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CLINICAL RESEARCHES IN REGIONAL RESEARCH INSTITUTE OF UNANI MEDICINE: A REVIEW

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Review Paper

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ABSTRACT

The impact of clinical trials not only extends to the individual patients by establishing a broader selection of effective therapies, but also to society as a whole by enhancing the value of health care provided. However, clinical trials also have the potential to pose unknown risks to their participants, and biased knowledge extracted from flawed clinical trials may lead to the inadvertent harm of patients. Clinical research refers to all research carried out on humans (healthy or sick people). It focuses on improving knowledge of diseases, developing diagnostic methods and new treatments or medical devices to ensure better patient care. It must have the goal of increasing medical knowledge, be carried out by competent persons, take all necessary measures to protect those who lend themselves to research, obtain regulatory approvals and take all the necessary legal and ethical steps, collect the consent of those involved in research. This review paper is helpful by learning the different clinical studies which had been done in RRIUM, Srinagar in a different topics which are common in Srinagar with several drugs and therapies giving a significant results in Unani treatments. The studies where done with the use of appropriate statistical method with the purpose to reflect the significant result of these studies and a help to new researchers on this field the present remaining was done in the library of RRIUM, Srinagar and studied in the title "Clinical Researches in RRIUM, Srinagar"- A Review Contempleted.

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Keywords: Clinical trials, Clinical studies.

INTRODUCTION

Unani System of Medicine is one of the well known traditional medicine and draws on the ancient traditional system of medicine of India. Greece and was developed by Arabs into an elaborate medical science based on the frame work of the teaching of Buqrat (Hippocrates) and Jalinus (Galen). Since that time Unani Medicine has been known as Greco-Arab Medicine. Traditional medicine is widely and increasingly being used in both developing and developed countries. Up to 80% of the population in Africa and 65% in India depend on traditional medicine to help meet their healthcare needs[1]. Research in which people, or data or samples of issue from people, are studied to understand health and diseases. In Regional Research Institute of Unani medicine, there are PG scholars are working with the uses which were done data from OPD and IPD department of their institute to carry out research on health and diseases and to developed new treatments by comparing with modern treatment. The researches which are done one can easily learned how the

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scholars did their researches in this period and what the significant results are during trials.

A study done by PG scholar in the topic of "Clinical study of *Sal 'a Ghudda-i-Madhi* (Benign Prostatic Hyperplasia) with therapeutic Evaluation of *Habb-e-Muqil* In Its management" under the supervision of Dr. Shameem Ahmed Rathore,2019 in University of Kashmir.[2]

Benign prostatic hyperplasia is the enlargement of prostate gland in elderly males which results urinary symptoms in them. The prevalence of BPH is age dependent with the initial development usually after 40 years reaching 90 percent in eighth decade. Since BPH itself is not a fatal disease but its most important outcome is urinary flow obstruction, which affects physical activities and mental health of the person. The symptoms of PH include hesitancy, increased frequency of micturition, dribbling, narrow stream, nocturia, retention of urine, urgency, incontinence etc. Literal translation of BPH is *Sal'a Ghudda-i-Madhi, Azm-i-Ghudda-i-Madhi or Waram-i-Ghudda-i-Madhi*. However we found no word in our classical texts of Unani medicine like this and the most appropriate term to which it correspond is *Waram-i-Unuq al-Math□na*. Whereas the medical therapy is effective in reducing the symptoms and prostate size, but allopathic medicine do have various side- effects. Unani physicians are treating the symptoms of BPH for centuries with safe herbal remedies. However, no reliable and easy to use medicine which could be appropriate for the BPH has yet been developed or scientifically evaluated in our pathy. In this scenario, *Habb-i-Muqil*, an age old Unani formulation has been tested to evaluate its efficacy on scientific parameters.

The Method in this study was conducted as a single blind, randomized and standard controlled trial. We selected 60 patients of age group 40 to 79 years. 30 eligible patients were randomly selected and assigned for test group, to receive test drug, while as 30 patients were assigned for control group who received the control drug. Test drug formulation consisting of, *Mukil, Halela Zard, Halela Siya, Halela Kabli, Amla Khushk, Sakbinaj, Khardal, Roghan-i-Badam* in the pill form after making the same in *Ab-i-Gandan□*, was given to the test group in a dose of 1 gram twice a day orally. Because each tablet was made with a weight of 250 mg, a patient needed to take 4 such pills twice a day, appropriately leaving a twelve hour gap between the two doses. The other group that is the control group was given conventional medicinal therapy that is, Tamsulosin 0.4 mg in the tablet form only once a day orally. Both the drugs were continued for a period of 90 days in each patient. After which all the patients were assessed for subjective and objective parameters. The results were analyzed statistically using students 't' test (paired and unpaired).[2]

A study done by PG scholar "Clinical Study to Compare Safety & Efficacy of Unani Formulation with Metformin in Patients with *Ziabetus Shakri* {Diabetes Mellitus Type-2) -A Randomized Open Clinical Study" Under the joint supervision of Dr. Tauseef Amin Rafiqi and supervisor of Prof. Naquibul islam in the department of Moalijat, RRIUM,2019.[3]

With the changing lifestyle and increasing obesity with the prevalence of DM has increased worldwide. Diabetes mellitus (T2DM) accounts for around 90% of all cases of diabetes. Complications of DM account for increased morbidity, disability, and mortality and represent a threat for the economies of all countries, especially the developing ones. Unani scholars have described several potent anti-hyperglycemic drugs, and all such drugs need to be validated on scientific parameters. Hence a clinical trial was planned to evaluate the Clinical Study to Compare Safety and Efficacy of Unani Formulation with Metformin in Patients with *Ziabetus Shakri* (Diabetes Mellitus Type 2).

The Method of this study was conducted as a randomized open clinical trial, on 50 patients of type 2 diabetes with the test (n =25) and control (n=25) groups for 90 days. Test group received test Unani formulation at the dose of 3 gm. in the form of *Safoof* twice a day one hour before breakfast & one hour before dinner with water whereas control group received 1 tablet metformin (500 mg) twice a day one hour before breakfast and one hour before dinner with water . Subjective and objective parameters were assessed on 0^{th}, 15^{th}, 30^{th},45^{th}, 60^{th}, 75^{th} and 90^{th} day and pre and post treatment response and statistical analysis was done on 0^{th} and 91^{st} day.

The results of the study effects on subjective parameters like polyuria, polydipsia, polyphagia, nocturia, giddiness and tiredness were found significantly reduced in comparison of control group. The objective parameter FBS and PPBS was found highly significant with $p<0.001$ in both groups whereas HbA1C was found moderately significant in test group. Moreover, control drug had also highly significant effect in HbA1C with $p<0.001$. The results were assessed statistically using two tailed student t test, paired proportion test and Fischer exact test.

The conclusion of this study on comparative analyses of test and control drugs was found statistically significant, and these effects were observed in subjective and objective parameters in test group in comparison of control group. It is concluded that the test Unani drug has significant effect on subjective as well as objective parameters and should be recommended for use on large sample size with multicentric.[3]

A study done by PG scholar with the title of "Clinical Study to compare safety and efficacy of *Kalawnjl (Nigella Sativa Lion)* with Metformin in Patients with *Marz-e-Akyas Khusyatur Rahim* (Polycvstic Ovarian Syndrome)-Open Randomized Controlled Clinical Study" Under the guidance of a Mohammed Sheeraz Mushtaq Ahmed in RRIUM, 2019.[4]

Polycystic Ovarian Syndrome is one of the commonest endocrine disorders. It describes a constellation of clinical and biochemical features. The incidence varies between 0.5 - 4 %. It is prevalent in young reproductive age group (20 -30%). Various Unani drugs Viz; *Abhal (Juneperus communis Linn), Darcheeni (Cinnamomum Zeylanicum Blume), Persiyawshan (Adiantum Capillus Linn), Taj (Cinnamomum cassia Blume), Afsanteen (Artemisia Absinthium Linn), Kalownji (Nigella Sativa Linn)* are claimed to be effective in the treatment of PCOS, but their effects are not validated. In order to validate scientifically, the present study entitled "Clinical Study to compare safety and efficacy of *Kalawnji (Nigella Sativa Linn)* with Metformin in Patients with *Marz -c- Akyas Khusyatur Rahim* (Polycystic Ovarian Syndrome"- Open Randomized Controlled Clinical Study, was designed.

The methodology of this study has diagnosed cases of *Marz- e -Akyas Khusyatur* Rahim aged between 14 to 43 years of females fulfilling the inclusion criteria were selected for the study and randomly allocated after obtaining voluntary informed consent into two groups of 33 each viz. group A (test group) and group B (control group. The follow up was carried out after every 15 days of treatment. Clinical assessment was done on O' day (before medication), 15% day, 30th day, 45 day and 60"" day. The data was assessed by BMI, FG Score, PBAC Score, acne global severity scale, W.C and W.H.R.The laboratory investigations, hormonal assessment and USG-pelvis were done on O' day and 61° day.

The results has a significant improvement was observed in symptoms and signs viz. irregular periods, hirsutism, acne, weight, waist circumference waist hip ratio and BMI. USG- pelvis were found normal in various patients with a significant reduction in ovarian volume. The data was found statistically significant in the both groups with p value $< 0.001^*$ in test group and 0.016 in control group.

This study revealed that both the groups were effective in improving the subjective and objective parameters. However in some parameters viz. hirsutism, weight, BMI, Sr. testosterone and USG-pelvis, test drug was more effective than control drug and in some parameters Viz. irregular periods, acne, waist circumference and waist hip ratio, control drug was more effective than test drug. However no change have been seen in the mean value of Sr. L.H before and after the treatment in both groups.[4]

A study done by PG scholar with the title of "A Comparative Clinical study on the Effects of *Hijama bil Shart* (Wet Cupping) and Tablet Acelofenac in Knee Osteoarthritis (*Waja-ur-Rukbah*)" under the guidance of Mohammad Sheeraz Mushtaq Ahmed in the year of 2019 in RRIUM, University of Kashmir.[5]

Waja ul-Mafasil (Osteoarthritis) is an broad term which includes almost all the painful condition of joints. The clinical presentation of *Waja-ul-Mafasil*, similar to osteoarthritis, is more prevelant in elderly patients. This type of illness is difficult to manage partly because of the complex pathophysiology of the disease and partly because of the non availability of drugs that can cure it successfully. Moreover the drugs available either to treat or for symptomatic relief causes serious toxicity and adverse drug reaction (ADR). Elderly patients who frequently suffer from this disease are more susceptible for ADR. Therefore, a device evolving non-drug management of disease has always been welcomed and appreciated. *Hijama* therapy is one such method used in Unani System of Medicine to manage a number of diseases including the *Waja-ul-Rukba*. It has been described to be effective and that too without any chance of producing side effects. In view of the high prevalence of A and the safety concerns related with the allopathic drugs used for its treatment, present study was designed to evaluate the efficacy of *Hijama* therapy in patients of *Waja-ul- Rukbah.*

This study was conducted as a comparative, open, randomized, control clinical trial on 60 patients, 30 patients in test group (wet cupping) and 30 patients in control group (Aceclofenac). Both groups were treated

continuously for 60 days. The pre and post treatment effects were assessed with subjective and objective parameters.

The results of the study has subjective parameters in terms of pain in knee joint, morning stiffness and difficulty in movement were found highly significant in either groups ($p < 0.001$), whereas, In test group, VAS Score, WOMAC Index scores were found highly significant ($p<0.001$ vs control group $p<0.005$) whilst, AROM were found equally effective ($p <0.001$) in both groups. *Hijama bi'l Shart* group shows superiority in responses over control group. The results were analyzed statistically by using Paired't test, Friedman test with post test, One way ANOVA with post test and Kruskal Wallis test with Dunn's multiple compare test.

These comparative trials revealed that intervention of both groups are effective in ameliorating the symptoms of osteoarthritis knee. Test group were found comparatively little more effective than control. Moreover, interventions of both groups were found to be effective without any adverse effect.[5]

A study done by PG scholar in the title of "Therapeutic Evaluation of effects of *Hijamah Bil Shart* in the management of *Zaghtuddam Qawi Ibtaidae* (Primary hypertension) in comparison with Amlodipin under the guidance of Prof. Naquibul Islam in the Department of *Moalijat,* 2020.[6]

Hypertension or high blood pressure is a chronic medical condition in which the systemic arterial blood pressure is persistently elevated during rest above an arbitrary limit of 140/90 mm Hg. It is classified as either primary (essential) or secondary. About 90-95% of cases are termed as "primary hypertension", which refers to high blood pressure for which no medical cause can be found. The remaining 5-10% of cases, termed as secondary hypertension is caused by other conditions due to the involvement of kidneys, arteries, heart, or endocrine system. It is defined in an adult as a sustained elevation of blood pressure greater than or equal to 140 mm Hg systolic pressure or greater than or equal to 90 mm Hg diastolic pressure under rest.

In Unani system of medicine, *Zaghtuddam* (hypertension) and its clinical features have been described under the heading of *Imtila* (congestion). *Imtila* is an increase in blood volume leading to increased vascular pressure. In this condition, blood volume increases which raises intra-arterial pressure making the pulse hypovolemic. Such patient develops the tendency of frequent epistaxis, headache, visual disturbance and rupture of blood vessel causing the death.

The clinical features of target organ damaged due to *Zaghtutdam Qawi Ibtidae* (primary hypertension) correspond with the clinical features of *Imtila.* In Unani system of medicine, the management of the clinical features of *Imtila*, besides by oral medicines (treatments) has also been recommended by Regimental Therapies. Among them, *Hijama-Bi'1-Shart* (wet cupping) is one of the important modes of Unani Regimental Therapies. (Managements) is recommended for reducing the *Imtila*. Hence, a clinical trial was conducted for Therapeutic Evaluation of Effects of *Hijama-Bi'l-Shart* in the Management of *Zaghtuddam Qawi Ibtidae* (Primary Hypertension) in Comparison with Amlodipine' on scientific parameters.

A Randomized open standard controlled trial was conducted on 60 patients which randomly assigned into two groups; test and control groups. Test group of 30 patients was subjected to the test procedure, ie., *Hijama-Bi'l-Shart* (wet cupping) once in 15 days and control group of 30 patients was treated with the standard control drug, Amlodipine, 5 mg once daily and both groups were followed up for 60 days. All the patients were assessed for subjective and objective parameters. The results were analyzed statistically by Chi-square test, Mann- Whitney Test and McNemar-Bowker's test.

Results and conclusion of the study has been observed that there is a Significant difference (p value <0.001) before and after treatment with respect to systolic and diastolic blood pressure in both test and control group. because the percentage of patients with hypertension and high normal blood pressure reduces significantly to either normal or high normal blood pressure which means that both that treatment are equally effective. However, we found a significant difference (p value <0.001) between test and control group with respect to systolic blood pressure because the percentage of patients with high systolic pressure turning normal in control group after treatment is statistically higher then test group. But we did not notice any significant difference between test and control group with respect diastolic blood pressure. This study reveals that the test procedure has statistically significant response in SBP>DBP. No

adverse effects were observed during the trial. Thus, it can be concluded that this. Test Procedure, ie., *Hijma-Bi'l-Shart* (wet cupping), is safe and effective and this clinical study/clinical trial validates the use of this Test Procedure in the management of *Zaghtuddam Qawi Ibtidae.* (Primary Hypertension).[6]

A Study done by PG scholar in 2020 in the topic of "Clinical Study to Compare Safety & Efficacy of Unani Formulation U*shq (Dorema ammoniacum) & Sirka (Vinegar)* with Terbinafine in Patients of *Qubä* (Dernatophytosis, Ringworm)"under the guidance of dr. Shameem Ahmad Rather in the department of Moalijat, RRIUM.[7]

Dermatophytosis or ringworm (*Quba*) is one of the commonest and oldest skin diseases existing before its true mycological nature were discovered. More than a million healthy as well as immuno compromised are the victims of this infection worldwide. *Quba* is a well-known disease entity in Unani medicine and is treated successfully since centuries. Ancient Unani Scholars have discussed a lot regarding various dermatological and cosmetic disorders along with its proper management protocol widely. the present study was designed to evaluate the clinical presentation of the disease and to compare the safety and efficacy of Unani formulation with Terbinafine in its management.

60 diagnosed cases of *Quba* (Dermatophytosis, Ringworm) aged between 15-60 years fulfilling the inclusion and exclusion criteria were selected for the study and randomly allocated after obtaining voluntary informed consent into two groups of 30 each viz. Group A (test group) and Group B (control group). Unani topical formulation, *Ushq (Dorema ammoniacum*) & *Sirka* (Vinegar) was applied locally twice a day in test group and Terbinafine 1% Cream in control group was applied locally twice a day for 60 days. Patients were followed and assessed clinically for severity score of colour, scaling, itching, margins, size of the lesion and Dermatology Life Quality Index score on every visit and KOH examination of skin scraping was done before and after the study.

Results and conclusion of the study was the test and control drugs showed statistically significant reduction in scores ($p<0.0001$) of most of the parameters and KOH scraping score ($P<0.001$) in intra group analysis, while the reduction was not found to be statistically significant in inter group analysis. Unani topical formulation, *Ushq (Dorema ammoniacum)* & *Sirka (Vinegar*) and Terbinafine 1% Cream are safe and effective in treating *Quba* (Dermatophytosis, Ringworm) with no adverse effect reported during the trial.[7]

A study done by PG scholar with the title of "A Comparative Clinical study of the effects of *Hijama bil' shurt* (wet cupping) and *Hijamah bil' Nar* (fire cupping) in *Irq-al-nisa* (Sciatica)" In the department of Moalajat under the guidance of Dr. Shameem Ahmad Rathor in RRIUM,2020.[8]

Irq al-Nisa is one of the commonest neuralgic pain in lower limbs. Prevalence of sciatica estimated from different studies is 1.2 % to 43 %. Sciatica relatively is a common disorder its prevalence among normal population varies between 2 % & 5 %. Incidence of the sciatica rarely occurs before the age of 20. Incidence peaks in the fifth decade decline thereafter. There are many environmental and inherent factors which influence it. Various Unani regimens are used for management of different kinds of diseases and pain management like massage, Wet Cupping therapy, and dry Cupping therapy, *venesection, Takmeed, Leeching, Zimaad, Tila, Nutool* and are claimed to be effective in the treatment of *Irq al Nasa*, but most of these regimens are not Scientifically validated. In order to validate scientifically, two different regimens were selected and present study contemplated as "A comparative clinical study of the effects of *Hijama bi'l Shart* (wet cupping) and *Hijama bi'l Nar* (fire cupping) in *Irq al-Nisa*.

The Study was conducted as an open randomized and Comparative Study. 60 Patients of Sciatica were selected in the age group of 20 to 65 years after taking consent and fulfilling the inclusion criteria and they were randomly allotted into two groups 30 in each group. Group A patients were selected for *Hijama bil Shart* and group B patients for *Hijama Bil Nar*. Treatment protocol was followed for 45 days in both group by recording subjective and objective parameters in each follow up i.e., 15th, 30th, and 45th day, the results were analyzed Statically using Independent t-test, paired t-test, Chi square test/ Fisher t-lest.

Result and conclusion of the study has a significant improvement was seen in Subjective and Objective parameters in both the groups with. P value 0.0001 in each group. Although this study revealed that the both regimens are effective in diminishing the symptoms of Sciatica but effect of *Hijama Bil Shart* was found more than that of *Hijama Bil Nar*.[8]

A study done by PG scholar in the topic of "A Clinical Study of the Effects of Unani Formulation (*Joshanda*) with reference to the Standard Control in the Management of *Ilitha Tajawlf Al-Anf Muzmin* (Chronic Sinusitis) Under the guidance of a Mohammed Sheeraz Mushtaq Ahmed in RRIUM, 2020.[9]

In ancient Unani Literature, when we go through the symptoms and signs of *Nazla Barid Muzmin* they are very similar to the symptoms of chronic sinusitis. As a result, *Nazla Barid Muzmin* was considered as *Iltihab Tajawif Al-Anf Muzmin* (Chronic Sinusitis). Chronic Sinusitis *Ilihab Tajawtf Al-Anf Musmin*) is a chronic inflammation of the paranasal sinuses that affects people of all ages. It is usually followed by coryza and cold or sometime resultant of dental infection, deeply seated in upper jaw. The maxillary sinuses are usually involved in the majority of cases. Other sinuses on one or both sides, however, may be affected. It has remained a challenge despite the use of several newer treatment regimens due to relapse, recurrence and resistance. The holistic method of Unani treatment can thrive in diseases with temperamental association and evidences of Unani medicine's effectiveness in *Iltihab Tajawif Al-Anf Muzmin* (Chronic Sinusitis) have been found throughout history, but it lacks the scientific data for validation. As a result, an Unani formulation was chosen for the clinical trial in *Nazla Barid Muzmin* to assess safety and efficacy on scientific parameters.

Objectives of this study are: 1. To Study various aspects of chronic sinusitis with reference to classical as well as modern literature 2.To Study Safety and efficacy of Unani formulation (*Joshanda*) in the management of chronic sinusitis. 3. To compare the effects of Unani formulation with the known standard control.

The study was conducted as an open labelled, randomized and standard controlled trial. 40 patients were selected between the age group of 20 to 60 years. 20 eligible patients were randomly selected and assigned to test group, to receive test drug, while as 20 patients were selected for control group who received the control drug. Test drug formulation consisting of, *Asl-us-soos, Badiyan, Gul-i-Banafshan, Hansraj, Barg-i-Gaozaban, Sapistan, Maveez Munagga and Misri* in the form of decoction (*Joshânda*) was given to the test group in a dose of 100ml once a day orally. The other group that is the control group a decoction of the "*Nuskha Joshanda Nazla Barid*" *comprising Gul-i-Banafsha, Tukhm-i-Khatmi, Tukhm-i-Khubazi, Barg-i-Gaozaban, Unnab* and *Misri* was given in a dose of 100ml twice a day orally. Both the drugs were continued for a period of 45 days in each patient. After which all the patients were assessed for subjective and objective parameters. The results were analyzed statistically using Chi Square test, Student's independent t-test and Paired t-test.

Results has a significant improvement was observed in subjective parameters viz. nasal obstruction, nasal discharge, Sinus Pressure, Chronic cough and Halitosis. While in objective parameters viz, SNOT Score and X-ray PNS-Opacity, a significant improvement was observed.

This study revealed that both the groups were effective in improving the subjective and objective parameters. However, in some parameters viz. Nasal obstruction, sinus pressure, SNOT score and X-ray PNS-Opacity, test drug was more effective than control drug and, in some parameters, viz. nasal discharge and chronic cough, control drug was more effective than test drug. However, no changes were seen in the mean value of AC before and after the treatment in both groups.[9]

A study done by PG scholar in the topic of "À Clinical Study to Evaluate the Therapeutic Safety and Efficacy of Oral Administration of *Joshanda* (Decoction) of *Parsiaoshan (Adiantum capillus-veneris Linn*.) in the management of *Hasah al-Kulya* (Nephronthiasis)" Under the guidance of Prof. Zaffar Hussain Head of department of Moalajat in university of Kashmir in 2021.[10]

Man has been affected with Kidney Stones since centuries dating back to 4000 B.C. Kidney stones are solid concretions or aggregations of crystals formed in kidney due to dietary minerals in urine. Individuals of all countries and ethnic groups are commonly involved in renal stones disease. After urinary tract infection, prostate hyperplasia, nephrolithiasis is the third common disorder of urinary tract. Despite the substantial improvement in the development of new therapies in the management of nephrolithiasis, its incidence is increasing globally and 3-20% of population has tendency to form urinary stone during their lifetime of 70 years. In India analysis shows an increase from 0.9% to 9% over 20 year. In India it affects about 2 million people every year. Kidney stone affects socially, economically owing to the cost of hospitalization and number of days lost from work. Hash al-Kulya (Nephrolithiasis) has been recognized as a systemic disorder linked with chronic kidney

disease, hypertension and Type 2 diabetes mellitus. Men are 2-3 times more affected than women. In menopausal females, frequency for nephrolithiasis is more than premenopausal postulated mainly due to low estrogen levels. Kidney stones are heterogenous but often grouped together. Formation of stone is a multiplex process, involving saturation of urine with crystals, crystal nucleation followed by crystal growth and aggregation. Nephrolithiasis is attributed to various factors like nutritional disorders, genetic disorders and physiological disorders. Nephrolithiasis may sometimes be asymptomatic, may cause severe colic, may even cause significant damage to kidney. Whereas the medical therapy is effective in treating the nephrolithiasis, but allopathic medicine does have various side effects like gastrointestinal tract disturbance, hyperkalemia etc. Revolutionary break through over last several decades in minimally invasive and non-invasive therapy of stone disease have considerably facilitated stone removal, although beneficial, they have complications, recurrence, expensive and all these do little to alter the progression of disease. Unani physicians are treating the Hash al-Kulya for centuries and various single and compound drugs are mentioned in Unani literature for its management. Parsiaoshan (Adiantum capillus-veneris Linn.) is one of the drug mentioned in classical Unani literature having lithotriptic property. In the light of above discussion, this study was carried out to evaluate the efficacy of Adiantum capillus-veneris Linn in the management of nephrolithiasis.

The present study conducted was a single blind, randomized, standard controlled trial. 60 eligible patients were selected and were randomly allocated to test and control group,with 30 patients in each group. Patients in test group were administered decoction of Parsiaoshan (Adiantum capillus-veneris Linn.) 70 grams orally in single dose before breakfast for 60 days. In control group Potassium citrate and citric acid 15ml in syrup form was given twice a day after meals with water for same duration. Subjective parameters were assessed at baseline and at 15, 30th 45th and 61s day of study. Objective parameters were assessed before and after the treatment and the data was analyzed statistically using chi-square test, Fishers exact test, Mc-Nemar-Bowker's test, Wilcoxon rank sum square test and students t-test (paired/unpaired).

Results of this study was test and control drugs were equally effective in resolving the subjective parameters- flank pain, dysuria, hematuria, nausea and vomiting. Among the objective parameters, test group with a p-value of < 0.0001 showed highly significant improvement in USG findings (Renal calculi) in comparison to the control group with p-value = 0.05. Interpretation and conclusion: The study revealed that decoction of Parsiaoshan in a dose of 70 g has a good response in improving the subjective parameters. However, control drug was equally effective in resolving the subjective parameters. Among the objective parameters,the test drug showed highly significant improvement in eliminating the renal calculi from kidneys in comparison to the control group. No side effects or toxicity was reported during or after the trial. Thus, it can be concluded that the test drug is safe and effective in the management of Hasäh al-Kulya.[10]

A study done by pg scholar "Clinical Study of Primary Knee Osteoarthritis (*Waja'ur-Rukbah*) with therapeutic Evaluation and Safety of *Bozidan (Pyrethrum indicum*) in its Management". Under the guidance of Dr Shameem Ahmed Rathore in university of Kashmir, RRIUM,2021[11]

Osteoarthritis is the most frequent type of arthritis, as well as the most common joint disorder and the largest cause of disability in the world. Joint space narrowing and osteophytes are two key characteristics of knee osteoarthritis. The progressive degeneration of articular cartilage is the characteristic feature of osteoarthritis. There is an increased incidence of osteoarthritis in the knee after the age of 40; nearly half of the population aged 65 and above has osteoarthritis in the knee, although it can also affect young people. Knee osteoarthritis is the most common rheumatologic condition in India and it is the most common joint disease, with a prevalence of 22% to 39%. In the Unani system of medicine osteoarthritis is defined as the pain which occurs in joints not associated with a particular part, but the pain which occurs in both the joints of upper and lower limbs and when the same type of pain occurs in the knee it is known as knee osteoarthritis (*Waja' ur-Rukbah*). In the modern system of medicine, Non-steroidal anti-inflammatory drugs, such as selective cox-1 and cox-2 inhibitors, corticosteroids and others, are commonly used to treat the disease. However, significant side effects along with remission and exacerbation as well as concerns regarding renal, hepatic and cardiovascular safety, especially in elderly people with comorbidities, limit their use. *Waja' ur-Rukba* has been effectively treated by Unani physicians for

centuries. However, there is a dearth of data on modern scientific aspects, and no controlled clinical trials on the below mentioned Unani medicine have been done till date. Hence the present study was designed to draw a valid inference about the safety and efficacy of *Bozidän* and possibly validate its usage on scientific grounds in comparison to standard control in the management of primary knee OA.

The present study was designed as a single-blind randomized standard controlled trial. Diagnosed cases of (*Waja' ur-Rukba*), aged between 40 to 70 years fulfilling inclusion criteria were selected for the study and randomly allocated through the computer-generated method into the test and control groups of 30 patients each after obtaining voluntary written informed consent. Participants in the test group were administered *Bozidan* 5 grams in powder form and the control group was given Glucosamine sulfate 1500 mg once daily after meals for 45 days. Both groups received the intervention in opaque self-locking bags. The follow-up was carried out after every 15 days for the assessment of subjective parameters. Objective parameters were assessed pre and post-trial. Pre and post-treatment scores of various subjective and objective parameters in both groups (Test and Control) were recorded and statistically analyzed using Wilcoxon signed-rank test, Chi-square test, Student t-test (paired/unpaired) at the completion of the study.

Results and conclusions has the test group exhibited statistically significant improvement in the subjective parameters: pain (p-value <0.0001), swelling (p-value<0.0001), tenderness (p-value<0.0001) and restriction of movement (p-value<0.0035) in comparison to the control group. Intergroup comparison for the objective parameters revealed a better improvement in WOMAC score after the treatment in the test group (p-value<0.0017) than in comparison to the control group. However, no change was observed in the X-ray knee in both the test and control groups. Interestingly both the drugs were found safe as they didn't produce any renal or hepatic toxicity during and after the study. The present study reveals that intervention of both groups is effective in alleviating the symptoms of knee OA. However, the test drug was found comparatively more effective than the control drug. Further, the test drug was safe with no side effects and was well tolerated by the patients. Thus, it can be concluded that the test drug *(Safùf Bozidan*) is safe and effective and validates the use of test drug formulation in the treatment of primary knee OA (Waja' ur-Rukba).[11]

A study done by PG scholar "Clinical Study to Evaluate the Safety and Efficacy of *Darchini (Cinnamonum zeylanicum Blume*) in the Management of Non-Alcoholic Fatty Liver Disease" under the guidance of Professor Zaffar Hussain, in the department of Moalijat,2021.[12]

Non-alcoholic fatty liver disease is the most common chronic liver disease worldwide. In Non-alcoholic fatty liver disease, there is an accumulation of fat mainly triglycerides in the liver hepatocytes, detected either by liver imaging or liver histology without the evidence of any secondary causes of hepatic fat accumulation. In the Unani system of Medicine, there is no direct concept of Non-alcoholic fatty liver disease but the manifestations mentioned under the liver disorders, like the *Su-i-mizaj kabid b□rid* (abnormal/pathological cold temperament of the liver) and *Waram al-kabid balghami* (phlegmatic hepatitis) closely resemble the clinical features of this disease. The patients with Non-alcoholic fatty liver disease are at increased risk of developing liver-related complications, particularly the patients with Non-alcoholic steatohepatitis, who are at increased risk of liver-related mortality. Non-alcoholic fatty liver disease affects 25% of the adult population globally and is roughly estimated to affect one-third of the general population. The prevalence of NAFLD varies from 9% to 32% in India. Although Nonalcoholic fatty liver disease is a highly prevalent chronic liver disorder and intensive research going on in evaluating the management or treatment protocol for it, there is no Food and Drug Administration approved therapy or pharmacologic treatment for it. The approach is mainly centered on dietary modification based on metabolic profile and to promote physical activity and management of associated co-morbidities (obesity and components of metabolic syndrome). Eminent Unani physicians have been treating liver disorders for centuries and various compound and single drugs are mentioned in classical Unani literature for the management of *Su-i-mizaj kabid b□rid* and *Waram al-kabid balghami. D□rchini (Cinnamomum zeylanicum Blume)* is one of the drugs mentioned in classical Unani literature having beneficial effects in liver disorders. In the light of the current situation, this study was carried out to evaluate the efficacy of *Därchini* in Non-alcoholic fatty liver disease.

The present study was designed as a single-blind randomized standard controlled trial to evaluate the efficacy of *Därchini (Cinnamomum zeylanicum Blume*) in Non-alcoholic fatty liver disease. The

sample size was 60. The patients were randomly assigned into test and control groups through computer-generated method, with 30 patients in each group. Patients in the test group were administered *D□rchini (Cinnamomum zeylanicum Blume)* 1 gram, in two divided doses in the form of 500 mg capsules daily after meals and the patients in the control group were given vitamin E 400 mg capsules twice daily for 60 days. Patients were asked to follow up every 15 days of the study for the assessment of subjective parameters. Department of *Mo'alajät,* RRIUM, Srinagar Obiective parameters were assessed pre and post-trial. The results were analysed statistically using Chi-square, McNemar-Bowker's test and Student t-test (paired/unpaired).

Results has been concluded that test group exhibited statistically significant improvement in subjective parameters, dull ache in right hypochondrium ($p<0.0001$), dyspepsia ($p<0.0001$), anorexia ($p<0.0001$), malaise ($p<0.0001$). In comparison to the control group, the results were equal in the case of a dull ache in the right hypochondrium and malaise with a p-value of 0.718 and 0.183 respectively. Whereas, it was found that in the case of dyspepsia and anorexia in comparison to the control group, the test group showed excellent results with a p-value of <0.0001 in both. The objective parameter, USG, showed statistically a significant reduction in grade of fatty liver with a p-value<0.0001 in both groups. However, there was an insignificant difference between test and control with a p-value of 0.4204, which means both the treatments are equally effective in improving US related findings in Non-alcoholic fatty liver disease. The LFT parameters were not much impacted statistically in both the groups, however, there was a significant difference in ALP before and after the treatment in the case of the test group with a p-value <0.0001 and SGOT and ALP in the case of the control group with a p-value <0.0001. In lipid profile parameters there was no significant difference before and after the treatment in both groups with a p-value of >0.05 in both the groups. This study lays out that *D□rchini (Cinnamomum zevlanicum Blume*) has a good response in improving all the subjective parameters (dull ache in the right hypochondriac region, dyspepsia, anorexia, malaise). It was found that in the case of the objective parameter US, the test drug showed significant results and it was interpreted that the test drug is equally effective in treating Non-alcoholic fatty liver disease in comparison to the control drug. However there was no effect on the other two objective parameters (LFT and Lipid profile). There was no adverse effect observed during the trial. Thus, it is concluded that *Därchini (Cinnamomum zeylanicum)* is safe and effective in the therapeutic management of Non-alcoholic fatty liver disease.[12]

A Study done by PG scholar with the title "Clinical Study of Cervical Spnondylosis (*Waja' al-'Unuq*) with therapeutic Evaluation and Safety of *Habb Waja' al-Mafasil* in its management" under the guidance of Dr. Shameem Ahmad Rathore In the department of *Malalijat* RRIUM,2021.[13]

Cervical Spondylosis is a degenerative disease of intervertebral discs and adjacent vertebral bodies of the cervical region with or without neurological sign. Advancing age, strenuous occupation, faulty posture for long hours, sudden jerks to neck, severe stress and anxiety etc. are considered to be the prime factors for the causation of this disease. It is one of the leading cause of musculoskeletal disability in the general population with incidence rate of 83 per 100,000 population and prevalence of 3.3 cases per 1000 people with enormous socioeconomic burden. Cervical Spondylosis is common and disabling condition and that is why various approaches have been made and despite the advancement in pharmacological, non-pharmacological and surgical interventions, the management remains unsatisfactory due to high cost, adverse effects and unusual eventualities. Unani physicians managed such joint disorders with diverse treatment modalities viz., diet, drugs, regimens such as *Dalk, Riyädat, Hijama, Fasd, Bukhoor* etc, but most of these drugs and treatment modalities are not scientifically validated till date. Hence, a clinical trial was designed namely "Clinical Study of Cervical Spondylosis (Waja 'al-'Unuq) with Therapeutic Evaluation and Safety of *Habb Waja'al-Mafäsil* in its management".

The study was conducted as an Open, randomized and standard controlled trial. We selected 60 patients of age group 20 to 70 years. 30 eligible patients were randomly selected and assigned to test group, to receive test drug, while as 30 patients were assigned to control group who received the control drug. Test drug formulation consisting of, *Sibr, Halela zard, Suranjaan,* and *Saqmooniya* all were ground to fine powder and were doughed with *Aab-e-Makoh* and pills were made. Three pills were given orally twice a day after meals to the test group. The other group that is the control group was given conventional medicinal

therapy that is, Ibuprofen 400mg one tablet thrice daily after meals. Both the drugs were continued for a period of 30 days in each patient. After which all the patients were assessed for subjective and objective parameters. The results were analysed statistically using students 't' test (paired and unpaired).

Results and conclusion of the study was an insignificant difference between test and control treatment with respect to subjective parameters, axial neck pain ($p < 0.353$), swelling ($p < 0.143$), stiffness ($P < 0.056$) which means both the treatments are equally effective in resolving them. However standard treatment has shown a better response in treating the restriction of movements compared to test drug Intergroup comparison for the objective parameters revealed that Cervical Spondylosis was present in both the groups before and after the treatment. Most of the patients had (C5, C6) cervical spondylosis in both the groups. However, the difference between the groups was insignificant with a p-value of 0.280 We observe that NP improved significantly with both test drug and standard treatment (p-value $<0.0001^*$). Unpaired t-test revealed an insignificant difference (P-value 0.68) in NPQ, which implicates that both these treatments are equally effective. Both the treatments show a significant improvement in resolving Spurling sign (P-value $<0.0001^*$) within test and control group but the difference was insignificant between the groups which means both these treatments are equally effective in resolving it.

The study reveals that the both the drugs have good response in improving almost all the parameters. However, in restriction of movements of neck marked effect by the standard drug was observed in comparison to the test drug and almost equal effect was seen on rest of the subjective parameters. Interestingly In case of objective parameters the test drug formulation was considerably effective in reducing the overall NPQ score and resolving spurling sign. No side effect or toxicity was observed during and after the trial. Thus, it can be concluded that the test drug is safe and effective and validates the use of test drug formulation in the treatment of Cervical Spondylosis (*Waja'al-'Unuq)*[13].

A study done by PG scholar in the topic of "Therapeutic Evaluation of the efficacy of a Polyherbal Unani Formulation in the Management of *Niqris Muzmin* (Chronic gout-Hyperuricemia)" Under the guidance of a Mohammed Sheeraz Mushtaq Ahmed in RRIUM, 2022.[14]

Niqris (Gout) is a systemic disease resulting in the inflammation of the joints. The precipitation of rate crystals from the super saturated extracellular fluid leads to the accumulation of rate crystals in and around joint cavities resulting in their inflammation. In Unani system of medicine, the accumulation of abnormal *Akhlat* (Humors) in and around joints results in the inflammation of the joint. The prevalence and incidence of Niqris vary widely with a range from <1% to 6.8% and an incidence of 0.58-2.89 per 1,000 person-years. In modern medicine gout is treated by NSAIDS, XOIs, Uricosuric drugs which have been found having significant side effects with remissions and exacerbations of the disease. Gout has been effectively treated in Unani System of Medicine, however there is less available data based on modern scientific parameters related to the disease and no Controlled Clinical Trial has been done on the drug combination used in this study. Hence the present study was designed to draw a valid inference using scientific parameters about the safety and efficacy of Polyherbal Unani formulation in the form of *Habb* and the ingredients used are: Halela zard (*Terminalia chebula*), Turbud (*Operculina turpethum*), Babonaj (*Matricaria chamomile*), Suranjan shireen (*Colchicum autumnale*), Bozidan (*Pyrethrum indicum*). The binders used Ma ul Lablab (*Dolichos lablab*) and Arq Inab ul Salab (*Solanum nigrum*) and then validating its usage on scientific grounds after applying proper statistical analysis on subjective and objective parameters before and after the treatment.

The present study was designed as a Single Blind Randomized Standard Controlled Trial. 60 diagnosed cases of Niqris between the ages of 25-60 years of either gender fulfilling the inclusion criteria were selected for the study with their proper voluntary consent and were randomly allocated the Control or the Test group 30 in each. In the control group Allopurinol 300 mg per day was given and in test group, test drug in the form of *Habb* (Pill) 9gm per day was given for a period of 28 days. Subjective and objective parameters were recorded in each follow-up. Subjective parameters were recorded on CRF at each follow up done at 14" and 28" day and for objective parameters, the investigations were done on baseline ie Day 0 and on Day 29th. Pre and post treatment values of subjective parameters were analysed by using Related Samples Friedman's Test for intra group comparison and for intergroup we applied Kruskalwallis Test. The objective parameters were analysed by paired t-test for intra group comparison and for inter group we used independent t-test.

Results and conclusion of this study has subjective parameters in both Test and Control Group depicted a statistically significant decline after the treatment in both the groups with p-value < 0.05. The inter group comparison showed no significant difference in reducing the subjective parameters of pain, tenderness, swelling and mobility in the two groups. The mean of Uric Acid in both the groups reduced significantly (p-value <0.05). Hence both the Test drug and Control drug were found effective. The mean of ESR reduced in Control group after the treatment but was not statistically significant (p- value >0.05) while as in case of Test group mean of ESR reduced significantly after the treatment (p-value <0.05). For ESR, Inter group comparison showed a p-value of 0.233 which is statistically insignificant. There was no change in means of safety parameters CBC, LFT and KFT before and after the treatment in both the groups. However SGOT, SGPT, Sr. Alkaline phosphatase, and Creatinine levels were found increased in Control group after the treatment but the changes were insignificant and were totally in range.The study reveals that both the test and control drug are effective in relieving the symptoms of Gout and also in reducing the elevated Uric Acid levels and ESR. The decrease in ESR was found statistically significant in Test group while as in Control group the level of ESR decreased but not significantly. Moreover no adverse effects were noticed in the course of treatment with Test drug and Control drug. The safety parameters including Hb, TLC, DLC, Serum Bilirubin, SGOT, SGPT, Sr. Alkaline Phosphatase, Urea, and Creatinine also were within normal range before and after the treatment in both Test and Control group with mild fluctuations but not out of range.[14]

DISCUSSION AND CONCLUSION

The studies has been done in RRIUM has a significant results so it has been concluded from this review paper that Unani system of medicine provide a wide range of management options in various diseases. The studies discussed in this review article shows that Unani system of medicine is safer, non-invasive, herbal and better treatment options for various illness like *Hasah-al-kulva, Zaghtuddam Qawi Ibtaidae, Waja'ur- rukbah, ziabetus shakri, waja' al unuq, Niqris Muzmin, Irq-al-nisa, Quba*. Unani System of Medicine carries herbal based, holustic approach to treat variety of ailments. We need such studies to be done clinically for validation of various drugs and regimen under Unani system of medicine and co relate it with more scientific regimens.

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