Root.

Root powder (1 small spoonful) is taken for stomach complaint (SC & other villagers).

Paederia foetida L. (Rubiaceae); Pasaruni (Gandhali); Nikirei-10517; Acidity and back pain; Whole plant, leaf.

Decoction of whole plant is taken to cure acidity problem (villagers).

Leaves of the plant with rice grain and water grinded and made into a paste. The paste is applied topically for back pain (SC & other villagers).

Passiflora foetida L. (Passifloraceae); Banboda; Odanga-10048; Itching; Leaf.

Leaf paste is used for itching (Santal & other villagers).

Pithecellobium dulce (Roxb.) Benth. (Mimosaceae); Vilayti imbli; Arua-10529; Eczema and fever; Leaf, bark.

Paste of leaves is used for eczema (villagers).

Decoction of bark is given to cure fever (villagers).

Pongamia pinnata (L.) Pierre syn. *Pongamia glabra* Vent. (Fabaceae); Karanjo; Karanj; Andara-10543; Dental care, scabies and rheumatic pain; stem bark, seed.

Stem bark is use for cleaning teeth (villagers).

Seed oil is applied topically to cure scabies and rheumatic pain (villagers).

Portulaca oleracea L. (Portulacaceae); Chaulayi-gudi, Badluniya; Karandia-patana-10492; Anemia; Whole plant.

Whole plant is consumed as vegetable to cure anemia (villagers).

Sapindus emarginatus Vahl (Sapindaceae); Ritha phal; Ritha; Darabachha-10494; Hair care and itching; Fruit.

The fruit is used to wash hair and kill lice (villagers).

Fruit paste is applied for itching (villagers).

Sida acuta Burm.f. (Malvaceae); Misri, Bajramuli; Podana-10487; Teeth cleaning and wound healing; Leaf, stem.

Leaves paste is applied on wounds for healing (villagers).

Stem used for teeth cleaning (villagers).

Smilax perfoliata Lour. syn. *Smilax prolifera* Roxb. (Smilacaceae); Ramdatun; Tunapur-10504; Gastric problem and dental care; Stem, root.

Root powder is used for gastric problem (villagers).

Stem is used for cleaning teeth (villagers).

Solanum torvum Swartz. (Solanaceae); Bheji-bengan; Arimula-10481; Cuts/ wounds; Fruit.

Paste of fruits is used on cuts/wounds (Santal & other villagers).

Solanum trilobatum L. (Solanaceae); Bhejikanta; Andara-10541; Itching; Stem.

Stem paste is applied for skin itching (villagers).

Streblus asper Lour. (Moraceae); Sahada; Sahada, Sehura; Narilo-10512; Acidity and dental care; Leaf.

The decoction of leaves is taken for acidity problem (villagers).

Plant twigs are used as tooth brush to strengthen teeth (SC & other villagers).

Terminalia arjuna Wight. & Arn. syn. *Pentaptera arjuna* Roxb. ex DC. (Combretaceae); Kowa/ Arjuna; Arjun; Dandisahi-10536; Diarrhea; Bark, leaf.

About 15 ml decoction of the bark is given to cure diarrhoea (SC & other villagers).

Trichodesma indicum (L.) Lehm. (Boraginaceae); Hatamunda; Andhawli; Odanga-10484; Skin problem (boil, eczema, cuts and wounds); Leaf.

Leaf paste is used for skin problem such as boil, eczema, cuts and wounds (Santal & other villagers).

Vitex negundo L. (Verbenaceae); Begonia (Sambhalu, Irkul, Sindware); Dandisahi-10537; Dental care, headache and rheumatism; Stem, leaf.

Leaf paste is used for headache and rheumatic pain (villagers).

Stem is used as tooth brush to make teeth strong (SC & other villagers).

Amaranthus viridis L.

Artocarpus lacucha Roxb. *ex* Buch.-Ham.

Bauhinia malabarica Roxb.

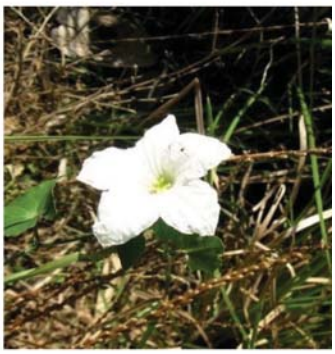
Bombax ceiba L.

Butea monosperma (Lam.) Taub.

Capparis sepiaria L.

Capparis zeylanica L.

Chrozophora rottleri (Geiseler) A. Juss. ex Spreng.



Coccinia grandis (L.) Voigt

Crataeva nurvala Buch.- Ham

Gmelina arborea Roxb.

Heliotropium indicum L.

Figure 1: Some ethnomedicinal plants of Kendrapara district, Odisha

Justicia gendarussa Burm.f.

Lippia javanica (Burm.f.) Spreng.

Mucuna monosperma Wight

Nicotiana plumbaginifolia Viv.

Operculina turpethum (L.) Silva-Manso

Smilax perfoliata Lour.

Figure 1: Some ethnomedicinal plants of Kendrapara district, Odisha

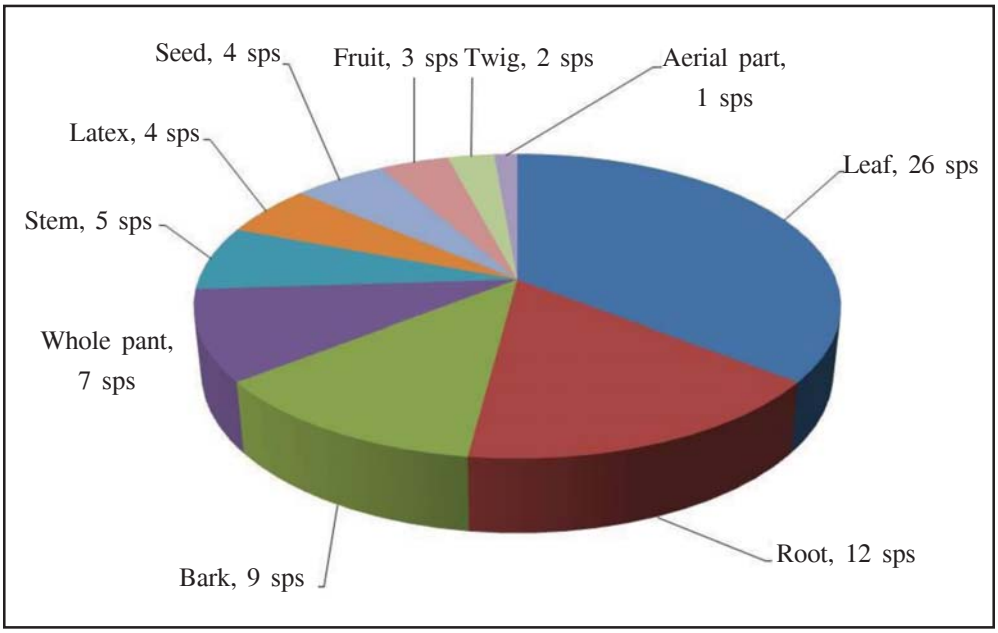


Figure 2: Pie diagram showing different plant part used for curing various ailments

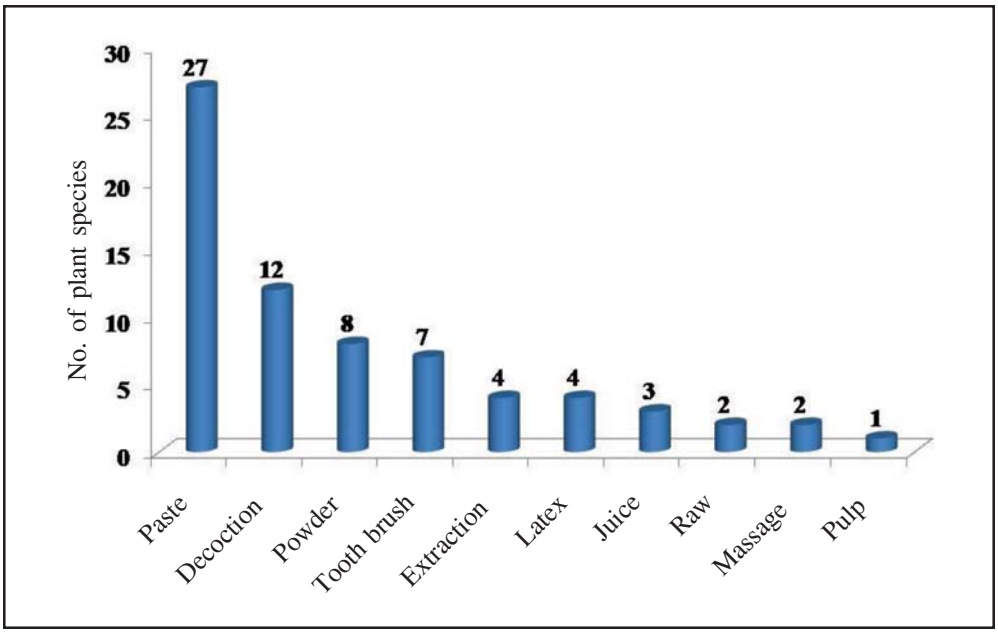


Figure 3: Different form of herbal preparation of medicinal plant

Table 1: Disease-wise ethnomedicinal species of the study area

	Ailment category	Ailment(s)	Number of plant species to cure ailment
1.	Circulatory system	Anemia	*Portulaca oleracea* L.
2.	Gastro-intestinal diseases	Diarrhoea, dysentery, stomachache, indigestion, acidity	*Aerva lanata* (L.) Juss., *Alangium salvifolium* (L.f.) Wang, *Bauhinia malabarica* Roxb., *Butea monosperma* (Lam.) Taub., *Cassia fistula* L., *Centella asiatica* (L.) Urban , *Crataeva nurvala* Buch.- Ham, *Crateva religiosa* G. Forst., *Cuscuta reflexa* Roxb., *Eclipta prostrata* (L.) L., *Lippia javanica* (Burm.f.) Spreng. , *Mallotus nudiflorus* (L.) Kulju & Welzev, *Operculina turpenthum* (L.) Silva-Manso , *Paederia foetida* L., *Smilax perfoliata* Lour., *Streblus asper* Lour., *Terminalia arjuna* Wight. & Arn.
3.	Respiratory	Cold, cough	*Cocculus hirsutus* (L.) W.Theob., *Mucuna monosperma* Wight
4.	Reproductive disorders	Leucorrhoea, lactation (in cattle)	*Gmelina arborea* Roxb., *Euphorbia tithymaloides* L.
5.	Musculo-skeletal swellings	Joint pain, headache,	*Alangium salvifolium* (L.f.) Wang, *Artocarpus lacucha* Roxb. *ex* Buch.-Ham., *Capparis sepiaria* L., *Centella asiatica* (L.) Urban, *Paederia foetida* L., *Pongamia pinnata* (L.) Pierre, *Vitex negundo* L.

	Ailment category	Ailment(s)	Number of plant species to cure ailment
6.	Dermatological conditions	Skin rashes, skin eruption, allergy, cuts/ wounds healing, boil, eczema, ringworm, skin infections, itching, warts	*Amaranthus viridis* L., *Artocarpus lacucha* Roxb. *ex* Buch.-Ham., *Bombax ceiba* L., *Butea monosperma* (Lam.) Taub., *Calotropis gigantea* R. Br., *Capparis zeylanica* L., *Cassia fistula* L., *Chromolaena odorata* (L.) R. M. King & H.Rob., *Chrozophora rottleri* (Geiseler) A. Juss. ex Spreng., *Coccinia grandis* (L.) Voigt, *Cocculus hirsutus* (L.) W.Theob., *Coldenia procumbens* L., *Crotalaria pallida* Aiton DC., *Cuscuta reflexa* Roxb., *Euphorbia tithymaloides* L. , *Heliotropium indicum* L., *Jatropha curcas* L., *Justicia gendarussa* Burm.f., *Mallotus nudiflorus* (L.) Kulju & Welzev, *Murraya koenigii* (L.) Spreng, *Nicotiana plumbaginifolia* Viv., *Passiflora foetida* L., *Pithecellobium dulce* (Roxb.) Benth., *Pongamia pinnata* (L.) Pierre, *Sapindus emarginatus* Vahl, *Sida acuta* Burm.f., *Solanum torvum* Swartz., *Solanum trilobatum* L., *Trichodesma indicum* (L.) Lehm.
7.	Infectious diseases	Tonsillitis (in cattle)	*Coccinia grandis* (L.) Voigt
8.	Fever	Common fever	*Pithecellobium dulce* (Roxb.) Benth.
9.	Renal complaint	Kedeny stone	*Aerva lanata* (L.) Juss.
10.	Endocrine	Diabetes	*Bombax ceiba* L., *Clerodendrum infortunatum* L., *Glycosmis pentaphylla* (Retz.) DC
11.	Liver complaint	Jaundice	*Eclipta prostrata* (L.) L.
12.	Dental care	Strengthen the teeth, gum swelling, gingivitis	*Glycosmis pentaphylla* (Retz.) DC, *Jatropha curcas* L., *Jatropha gossypifolia* L., *Mimosa pudica* L., *Pongamia pinnata* (L.) Pierre, *Sida acuta* Burm.f., *Smilax perfoliata* Lour., *Streblus asper* Lour., *Vitex negundo* L.
13.	Hair care	Hair loss, dandruff and to kill lice	*Lawsonia inermis* L., *Sapindus emarginatus* Vahl

Results and Discussion

The rural people of the district live in complete harmony with nature and their daily needs are met by the natural surroundings. In the absence of modern facilities, these people usually depend upon herbs and other materials for treatment of diseases. During field studies 54 plant species belonging to 50 genera and 29 families have recorded to be used locally by the tribal and rural inhabitants

(Figure 1). The most dominant plant families reported herein are Euphorbiaceae with five species followed by Capparaceae, Fabaceae, Verbenaceae (four species each), Boraginaceae, Mimosaceae, Solanaceae (three species each), Amaranthaceae, Asteraceae, Caesalpiniaceae, Moraceae, Rubiaceae, Rutaceae (two species each). The rest of the families were represented by one species each. All the genera were represented by one species each except *Capparis, Crataeva*, *Jatropha and Solanum* (two species each).

The plant parts used for making herbal preparations were the roots, leaves, stem bark, seeds and other aerial parts. The leaves were the most commonly used (26 species) followed by the roots (12 species), stem bark (9 species), whole pant (7 species), stem (5 species), latex & seeds (4 species each), fruits (3 species), twigs (2 species) and aerial parts (1 species) (Figure 2). The frequent use of leaves to prepare herbal remedies may be due to easy availability almost throughout all seasons of the year, and also due to presence of high concentration of bio-active compounds (Vitalini *et al.*, 2009). The use of leaves enhances the sustainable management of availability of plants as compared to use of roots, seeds, fruits, flowers and whole plant which leads destructive effects on the growth of plants population in nature (Amri and Kisangau, 2012; Ghimire *et al.*, 2008; Mahmood *et al.*, 2012).

The usual methods reported for preparation of medicine include paste, decoction, powder, extract, juice etc. (Figure 3). These herbal preparations applied internally or topically depending upon the condition of disease. Stem, stem bark, and twigs of *Glycosmis pentaphylla* (Retz.) DC*, Jatropha curcas* L.*, Jatropha gossypifolia* L., *Pongamia pinnata* (L.) Pierre, *Sida acuta* Burm.f., *Smilax perfoliata* Lour., *Streblus asper* Lour, *Vitex negundo* L. have been reported to be used as toothbrush for cleaning and strengthening the teeth; latex of *Jatropha gossypifolia* L. along with salt is massage for gum swelling, whereas *Portulaca oleracea* L. is consumed as vegetable to cure anemia. Seed oil of *Pongamia pinnata* (L.) Pierre is applied topically to cure scabies & rheumatic pain and fruit pulp of *Mallotus nudiflorus* (L.) Kulju & Welzev is used for wound healing. In veterinary use leaves of *Euphorbia tithymaloides* L. are given to cattle (cow) to increase lactation and leaf paste of *Coccinia grandis* (L.) Voigt, is used for tonsillitis in cattle.

A wide variety of medical conditions were treated by local folk healers by using herbal remedies made from locally available medicinal plants. Preparations made from a single plant species were the most dominant in the study. The most frequent ailments treated were those categorized as specific diseases/conditions (Table 1). Dermatological conditions such as rashes, skin eruption, allergy, cuts, wounds, boils, eczema, ringworm, skin infections, itching, warts etc. were treated, using the largest number of herbal remedies (30 ssp.) followed by gastro-intestinal diseases (17 ssp.), dental care (09 ssp.), Musculo-skeletal (07 ssp.), endocrine

(03 ssp.), respiratory, reproductive disorders, hair care (02 ssp. each). On the lower end infectious diseases, fever, renal complaint , liver complaint are reported to be cured by using one species each only.

The data on folklore uses have been compared with recent available literature from Odisha (Ali *et al*., 2010; Ambasta, 1986; Aminuddin *et al*., 2013; Aminuddin and Girach, 1996; Anonymous, 2001; Behera *et al*., 2006, 2008; Brahmam. & Saxena, 1990; Dhal *et al*., 2014; Girach *et al*., 2008, 2011; Jain, 1991; Kandari *et al*., 2012; Khare, 2007; Kirtikar & Basu, 1935; Mallik *et al*., 2012; Mukesh *et al*., 2011, 2012, 2014a & 2014b; Murty *et al*., 1997; Panda and Das, 1999; Panda *et al*., 2013; Pandey and Rout, 2006; Patra *et al*., 2014; Pattanaik *et al*., 2008a, 2008b; Prusti, 1998; Prusti and Behera, 2007; Raut, 2013; Rout *et al*, 2009a, 2009b, 2009c; Rout and Pandey, 2007; Sahu *et al*., 2010, 2013a & 2013b; Sarkar *et al*., 1999; Satapathy, 2010, 2015; Satapathy and Brahmam, 1999; Satapathy & Chand, 2003; Satapathy, *et al*., 2012 and Usha *et al*., 2014, 2015a, 2015b & 2016). However, the therapeutic claims of most of the folk medicine are duly reported in literature, but their mode of application, ingredients and part used are different. Therefore, present study represents the contemporary uses of medicinal plants for the area investigated. Further it would be worthwhile to subject all these folk drugs to scientific testing in the context of claims reported herein.

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A Bibliographic Review of Pharmacognostic Profiles on Herbal Drugs of Bark Origin#

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Abstract

Bibliographies are important tool of literature on any aspect of past and present status of knowledge in a specified subject. They are considered the key to initiate research in any field and provide lead material. The present communication covers the references in respect of works carried out on pharmacognostical profiles of some 192 bark drugs either pharmacopoeial or monographic.

Keywords: Bibliography, Pharmacopoeia, Pharmacognosy, Herbal drugs.

Introduction

Ayurveda, Siddha, Unani and Homoeopathic systems of medicine are practiced in India. Materia Medica of these systems prescribe major source of drugs from herbal origin. To derive the herbal drugs various morphological parts of a plant species viz. leaves, stem, roots, barks, heartwood, flowers, fruits, seeds and various exudates are collected and resourced by the manufactures to formulate the medicines of these systems. It is estimated that more than 960 medicinal plant species are the source of 1289 botanical raw drugs in trade in this country (Ved and Goraya, 2008). Bark drugs are specifically termed for all the tissues of a woody stem or root outside the vascular cambium. Barks are all stripped away from the woody core for herbal drug purposes. Barks drugs after extracting from the tree are dried. Dried bark drugs morphologically resemble each other which leads to confusion leading to fair chances for adulteration. However, minor variations can be observed in barks related to its shape, surface (inner and outer), colour, odour, taste, fracture etc. for identification purposes. Pharacognostic profiles explain diagnostic characteristics of a herbal drug so as to authenticate and differentiate from adulterants or substitutes.

Bibliographies explicit the literature published so far in a particular subject. Major existing bibliographies on the pharmacognostic aspects (Iyengar, 1976 and; Mitra, 1985) and relevant available sources have been consulted (Rai *et al*., 2012; Tiwari *et al.,* 2013). Pharmacopoeias (regulatory standards) and monographic works are listed as these works are pertinent to pharmacognostical profiles on herbal drugs which can be referred to evaluate bark drugs in a quality control laboratory. Research publications on this aspect are not included in present review.

The table-1 enumerates the bark drugs and citations (acronym) for their references in literature. Acronyms are given at the last of the bibliographic references in parenthesis.

#Invited paper

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Table 1

Sl. No.	Botanical Name (as specified in references/literature)	Name of the Bark drug	Morphological Part specified as drug	Pharmaco-Poeial/ Regulatory Reference	Monographic work
1.	*Abies canadensis* Michx.	Abies Canadensis	Bark	HPI-II	-
2.	*Acacia catechu* (Linn. f.) Willd.	Khadira	-	-	MRPD IHP
3.	*Acacia farensiana* (Linn.) Willd. syn. *Mimosa farnesiana* Linn.	-	Stem Bark	-	QSIMP-12
4.	*Acacia leucophloea* (Roxb.) Willd	Arimeda, Kath, Babbula	Stem bark	API-II UPI-VI API-I	QSIMP-10 MRPD QSIMP-9
5.	*Acacia nilotica* (Linn.) Willd. Ex Del. Ssp. *indica*	Babbula	-	-	MRPD PID-1
6.	*Acronychia pedunculata* (Linn.) Miq.	Akenda	-	-	MRPD
7.	*Aegle marmelos* (Linn.) Corr.	Bilva	Stem bark	API-IV	QSIMP-8 BD MRPD PAD
8.	*Aesculus hippocastanum* Linn.	Aesculus Hippocasta-numcortice	Bark	HPI-IX	-
9.	*Ailanthus excelsa* Roxb.	Aralu	-	-	QSIMP-3 BD PABD MRPD
10.	*Ailanthus excelsa* Roxb.	Aralu	Stem bark	API-III	-
11.	*Ailanthus glandulosus* Desf.	Ailanthus Glandulosus	Stem bark of young shoots and well developed flowers	HPI-IV	-
12.	*Alangium salvifolium* Lamk.	Akol	Root bark Stem bark	-	PAD
13.	*Albizia lebbek* Benth.	Sirisa	Stem Bark	API-III	QSIMP-2 BD MRPD PAD
14.	*Albizia marginata* Merr.	Kala Sirisa	Stem bark	-	PAD
15.	*Albizia odoratissima* (L.f.) Benth.	Sirisa	Stem bark	-	BD PAD

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16.	*Albizia procera* (Roxb.) Benth.	Sirisa	Stem bark	-	BD
17.	*Alnus serrulata* Wild.	Alnus Serrulata	Bark	HPI-VI	BD
18.	*Alstonia constricta* F. Muell.	Alstonia Constricta	Bark	HPI-V HPI-VII	-
19.	*Alstonia scholaris* (L.) R. Br.	Alstonia; Chhatim	Dried bark	IP-55	QSIMP-3 BD MRPD PAD
20.	*Alstonia scholaris* R. Br. (Roxb.) Wight & Arn.	Saptaparna Alstonia Scholaris	Stem bark Bark Bark	API-I HPI-IV HPI-X	-
21.	*Amoor arohituka* W & A	Amoora Rohituka	Bark	HPI-IV	QSIMP-6
22.	*Aphanamixis polystachya* (Wall.) R. Parker	Rohitaka	Stem Bark		BD PID-2
23.	*Anogeissus latifolia* Wall	Dhava	Stem bark	API-VI	QSIMP-3 BD
24.	*Anthocephalus chinensis* (Lamk.) A. Rich.	Kadamba	Stem bark	API-II	PAD QSIMP-5 MRPD
25.	*Anthocephalus indicus* A. Rich	Kadamba	Stem bark	-	PAD
26.	*Artocarpus heterophyllus* Lamk	Panasa	Root bark	API-VI	-
27.	*Aspidospermaque bracho* Blanco Schlwcht	Aspidosperma	Bark	HPI-VI	-
28.	*Azadirachta indica* (Linn.) A. Juss.	Nimba Azadirachta Indica Veppampattai Neem Nimba	Stem bark	HPI-VIII SPI-I UPI-IV API-II	MRPD BD QSIMP-8 PAD
			Root bark	API-V UPI-V	QSIMP-8
29.	*Baptisia tinctoria* Vent.	Baptisia Tinctoria	Root Bark	HPI-IX HPI-I	-
30.	*Bauhinia purpurea* Linn.	Kovidara	-	-	PABD MRPD
31.	*Bauhinia racemosa* Lam. Syn. *Bauhinia parviflora* Vahl.	Post-e-Kachnal	Stem Bark	UPI-II	SSD

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32.	*Bauhinia variegata* L.	Kancanara	Stem bark	API-I	MRPD QSIMP-5 QSIMP PID-1
33.	*Berberis aristata* DC	Berberis	Dried roots with the bark intact	IPL	-
34.	*Berberis vulgaris* Linn.	Berberis Vulgaris	Bark of Root	HPI-I	-
35.	*Betula utilis* D. Don.	Bhojpatr Bhurjah	Stem Bark	UPI-V API-V	QSIMP-12
36.	*Bombax ceiba* L.	Salmali Sembhal Salmali	Stem bark	API-III UPI-V	QSIMP-5 MRPD
37.	*Boswellia serrata* Roxb. ex Colebr	Loban	Stem bark	-	BD
38.	*Buchanania lanzan* Spreng.	Priyala	Stem bark	API-IV	-
39.	*Butea monosperma* (Lam.) Kuntze.	Palasa	Stem bark	API-II UPI-V	MRPD PABD
40.	*Caesalpinia crist*a Linn.	Putikaranja	Stem bark	API-V	
41.	*Calophyllu minophyllum* Linn.	-	Stem bark	-	QSIMP-3
42.	*Calotropis gigantea* Corr	-	Root bark	-	-
43.	*Calotropis procera* (Ait.) R.Br.	Arka	Stem bark	API-III	-
		Madar	Rootbark	UPI-IV	PID-1
44.	*Capparis zeylanica* L.	-	-	-	PID-2
45.	*Capparis sepiaria* L.	-	Rootbark	SSD	
46.	*Carissa carandas* L.	Karamarda	Stem bark	API- II	MRPD
47.	*Cassia fistula* L.	Aragvadha Konraippattai	Stem bark	API- V SPI-II	QSIMP-12
48.	*Cedrela toona* Roxb.	Tuni	Stem bark	API- V	-
49.	*Terminalia arjuna* (Roxb) Wight & Arn	Arjuna, Terminalia arjuna Bark	Dried stem bark	IP 2007 IP 2010 IP 2014	-
50.	*Chionanthus virginicus* Linn.	Chionanthus Virginica	Bark	HPI-III	-
51.	*Cinchona calisaya* Wedd.	Cinchona	-	-	MRPD
52.	*Cinchona ledgeriana* (Howard) Moens et Trimen	Cinchona febrifuge	Bark	IP-55 IP-66	-

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53.	*Cinchona officinalis* L.	Kanakana Cinchona Officinalis	Bark	UPI-III HPI-X HPI-I	BD QSIMP-1 IHD
54.	*Cinnamomum aromaticum* Nees	Tvak (cassia)	-	-	MRPD
55.	*Cinnamomum camphora* (Linn.) Pers.	-	Stem bark	-	QSIMP-3
56.	*Cinnamomum cassia* Blume. Syn. *Cinnamomum aromaticum* Nees & Eberm.	Cinnamomum, Cassia Cinnamon Qirfa	Stem bark	IP -55 IP- 66 UPI-III	-
57.	*Cinnamomum tamala* (Buch. Ham.) Nees and Eberm.	Sazaj Hindi	Dried stem bark	UPI-III	-
58.	*Cinnamomum verum* Presl.	Ilavankappattai Tvak	Bark	SPI-I	MRPD
59.	*Cinnamomum zeylanicum* Blumesyn.verum Presl.	Cinnamomum Darchini Tvak Cinnamomum, Cinnamon	Bark	HPI-II UPI-I API- I IP- 55 IP- 66	QSIMP-1 SSD
60.	*Comocladia dentata* Jacq.	Comocladia Dentata	Leaf and bark	HPI-V	
61.	*Cordia dichotoma* Forst. f.	Slesmataka	Stem bark	API-VI	MRPD
62.	*Coscinium fenestratum* (Gaertn.) Colebr	Daruharidra	Root bark	-	PAD
63.	*Cornus circinata* L Herit	Cornus Circinata	Bark	HPI-VI	-
64.	*Cornus florida* Linn.	Cornus Florida	Bark	HPI-III	-
65.	*Crataeva nurvala* Buch.-Ham.	Varuna	Stem bark	API- I	BD IHP PID-2
66.	*Crateva magna* (Lour.) DC.	Varuna Mavilanka- ppattai	-	SPI-I	QSIMP-10 MRPD PID-2
67.	*Crataeva religiosa* Hook	Varuna	Stem bark	-	PAD
68.	*Croton eluteria* Benn.	Cascarilla	Bark	HPI-III	-
69.	*Dalbergia sissoo* Roxb.	Simsapa	Stem bark	API-III	MRPD
70.	*Daphne indica* Hook and Arn.	Daphne Indica	Bark of branches	HPI-IV	-
71.	*Daphne mezereum* Linn.	Mezereum	Bark	HPI-I	-

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72.	*Dendrophothoe falcata* (Linn. f.) Etting syn. *Loranthus longiflorus* Desr.	Banda	Stem bark	-	QSIMP-3
73.	*Diospyros tomentosa* Roxb.	Virala	Stem bark	API-V	-
74.	*Dirca palustris* Linn.	Dirca Palustris	Inner bark of stem	HPI-VII	-
75.	*Drypetes roxburghii* (Wall.) Hurusawa	Putrajivaka	Stem bark	-	MRPD
76.	*Erythrina indica* Lam.	Paribhadra Rohitaka	Stem bark	API-II	PAD PID-2
77.	*Erythrina variegata* Linn. var. *orientalis* (Linn.) Merrill	Paribhadra	Stem bark	-	QSIMP-5 PABD MRPD
78.	*Euonymus atropurpureus* Jacq.	Euonymus Atropurpurea	Bark	HPI-III	-
79.	*Ficus arnottiana* (Miq.) Miq.	Nyagrodha Parisa	Stem bark	-	PABD
80.	*Ficus bengalensis* L.	Nyagrodha	Stem bark	API-I	QSIMP-7 MRPD PAD PAD
81.	*Ficus glomerata* Roxb.	Vatah	Stem bark	-	PAD
82.	*Ficus hispida* L.	Post-e-Anjeer Dashti	Stem Bark	UPI-VI	-
83.	*Ficus lacor* Buch.-Ham	Plaksa	Stem bark	API-II	-
84.	*Ficus microcarpa* L.f.	Plaksa	Stem bark	-	PABD
85.	*Ficus racemosa* L.	Udumbara Attippattai Post-e-Gular Udumbara	Bark	API-I SPI-I UPI-I	QSIMP-9 PABD MRPD IHP
86.	*Ficus religiosa* L.	Asvattha	Stem Bark	API-I	QSIMP-3 PABD MRPD PAD
87.	*Ficus retusa* L.	Palaksh	Stem bark	-	PAD PID-2
88.	*Ficus tjiela* Miq.	Palaksh	Stem bark	-	PAD
89.	*Ficus tsiela* Roxb.	Plaksa	Stem bark	-	MRPD PID-2 PAD

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90.	*Ficus talboti* King	Palaksh	Stem bark	-	PAD
91.	*Ficus virens* Ait. Syn. *F. infectoria* Roxb.; *F. lacor* Buch.-Ham.	Palaksh	Stem bark	-	QSIMP-3
92.	*Flacourtia indica* Merr.	Sruvavrksa	Stem bark	API- IV	-
93.	*Fraxinus americana* Linn.	Fraxinus Americana	Inner bark	HPI-IV	-
94.	*Galipea officinalis* Hancock	Angustura	Bark	HPI-III	-
95.	*Gmelina arborea* L.	Gambhari	Stem bark	API- IV	QSIMP-6 BD MRPD
			Root bark	API- I	MRPDPAD
96.	*Gossypium herbaceum* Linn.	Gossypium Herbaceum	Inner bark of root	HPI-II	-
97.	*Grewia tenax* (Forsk.) Aschers & Schwf.	Gangeru	Stem bark	API- II	-
98.	*Guarea trichiloides* Linn	Guarea Trichiloides	Bark	HPI-IV	-
99.	*Hamamelis virginica* Linn.	Hamamelis Virginica	Stem and Root bark	HPI-I HPI-IX	-
100.	*Harongamadagas cariensis* Choisy	Harungana Madagas-cariensis	Leaf and stem bark	HPI-VIII	-
101.	*Hippomaneman cinella* Linn.	Mancinella	Leaf, bark and fruit	HPI-V	-
102.	*Holarrhena antidysenterica* (Roth) A.DC.	Kutaja Kurchi Holarrhena Antidy senterica	Stem bark	API- I IP-55 IP-66 HPI-I	QSIMP-1 IHD SHD PAD SSD
			Root bark	-	PAD
103.	*Holarrhena pubescens* Wall.ex Buch.-Ham.	Kutaja	Stem bark	-	BD MRPD PABD
104.	*Holoptelea integrifolia* Planch.	Cirabilva	Stem bark	-	QSIMP-5 BD MRPD PAD
105.	*Hemidesmus indicus* (Linn.) Schutt	-	Stem bark	-	PID-2

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106.	*Juglans cinerea* Linn.	Juglans Cinerea	Inner bark of root and branches	HPI-IV	-
107.	*Juglans regia* L.	Akhroa	Stem bark	-	BD
108.	*Lannea coromandolica* (Houtt.) Merrill	Jingini	Stem bark	-	MRPD
109.	*Litsea chinensis* Lam.	Medasakah Meda Lakri	Stem Bark	API-V UPI-V	-
110.	*Madhuca longifolia* (Koen.) Mac Bride	Madhuka	Stem bark	MRPD	
111.	*Mangifera indica* L.	Amra Mango; Mangifera-indica	Stem bark	API- III IP 2007 IP 2010 IP 2014	PABD
112.	*Mangifera indica* L.	Aam Mangifera Indica	Stem Bark	UPI-IV HPI-VII	PABD
113.	*Marsdenia condurango* Nichols.	Condurango	Bark	HPI-VIII	-
114.	*Marsdenia cundurango* Nichols.	Cundurango	Bark	HPI-II	MRPD
115.	*Melia azedarach* L.	Mahanimba	Stem bark	API- IV	QSIMP-9 PAD SSD
116.	*Melia azedarach* L.	Bakayin	Dried mature stem bark	UPI-III	-
117.	*Melia azedarach* Linn.	Maha Nimba	Stem bark	-	MRPD
118.	*Mimusops elengi* Linn.	Bakula	Stem bark	-	QSIMP-2 MRPD SSD
119.	*Mimusops kauki* (Linn.) Dub. *Syn. Manikarakauki*	Khirni	Stem bark	UPI-III	-
120.	*Morinda pubescens* Smith	Achchhuka	Stem bark	-	MRPD
121.	*Moringa oleifera* Lam.	Sigru Murunkai-ppattai	Stem bark	API-IV SPI-II	MRPD QSIMP-8 PAD
			Root bark	API-IV	PAD
122.	*Murraya koenigii* Spreng.	Karipatta	Stem bark	-	PAD
123.	*Myrica cerifera* Linn.	Myrica Cerifera	Bark of Roots	HPI-I	-

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124.	*Myrica esculenta* Buch. Ham. Syn. *Myrica nagi* Thunb.	Kaiphal	Stem bark	UPI-IV	QSIMP-8
		Katphala Kaifal	Stem bark	API-III UPI-II	BD
125.	*Neolamarckia cadamba* (Roxb) Bosser	Kadamba	Stem bark	-	PADAB
126.	*Oroxylum indicum* (Linn.) Vent.	Syonakah	Stem bark	-	BDMRPDPAD
127.	*Parthenocissus quinquefolia* Planch	Ampelopsis Quinquefolia	Bark and young twig	HPI-IV	-
128.	*Pausinystalia johimbe* K. Schum.	Yohimbinum	Bark	HPI-X	-
129.	*Piscidia erythrina* Linn.	Piscidia	Root Bark	HPI-III	-
130.	*Polyalthia longifolia* (Sonn.) Thwaites	Asopalav	Stem bark	-	BD MRPD
131.	*Pongamia glabra* Vent	Karanja	Stem bark	-	PAD
			Root bark		
132.	*Pongamia pinnata* (Linn.) Pierre	Karanja	Root bark	SPI-I	MRPD
			Root bark	UPI-IV	-
			Stem Bark	UPI-IV	QSIMP-5 PABD
			Root bark	API- II	-
			Stem Bark	API- II	-
133.	*Populu stremuloides* Michx.	Populus Tremuloides	Inner bark	HPI-V	-
134.	*Premna serratifolia* L.		Stem bark	-	BD
135.	*Prunus avium* L.	Elavalukam	Stem bark	API-VI	-
136.	*Prunus padus* Linn.	Prunus Padus	Leaf and bark	HPI-V	-
137.	*Prunus serotina* Ehrh.	Prunus Virginiana	Inner Bark	HPI-III	-
138.	*Prunus virginiana* Linn.	Prunus Virginiana	Inner bark	HPI-VII	-
139.	*Ptele atrifoliata* Linn.	Ptelea Trifolia	Bark	HPI-IV	-
140.	*Pterocarpus marsupium* Roxb.	Asana	Stem bark	API- III	PABD MRPD MPPD
141.	*Punica granatum* Linn.	Granatum Dadima	Root Bark Stem bark	HPI-III -	MRPD MRPD SSD PAD
142.	*Pyrus americana* Marsch.	Pyrus	Bark	HPI-V	-

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143.	*Quillajas aponaria* Molina and other species of *Quillaja*	Quillaya Saponaria Quillaia	Bark	HPI-VI IP 55 IP 66	-
144.	*Radermachera xylocarpa* K. Schum	-	Root bark	-	PAD
145.	*Rhamnus californica* Eschscholz	Rhamnus Californica	Bark	HPI-VI	-
146.	*Rhamnus frangula* Linn.	Rhamnus Frangula	Bark	HPI-III	-
147.	*Rhamnus purshiana* DC.	Cascara Sagrada	Bark	HPI-II	-
148.	Rhizophora mucronata Lamk.	-	Bark	QSIMP-6	-
149.	*Robinia pseudocacia* Linn.	Robina Pseudocacia	Bark of root and stem	HPI-V	SHD
150.	*Salix nigra* Marshall	Salix Nigra	Bark	HPI-II	-
151.	*Salix purpurea* Linn.	Salix Purpurea	Bark	HPI-III	-
152.	*Salvadora persica* L.	Pilu	Root bark	API-V UPI-V	-
153.	*Saraca asoca* (Rosc.) De Willd.	Asoka Janosia Ashoka	Stem bark Bark Stem bark	API-I HPI-X	MRPD PID-1 QSIMP-2 IHD
154.	*Saraca delinata* (Jack) Miq.	Asoka	Stem bark	-	BD
155.	*Saraca indica* L.	Ashoka, Ashok Janosia Ashoka	Stem bark	IP 55 IP 66 HPI-I	PAD
156.	*Sassafras officinale* Nees. & Eberum.	Sassafras	Bark	HPI-VII	-
157.	*Sesbania grandiflora* (Linn.) Poiret	Agastya	Bark	-	MRPD
158.	*Shorea robusta* Garertn.	Sal	Bark	-	QSIMP-6 BD
159.	*Spondia spinnata* (L.f.) Kurz.	Amrata	Stem bark	API-II	BD PABD
160.	*Stereospermum chelonoides* (L.f.) DC.	Patalai	Stem bark	API-IV	-
161.	*Stereospermum colais* (Buch.-Ham. Ex Dillw) Mabberley	Patala	Stem bark	-	PABD

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162.	*Stereospermum tetragonum* DC	Patala	Stem bark	-	PAD
163.	*Sterculia urens* Roxb.	-	Stem bark	-	BD
164.	*Streblus asper* Lour.	Sakhotaka	Stem bark	API-III	QSIMP-2 BD
165.	*Strychnos malaccensis* Benth.	Hoang Nan	Bark	HPI-VII	-
166.	*Symplocos racemosa* Roxb.	Lodhra Lodh Pathani	Stem bark	API-I UPI-I	QSIMP-4 PABD MRPD
167.	*Symplocos spicata* Roxb	Lodharan	Stem bark	-	PAD
168.	*Syzygium cumini* (Linn.) Skeels	Jambu Jamun Naval pattai	Stem Bark	UPI-IV API-II SPI-II	MRPD PABD SSD
169.	*Syzygium jambolanum* DC	Jamun	Stem bark	-	PAD
170.	*Tamarindus indica* L.	Tintidika, Tamarind	Stem bark	-	PAD
171.	*Tecomella undulata* (Sm.) Seem.	Rohitaka	Stem bark	API-VI	MRPD PID-2 QSIMP-3 BD
172.	*Terminalia alata* Heyne ex Roth syn. *T.punctate* Roxb.; *Myrobalanusbelerica* B. Gaertn.	Arjuna Bhed	-	-	QSIMP-1 MRPD
173.	*Terminalia arjuna* W. & A.	Arjuna Marutampattai Terminalia Arjuna	Stem bark	API- II SPI-I UPI-IV HPI-I HPI-X	MRPD PABD PID-1
174.	*Terminalia bellerica* (Gaertn.) Roxb.	Baheda	Stem bark	-	BD
175.	*Terminalia bialata* (Roxb.) Steud.	Leanben	Stem bark	-	BD
176.	*Terminalia catappa* L.	Badami	Stem bark	-	BD
177.	*Terminalia chebula* Retz.	Harra	Stem bark	-	BDSSD
178.	*Terminalia manii* King.	Kala Chuglan	Stem bark	-	BD
179.	*Thespesia populnea* (L.) Soland. ex Correa.	Puvaracam-pattai Kapitana	Stem bark	SPI-I API- V	MRPD

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180.	*Thespesia populnea* Soland. ex Correa	Parisa	Stem bark	-	-
181.	*Thevetia peruviana* (Pers.) K. Schum. Syn. *T. neriifolia* Juss. Ex Steud.	Kaner	Stem bark	-	QSIMP-1
182.	*Tinospora cordifolia* Miers.	Tinospora	Dried stem with bark intact	IPL	-
183.	*Ulmus fulva* Mischaux.	Ulmus Fulva	Inner Bark	HPI-VI	-
184.	*Viburnum opulus* Linn.	Viburnum Opulus	Bark	HPI-II	-
185.	*Viburnum prunifolium* Linn.	Viburnum Prunifolium	Bark	HPI-II	-
186.	*Wikstroemia veridiflora* Meillu	Daphne Indica	Stem Bark of branches	HPI-VII	-
187.	*Wrightia arborea* (Dennst.) Mabb.	Kutaja Krishna	Stem bark	-	QSIMP-4 MRPD
188.	*Wrightia tinctoria* R.Br.	Kutaja Sweta	Stem bark	-	BD PABD
189.	*Xanthoxylum fraxineum* Willd.	Xanthozylum Fraxineum	Bark	HPI-III	-
190.	*Zanthoxyium armatum* DC.	Tejovati	Stem bark	-	MRPD
		Tejovati	Stem bark	API- II	QSIMP-4
191.	*Ziziphus jujuba* Lam.	Kola	Stem bark	API- III	
192.	*Zizyphus mauritiana* Lamk.	Badari	Stem bark	-	MRPD

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Ethnopharmacological Studies Among the Tribal Communities of Bonai Forest Division in Sundargarh District of Odisha

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Abstract

The present paper deals with the ethnopharmacological observations on the flora of Bonai forest division of Sundargarh district in the state of Odisha. The predominant tribes inhabiting in this region are Bhuiyan, Paudi Bhuiyan, Munda, Routia and Oraon. They have good knowledge on medicinal potential of the available plant resources in their vicinity and use different parts of plants like roots, stem bark, leaves, flowers, fruits and seeds etc. for treating different diseases and conditions. These plant remedies are employed in the form of powder, paste, decoction and infusion etc.

Folk medicinal uses of 40 plants species from the study area are presented. The data recorded from the inhabitants and medicine men on medicinal uses of plants for treating ailments include: joints pain, fever, cold, cough, indigestion, diarrhoea, skin diseases, dental problems, cuts, wounds etc. It has been suggested that some of these potential species may be evaluated for their medical efficacy and safety on scientific lines to validate the claims. Data provided may also serve as lead material for the discovery and development of new drugs of plant origin.

Keywords: Ethnopharmacology, Tribal communities, Bonai forest division, Odisha.

Introduction

Tribal people are the repository of accumulated experience and knowledge of indigenous flora and fauna. Living close to nature, they are familiar with a large number of wild plants and animals. By empirical reasoning, trial and error method, these tribal communities have screened and developed a highly complex and very specific knowledge of the locally available plant resources. Therefore, the study on ethno-pharmacology among these primitive people may lead to find new information on unexploited natural resources and new uses on existing plant wealth as means of food, medicine, fibre, fodder etc.

The primitive communities inhabited in the forests and far flung remote areas in different regions have a traditionally self managed system of folk medicine. They have simple but effective remedies to treat common ailments like fever, cough, stomach disorders, injury, aches and pain, gastro-urinary disorders, impotency as well as methods to maintain or improve vigour and vitality. In recent times due to habitat displacement, deforestation, industrialization and developmental activities, there has been a lot of change in tribal attitude. This has led to the

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decline and even disappearance of rich knowledge on folk phyto-medicine. Thus there is an urgent need to record such information on folk medicines from different tribal and other pockets of India before these are lost forever.

The state of Odisha has diversified topography, climatic conditions, rich flora and sizeable tribal population including those of as many as 62 different tribes, and therefore has substantial scope for ethnomedicinal studies (Anonymous 1990). The forest in the study area of Sundargarh district is typically tropical dry deciduous type. Different tribal communities like Bhuiyan, Paudi Bhuiyan, Munda, Routia and Oraon inhabit in this area.

Since last three decades, there has been a renewed interest of scientists in recording information on ethno-medicines. People are interested in documentation and preservation of traditional knowledge and its scientific analysis to provide basic material for drug development programmes. Keeping in view this rationale, the forest areas of Bonai forest division in the state of Odisha were explored and ethnomedicinal information on available plant species used by the inhabitants of study area was recorded and presented in this communication.

Materials and Methods

The survey team from Regional Research Institute of Unani Medicine (RRIUM), Bhadrak, Odisha explored the Bonai forest division of Sundargarh district in the state of Odisha during 1993-94. Attempt was made to extract the ethnomedicinal information from medicine men or knowledgeable persons of the villages through personal interviews. During the study, large number of tribal men (Bhuiyan, Munda, and Oraon) and rural people were interviewed to gather the ethnopharmacological information. While collecting such information, care was taken to record only that information whose curative potentialities were confidently claimed by the informants. As a result, information on plants usage and voucher plant specimens were collected and identified following the method of Jain (1965) and Jain and Rao (1977). Herbarium sheets of all the plants specimens collected during field work have deposited in the Herbarium of the Regional Research Institute of Unani Medicine, Bhadrak, Odisha, for future reference and study.

Enumeration

The data on folk medicinal uses of plants recorded from the study area have been presented in table -1. Information on each folk medicinal plant has been provided in alphabetical order by their botanical name, field book number, local name, part used, locality, voucher specimen number, medicinal uses claimed, recipe and source of information i.e. name of tribal community.

Table 1

Botanical Name	Local Name(s)	F.B. No.	Part(s) used	Disease/ Condition	Mode of administration	Locality and Tribe
Achyranthes aspera L.	Apamari	4698	Root	Headache	Root paste is applied on forehead to relieve ache.	Nagaria (Munda)
Aegle marmelos (L.) Corr.	Belo	4544	Fruit	Abdominal disorders	Fruit pulp is given as cooling tonic.	Khandadhar (Bhuiyan)
Andrographis paniculata (Burm. f.) Wall.ex Nees.	Bhuineem	4558	Plant	Diarrhoea	Plant juice with desired quantity of honey (one tea-spoonful twice a day) is given to check diarrhoea.	Khandadhar (Bhuiyan)
			Leaf	Scabies	A handful of leaves pounded with Haldi (*Curcuma longa*) is applied on scabies.	Khandadhar (Bhuiyan)
			Leaf	Fever	Leaf decoction in desired quantity is given to alleviate fever.	Khandadhar (Bhuiyan)
			Leaf	Intestinal worms	Powdered leaves mixed with sugar are placed at anus of children as anthelmintic.	Khandadhar (Bhuiyan)
Ardisia solanacea Roxb.	Gulainchi/ Chauldhua	4688	Root	Post natal care	Root decoction (1/2 glass twice daily) is given for 3-4 days.	Toda (Munda)
Asparagus racemosus Willd.	Sibojata	4600	Root	Abortifacient	Fresh root with 11 black pepper is applied to terminate up to 3 months old pregnancy.	Jamdihi (Munda)
				Spermatorr-hoea	Powdered root is given in spermatorrhoea (Dhaturog)	Badabalijor (Routia)

Botanical Name	Local Name(s)	F.B. No.	Part(s) used	Disease/ Condition	Mode of administration	Locality and Tribe
				Diarrhoea	Powdered root (5g thrice a day) is given to check diarrhoea.	Toda (Bhuiyan)
Bauhinia purpurea L.	Koliari	4621	Stem bark	Diarrhoea	Powdered stem bark (5g twice a day) is given to check diarrhoea.	Soyimba (Oraon)
Careya arborea Roxb.	Kumbo	4545	Stem Bark	Abdominal disorders	Stem bark decoction (one tea-spoonful twice a day) is given to check diarrhoea/ dysentery.	Khandadhar (Bhuiyan)
				Wounds.	Stem bark paste is applied on wounds.	Jamdihi (Munda)
				Fracture	Stem bark paste is applied properly on fracture to knit bones.	Jamdihi (Munda)
				Postnatal care	Stem bark decoction (2 Tea spoonful at bed time) is given for about one week. To subside swelling, pain etc.	Toda (Bhuiyan)
				To maintain health	Stem bark decoction (1/2 tea spoon, twice a day) is given to infant as baby tonic.	Toda (Bhuiyan)
Catunaregam uliginosa (Retz.) Siva.	Thelko	4657	Unripe Fruit	Diarrhoea	Powdered unripe fruit (3g three times a day) is given to check diarrhoea.	Angarpada (Oraon)
Celastrus paniculatus Willd.	Pengu/Kujri	4551	Seed oil	Skin infection	Seed oil is applied locally on infections.	Khandadhar (Bhuiyan)
	Pengu/Kujri			Wounds	Seed oil applied on wounds.	Khandadhar (Bhuiyan)

Botanical Name	Local Name(s)	F.B. No.	Part(s) used	Disease/ Condition	Mode of administration	Locality and Tribe
	Pengu/Kujri			Body ache	Few drops of seed oil is drunk to relieve ache.	Khandadhar (Bhuiyan)
	Kujri			Postnatal complaints	Seed oil is taken after delivery to suppress pain.	Khandadhar (Bhuiyan)
	Kujri			Muscular/ Nerve pain	Seed oil is applied as massage and also taken orally.	Badabalijor (Routia)
Cissampelos pareira L.	Musakani	4683	Root	Stomach-ache	Root pounded with black pepper is given to treat stomach-ache.	Toda (Bhuyian)
Clausena excavata Burm. f.	Agnijal	4679	Root	Indigestion	Powdered root (5 g twice daily) is given to treat indigestion.	Raksi (Munda, Bhuiyan)
Croton xoxburghii Balak.	Putuli	4643	Root	Poison	Powdered root is used as an emetic to flush out poison.	Toda (Bhuiyan)
Curculigo orchioides Gaertn.	Masani Konda	4602	Root	Scorpion bite	Root as an antidote to scorpion bite.	Padampur (Munda)
Euphorbia fusiformis Don.	Banmuli	4651	Root	Oligogalactia	Powdered root (10 g twice a day) is given to treat deficient secretion of Milk.	Madhupur (Munda, Bhuiyan, Routia)
Flacourtia ramontchi L.	Bhuikant	4562	Stem bark	Postnatal care	Stem bark decoction (warm) (1/2 glass a day for 3-4 days) is given to reshape abdomen after delivery.	Lohanapani (Bhuiyan)

Botanical Name	Local Name(s)	F.B. No.	Part(s) used	Disease/ Condition	Mode of administration	Locality and Tribe
Flemingia chappar Buch.-Ham. ex Benth.	Rani/Galphuli	4594	Twig	Dental care	Twigs are used as tooth stick.	Jamdihi (Munda)
Hemidesmus indicus (L.) R.Br.	Tilamado	4615	Stem	Oligogalactia	Stems are tied as amulet to treat Oligogalactia.	Badjal (Munda)
			Root	Fever	Pieces of root are tied as an amulet in neck.	Toda (Bhuiyan, Oraon)
			Stem	'Puni' disease	Stem is tied as an amulet on foot of children.	Toda (Bhuiyan, Oraon)
Holarrhena pubescens (Buch. Ham.) Wall.ex G.Don	Kurai	4576	Stem bark	Wounds	Stem bark paste is applied on wounds.	Lohanapani (Bhuiyan)
Hyptis suaveolens (L.) Poit.	Gida	4685	Leaf	Skin erruption	Leaf paste (warm) is applied on skin irruption.	Toda (Bhuyia)
Ixora arborea Roxb. ex Sm.	Pettaldaru	4611	Leaf	Helminthiasis	Leaf applied with jodo (*Ricinus communis*) oil is placed at the anus of children as anthelmintic.	Angarpada (Oraon)
Litsea glutinosa (Lour.) Robins.	Maida	4656	Stem Bark	Diarrhoea	Powdered stem bark (5 g twice a day) is given in cases of diarrhoea.	Angarpada (Oraon)
Lygodium flexuosum (L.) Sw.	Mahadevjata	4608	Root	Joints pains, Stomach ache	Powdered root is given (5g twice a day) till cure.	Angarpada (Oraon)

Botanical Name	Local Name(s)	F.B. No.	Part(s) used	Disease/ Condition	Mode of administration	Locality and Tribe
Madhuca longifolia (L.) Macbride	Mahul	4607	Twigs	Toothache	Twigs are used as tooth brush in toothache.	Talabahali (Bhuiyan)
Murraya paniculata (L.) Jack.	Dhoda mohulia	4556	Stem bark	Cuts	Crushed stem bark is directly applied on cuts.	Khandadhar (Bhuiyan)
Ougeinia oojeinensis (Roxb.) Hochr.	Bandhan	4669	Wood oil	Skin infection	Oil extracted from wood is applied locally on skin infections.	Shilpunji (Munda)
Pentanema indicum (L.) Ling.	Anusirisa	4626	Root	Tooth ache	Root is tied as an amulet in ear to relieve ache.	Goali (Bhuiyan)
Phoenix acaulis Buch.-Ham. ex Roxb.	Bankhajuri	4603	Rhizome	Indigestion	Powdered rhizome (3g twice a day) is given in abdominal disorders.	Talabahali (Bhuiyan)
Pongamia pinnata (L.) Pierre	Tilamado	4618	Seed oil	Skin infection	Seed oil is applied locally to cure skin infections.	Badabaljor (Routia)
			Stem bark	Diarrhoea	Powdered stem bark (5 g Thrice a day) is given to check diarrhoea.	Jamudihi (Munda)
Pterocarpus marsupium Roxb.	Bija	4548	Stem exudate	Tongue ulcer, Gingivitis	Stem exudate oozing out on bark cut is applied in mouth.	Jamudihi (Munda)
*Schleichera oleosa (*Lour.) Oken	Kusum	4561	Seed oil	Skin infection	Seed oil is applied.	Lohanapani (Bhuiyan)

Botanical Name	Local Name(s)	F.B. No.	Part(s) used	Disease/ Condition	Mode of administration	Locality and Tribe
Semecarpus anacardium L.f.	Bhelia	4597	Seed oil	Wounds	Seed oil (black) is applied on wounds.	Jamdihi (Munda)
Sida acuta Burm. f.	Bariar	4658	Leaf	Boils	Leaf paste is applied locally.	Madhupur (Oraon)
Smilax zeylanica L.	Atkir	4593	Plant	Wounds	Young plant is crushed and applied on wounds.	Shilpunji (Munda)
			Root	Spermatorrhoea (Dhaturogo)	Powdered root is taken with water daily in the morning for about 20 days.	Shilpunji (Munda)
			Root	Cough/Cold	Powdered root with black pepper is given.	Shilpunji (Munda)
Soymida febrifuga (Roxb.) A.Juss.	Rohan	4650	Stem Bark (Cold)	Postnatal care	Stem bark decoction (1/2 glass twice a day) is given for 3-4 days in postnatal care.	Madhupur (Oraon)
Terminalia chebula Retz.	Harada	4710	Fruit	Indigestion	Powdered fruit (3 g Twice a day) is given to treat indigestion.	Toda (Bhuiyan)
Thespesia lampas (Cav.) Dalz & Gibs.	Bankappa	4670	Seed	Cough	Powdered seeds wrapped in Sal leaves and smoked as bidi to relieve cough.	Shilpunji (Munda)
			Root	Joints pain	Powdered root prepared in oil is applied locally on effected joints.	Angarpada (Oraon)

Botanical Name	Local Name(s)	F.B. No.	Part(s) used	Disease/ Condition	Mode of administration	Locality and Tribe
Tridax procumbens L.	Banbaitals	4684	Leaf	Cuts	Crushed leaves are directly applied on cuts.	Toda (Bhuiyan)
Triumfetta rhomboidea Jaq.	Chikiti	4673	Leaf	Boils	Crushed leaves are applied on cuts/boils.	Shilpunji (Munda)
Vanda tessellata (Roxb) Hk. f. ex G. Don.	Banda	4671	Leaf	Headache	Leaf paste is applied on fore head to treat ache.	Shilpunji (Munda)
				Earache	Leaf juice (warm) is used as ear drop in earache.	Shilpunji (Munda)
Woodfordia fruticosa (L.) Kurz.	Dhatangi	4570	Flower	Abdominal disorders	Dried flowers are kept in water over night and filtered. This infusion is taken in the morning.	Jamdihi (Munda)

1. *Ardisia solanacea* Roxb.

2. *Asparagus racemosus* Willd.

3. *Cissampelos pareira* L.

4. *Litsea glutinosa* (Lour.) Robins.

5. *Ougeinia oojeinensis* (Roxb.) Hochr.

6. *Pentanema indicum* (L.) Ling.

Figure 1: Some important folk medicinal plants of Bonai forest division, Odisha

7. *Semecarpus anacardium* L.f.

8. *Tridax procumbens* L.

9. *Woodfordia fruticosa* (L.) Kurz.

Figure 1: Some important folk medicinal plants of Bonai forest division, Odisha

Results and Discussion

The study has brought to light some interesting folk therapeutic methods employed by the natives of Sundargarh district of Odisha. A total of 60 therapeutic uses of 40 medicinal plants species recorded from the study area used for the treatment of various diseases e.g., Joints Pain, cough, skin infection, abdominal disorder, postnatal care, diarrhoea, spermatorrhoea, headache, dental care etc. are presented.

A detailed review of the ethnobotanical studies reveal that such studies have been conducted in different parts of Odisha (Ali, *et al*., 2010; Aminuddin *et al*., 2013; Bal, 1942; Brahmam & Dutta, 1981; Brahmam & Saxena, 1990; Chaudhury Rai *et al.,* 1985; Das & Mishra, 1987; Das & Kant, 1998; Dash *et al*., 2003; Girach *et al* ., 1998; Jain, 1971 & 1987; Kandari *et al*., 2012; Mohapatra and Sahoo,

2008; Mudgal and Pal, 1980; Mund and Satapathy, 2011; Murty *et al*., 1997; Rout, 2007; Sahu *et al*., 2013a, 2013b; Satapathy and Panda,1992; Prusti 1998; Saxena and Brahmam,1994-96; Saxena & Dutta, 1975; Singh, 2012; Tripathy and Behera, 2008). However, there appears no exhaustive study conducted in the study area particularly the Bonai forest division. While comparing the information recorded from the study area with the available literature (Aminuddin and Girach, 1996; Mukherjee and Namhata, 1990; Prusti & Panda, 2005; Prusti and Behera, 2007; Satapathy & Panda,1992; Satapathy & Brahmam, 1996; Satapathy & Chand, 2003; Singh *et al*., 2010) it was found that most of the folk medicinal plants are duly reported. However, some of the medicinal uses of plants were found to be new or less known as far as parts used, ingredients and mode of application, preparation of recipe is concerned. Present work, therefore, represents contemporary data on the use of folk medicines of the area investigated.

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