

Research in Unani Medicine: Challenges and Way Forward

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Rec date: December 14, 2015, Acc date: February 12, 2016, Pub date: February 20, 2016

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Abstract

Unani system of medicine is one of the oldest systems of medicine and existence of this system till now itself is an evidence of validity of its principles. However, the essence of any science is progress based on a continuous quest for new knowledge through research, development and newer applications. Unani medicine too should not be exception to this. With the same objective, Government of India established a Central Council for Research in Unani Medicine to develop this system in its own theoretical framework. But researches undertaken to revive the system have not been very rewarding except for the translations of some classical texts; which at least made the literature accessible to academicians and researchers. The past as well as the current trends have failed to reap desired results primarily due to use of inappropriate protocol designs for scientific research. Ironically, ongoing research is in line of modern medicine protocol without taking into consideration, the contrasting epistemology and principles of the systems. Thus, there is a need for a paradigm shift in the research methodology for evaluating Unani medicine. In this article, author advocates the need to adopt epistemologically sensitive methods to evaluate the Unani system of medicine.

Keywords: Unani medicine; Research; Evidence based medicine; Randomized controlled trials

Introduction

The Unani system of medicine as its name suggests has its origin in Greece. The core philosophy of Unani medicine was conceptualized by Hippocrates (460-370 BC). After him Roman, Arab and Persian scholars enriched the system considerably, of whom Galen (131-210 AD) stabilized the foundations on which Arab physicians like Razi (850-925 AD) and Ibne Sina (980-1037 AD) constructed an imposing edifice. It was introduced in India by the Mughals and soon it took firm roots on Indian soil. The system found immediate favour from the masses and soon spread all over the country [1]. Over the centuries, this system has assimilated so well in the Indian civilization that today it has become an integral part of the healthcare delivery system of India.

The Unani system of medicine is a comprehensive medical system, which meticulously deals with the states of health and disease. Its fundamentals are based on deep philosophical insights and scientific principles. This system fully appreciates and understands the creation of man, his nature, his constitution and his relationship to the environment. The strength of the system is its holistic approach, temperament based prescription and principles of six essential factors of life (*Asbab Sitta Zaruriya*); which are pivotal for maintenance of health. Its holistic approach focuses on how the physical, mental, emotional and spiritual elements of the body are interconnected to maintain wellness. Toning up organs and immune system is another unique feature of this system. This system offers an effective treatment for various gastrointestinal, respiratory, genitor-urinary, musculoskeletal, neurological, cardiovascular, lifestyle and metabolic disorders.

Research and Development in Unani medicine is by and large in the hands of the Central Council for Research in Unani Medicine (CCRUM). In 1969, the Government of India established a Central Council for Research in Indian Medicine and Homeopathy (CCRIMH) to develop research in branches of Indian medicine. In 1978, the council was split into four separate research councils, one each for Unani, Ayurveda and Siddha, Yoga and Naturopathy and Homeopathy to further develop these systems in consonance with their basic philosophies [2]. The government has accorded great importance to the multi-faceted development of Unani System of Medicine to make full use of its potential in the Indian healthcare delivery.

Despite of all these efforts, Unani system of medicine has not gained much recognition in the contemporary world. The reason is that the quantity and quality of the safety and efficacy data on Unani medicine is far from sufficient to meet the criteria needed to support its use worldwide. The reasons for the lack of research data are not only due to inappropriate health care policies, but also due to lack of adequate or accepted research methodology for understanding and evaluating Unani medicine.

Issues

Ongoing research in Unani medicine is focusing more on modern medicine than to the system itself. Predominantly, Research in preventive medicine has been confined to cross-sectional studies in line of modern medicine protocol without taking into consideration the contrasting epistemology and principles of the respective systems. Unani scholars defined *Ilm Hifze Sehat* as the science of regulating the healthy body to maintain it in health. They have described three major areas of concern of this branch: (a) Promotion or preservation of health (*Hifze sehat*) (b) Prevention of diseases by using prophylactic drugs or through non-pharmacotherapeutic approach (*Taqaddum bil Hifz*) and (c) protection of the susceptible (*Tadabeer Abdaane Zaeefâ*)

[3]. So the aim of research in Hifzane sehat should be to harness the knowledge of Unani system in preventive health care.

In the same way, research done on Unani drugs in the last six decades has benefitted the modern medicine fraternity and not enriching the Unani scholar. Similarly, we are conducting clinical Studies based exclusively on biomedical diagnosis and to fit Unani treatment into this diagnosis. This leads to trimming and modifying Unani treatment to fit the biomedical research design. Modern medicine has developed from the logic of modern science which follows the deductive approach; while the Unani medicine is known for its holistic approach. Thus, the application of modern concepts in the direction of clinical trials leads to the inevitable sacrifice of some of the important fundamental principles of Unani medicine. Consequently, the results of such ill designed studies are unlikely to add any value to the Unani system of medicine.

Opinion and Suggestions

The system needs a fresh wave of innovations to play its requisite role in the newly emerging era of medical pluralism. The rational approach to apprehend and extrapolate the basic concepts of the system must be regained to build a progressive future. We need to challenge assumptions, try to reinterpret meanings in modern scientific terms and most importantly, dare to experiment to generate fresh evidence. Since the last few years, it has been felt that the linear hierarchy of evidence is not fit for Unani medicine. In conducting research and evaluating Unani medicine, knowledge and experience obtained through the long history of established practices should be respected and therefore the separate protocols based on principles of Unani medicine should be prepared. Unani medicine requires extensive research in the following areas:

- Revision of Unani text with critical outlook so that they can give better insight of the principles of system.
- Revalidation of Unani fundamentals so that they can be inexplicably stated and understood.
- To find out better treatment modalities for existing diseases and for newer diseases.
- To standardize the treatment procedures scientifically.
- To establish dose, duration, indication and side-effect profile of drugs.

Revision of Unani text with critical outlook

Unlike sciences of the present day, the traditional systems of medicine are based on the literature written centuries ago. Literary studies should not be concerned with mere collection and reiteration of archeological facts about the history of the traditional system but should rather be concerned about taking the glory forward and adding to the knowledge unveiled by previous literary findings. Texts should be updated with new findings in research and also should be complemented with a critical outlook. In post-graduate courses, research schemes should place due emphasis to the study of the manuscripts and rare books of Unani medicine scattered all around the globe, many as prized possessions of overseas libraries and colleges. Maintaining threads of continuity and connectivity between the past and present is essential to show us the right direction into the future.

An appreciable work of CCRUM in literary research is publishing a compendium of 4000 terms of Unani System of Medicine titled "Standard Unani Medical Terminology" [4]. Follow suit, a

comprehensive classification and nomenclature for diseases in the Unani perspective should be developed. This is essential to preserve the individualized approach to treatment. Without a Unani diagnosis it is difficult for a physician to visualize a complete Unani treatment. Today, we are in such a situation that we need to be well versed with both International classification of diseases and Unani classification of diseases when reporting clinical outcomes of Unani medicines. Without modern scientific terminology of diseases, it may become difficult to communicate effectively. On the other hand, if we ignore the Unani classification of diseases, the individualized approach of the system is compromised. Thus, we need to develop a Unani classification of diseases, which would be internally consistent and would also allow correlation with modern nomenclature up to a considerable extent.

Similarly from public health perspective, we can elaborate water purification methods, concept of epidemics and prophylactic measures in accordance with classic Unani literature. These issues need to be taken up by clinicians, academicians and researchers and incorporated into research programmes of Unani medicine.

Revalidation of Unani fundamentals

Fundamental research is required for developing the theories and making generalizations of existing theories. It is beyond doubt that without understanding of its general principles, the goals of Unani system cannot be met. It has to be realised that, it is not the herbs but the framework of principles on which the Unani system of medicine is laid which lends it a unique position among contemporary systems of medicine. And these principles need to be understood rationally and universalised for sustenance of the system. There is an indispensable and undying need of empirical definitions of Unani basic parameters like "mizaj", "tabiyat" etc. For example, "tabiyat"- a wide term is interpreted as the immune system, "mizaj" as temperament, "Hararat ghariziya" as Basal metabolic rate, "Rutubat ghariziya" as protoplasm. The list of such terms is not short of stock. In absence of scientific definitions of these abstract ideas, they lend themselves to a large number of speculations, which are a subject of gross confusion. This is a major reason that the Unani concepts have not perceived in its entirety, which in turn hampers their extrapolation. Such terms and definitions are therefore in a desperate need of standardization. Untiring efforts are needed to develop operational definitions of these terms. The void of such definitions is felt in every aspect of Unani treatment, beginning from establishing a diagnosis up to assessment of treatment effects. And for these meta-physical terms and ideas to serve as diagnostic tools, they need to be standardised in form of various inventories and questionnaires, which can ensure their universal usage. All these facts underline the pivotal and crucial role which can be played by dedicated, rigorous and persevering efforts in fundamental research to bring about the much needed renaissance in the system.

Efficacy aspects of Unani drugs/therapy

Two questions are raised about Unani drugs; whether these drugs works and if yes, then how? When we think about generating evidence in context of these questions, we are talking about something which is already in use on human subjects unlike allopathic medicine in which the question about the evidence is regarding something that has not been introduced into practice. Therefore, the methods to generate evidence in modern medicine in which a drug has to undergo rigorous preclinical and clinical testing differ from those applicable to the Unani system. In the case of Unani system, the drug/therapy in question has

already been used on a huge though demographically dissimilar population which has attested to the drug's efficacy.

The gold standards for clinical evidence in biomedicine are randomized controlled trials and meta-analysis. This model of evidence is ill fitted to the Unani system because of its individualistic approach of treatment, which comes as a package of diet, behavioral and lifestyle changes along with drugs. The efficacy of any of these cannot be tested singularly in isolation with other items of the "package" to judge the efficacy in a given disease. A daunting task is to work out a technique for generating evidence of the efficacy of such "packaged interventions". In this regard, Medical research council of U.K. has published a document named "Developing and evaluating complex interventions" which provides valuable guidance for research on complex interventions [5].

"Whole System Research" (WSR) is also an emerging approach to evaluation of complementary and alternative medicine interventions that are too complex to be studied by conventional research designs like the RCT design. WSR aims to identify multiple variables involved in a clinical encounter as well as treatment outcomes. It looks into relationship between these variables. It also takes into consideration, the multiple targets of a clinical intervention and assesses the clinical outcomes at multiple levels [6].

Verhoef and Van der Greef have recommended some methods for evaluation of efficacy of traditional medicine. According to them though Randomized Controlled Trials (RCT) have the highest status in biomedical research; observational studies, factorial designs, and preference trials, seem to be better alternatives for improving and testing traditional medicine treatments [7,8]. Observational studies are more suitable for the evaluation of traditional medicine. They are cheaper, have higher external validity, and are better equipped to accommodate the medical logics and therapeutic goals of traditional medicine. Some other alternatives to the RCT design are the retrospective treatment-outcome survey (RTO), the comparison of prognosis and outcome study (CPO) – an 'outcome method' in which biomedical physicians monitor traditional treatments – and the dose escalating prospective study (PDE) which looks at the way experimental subjects respond to traditional single and compound drugs [9].

At this juncture, rigorous case-studies can also constitute as a starting point to collect the evidence of efficacy of Unani treatments. This will serve as a good starting point to find out whether the drug/therapy in question works or not. The CARE guidelines [10] can be adopted for reporting of case studies. We have discussed above the methods to generate evidence or to scientifically validate the efficacy of Unani drug/therapy. To answer the second question, scientists of AYUSH pointed out that 'Reverse pharmacology' approach of starting with clinical studies and then going retrospectively towards laboratory studies that aim to unravel the biological mechanisms behind the drug action is more suitable for generating evidence in Unani Medicine.

Safety Profile of Unani Drugs

In Unani System 90% of the drugs used are from herbal origins while about 5% each from mineral and animal sources. There is much hue and cry about the need for toxicology studies on herbo-mineral preparations. The Unani system categorizes all drugs into four levels in increasing order of their potency. The drugs with toxic potentials are then subjected to various processes of detoxification so that their non-toxic potency is harnessed. The consideration of the category of

potency in which the drug lies is a pre-requisite while its prescription in single drug form or for its inclusion in any compound formulation.

Validation of detoxified nature of these processed drugs can be done by conducting laboratory studies demonstrating what exactly happens when these toxic substances are pharmacologically processed through the methods prescribed in Unani texts and then testing them on animals for safety as well as for knowing their bioavailability, tissue distribution, histopathology, behavior and epigenetics. Another answer to this could be 'pharmaco-epidemiology'. A large number of patients in India are already treated with herbo-mineral preparations prescribed by Unani physicians across the country. Safety data can be salvaged from this pool of patients. If herbo-mineral preparations are found to be safe, it can advance as major evidence in support of Unani medicine.

Standardization of Unani Drugs

The drugs used in Unani and other systems of Indian medicine were collected, stored, processed and formulated by the physicians themselves. Quality control and other related issues were not in vogue. However, with the increasing use of herbal products worldwide and emergence of pharmaceutical houses on a large scale has led to increasing concern about the quality and purity issues. So, Standardization of Unani drugs is another area which needs diligent effort. Nanotechnology can be availed for pharmacognosy and genuine authentication of pharmacological activities attributed to a particular drug. This will help in preservation of hundreds of species with medicinal effects which are getting extinct day by day without any notice. The dosage of drugs along with their dosage forms and duration of their usage during acute and chronic conditions need to be quantified and laid down through strict scientific procedures. The shelf life of both crude as well as compound formulations needs to be worked out on basis of various scientifically valid tests of potency. The manufacturing and expiry dates should be clearly mentioned on drug packs. Setting up of drug manufacturing facilities of international standards in compliance with the GMP should be encouraged via various government policies to attract big investors in the trade of drugs of herbal and mineral origin which will directly help in raising the standards of their quality.

Conclusion

In evidence based era, we hope that remodeling the documentation process of generating evidence by taking into consideration the epistemology and principles of the system will surely help Unani medicine to regain its rightful place among the healthcare systems of the present day world with a dynamic, progressive and promising future. Inquisitive methods of reverse pharmacology, pharmaco-epidemiology, retrospective treatment-outcome survey and whole system research can transform the system to evidence based medicine.

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