ORIGINAL ARTICLE

Criteria for Evidence-based Practice in Iranian Traditional Medicine

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Abstract- The major difference between Iranian traditional medicine and allopathic medicine is in the application of evidence and documents. In this study, criteria for evidence-based practice in Iranian traditional medicine and its rules of practice were studied. The experts' views were investigated through in-depth, semi-structured interviews and the results were categorized into four main categories including Designing clinical questions/clinical question-based search, critical appraisal, resource search criteria and clinical prescription appraisal. Although the application of evidence in Iranian traditional medicine follows Evidence Based Medicine (EBM) principles but it benefits from its own rules, regulations, and criteria that are compatible with EBM.

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Introduction

In evidence-based medicine (EBM), decision making is based on the process of the medical information search, critical appraisal, and its accordance with diseases, judgment and usage of the best available evidence (1). However, some experts believe that self-assessment is the fifth required skill that affects decision-making (2).

Designing an answerable clinical question is considered as the first step of EBM. If a clinical question is designed precisely, the main problem of patients will be diagnosed properly, and its related evidence will be defined accordingly. In addition, it should be noted that an answerable clinical question includes four main parts which are called "PICO", in which, "*P*" represents "patient", "I" stands for diagnosis or therapeutic intervention, "C" stands for comparison and "O for final outcome (3).

The second stage of EBM is literature review to find evidence. Three main sources for review are periodicals (journals, magazines, and articles), databases and electronic papers, and expert opinion. The third stage of EBM includes an appraisal of evidence according to the proposed clinical question. Today, the aim of critical appraisal of the evidence is to identify weaknesses and strengths of research methods. To appraise utility of the obtained evidence, the following questions should be asked. Is there any significant difference between an imaginary patient and those in a control group? Is there any possibility to treat the patient? What are the advantages and disadvantages of a certain treatment? What is expected from a certain treatment (4,5)?

Iranian traditional medicine has been revived in Iranian settings after a long lapse. Nowadays, it is dealt with educational settings and famous Iranian universities. Moreover; since long ago, we inherited the knowledge of great leading Iranian scholars. Therefore, this study was an attempt to explore perspectives of traditional medicine experts regarding rules and regulations of the utility of evidence according to the specific criteria of Iranian traditional medicine.

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Materials and Methods

This qualitative study explores perspectives of Iranian traditional medicine experts. Ethical considerations and data confidentiality of this study were secured through approval of officials, explaining the nature and objectives of the research for the volunteers to participate, and participants signed informed consents.

Data was gathered through in-depth, semi-structured, individual, face-to-face interviews, and purposive sampling continued till data saturation. Interview sessions last for 40 to 60 minutes. The consent form was secured from interviewees at the beginning of each interview session. To secure anonymity, each participant was given a code (1 to 13). All the interviews were recorded by a voice recorder and a mobile phone simultaneously. The recorded data was transcribed and read and re-read for further analysis. Then, meaningful units and conceptual codes were identified, and all the scripts were searched line by line for indicators. Finally, all the obtained data were formulated according to each participant code number. The validity of the recorded data was checked by two experts (peer-check), and participants of the study (member check).

Results

In this study, 13 male participants including 6 physicians, 4 pharmacists, 2 basic sciences specialists and one paramedical graduate with the average age of 46.6 years (minimum 36-67 years) were interviewed. Nine participants were faculty members of Iranian medical sciences universities. The average familiarity of participants with traditional medicine was 19.1 years (four-50 years); however, their average work experience in this field was 13.5 years (3-50 years). Regarding traditional medicine expertise, three participants learned it in private institutions, five learned it academically, and five participated in Iranian traditional medicine training courses. All participants were actively engaged in Iranian traditional medicine research and education. A total of 11 participants were active authors and 7 of them were active in clinical practice. Findings of the study including the rules and regulations of Iranian traditional medicine are presented in Table 1.

Clinical question design and clinical question-based search

Traditional medicine masters believe that to search evidence in Iranian traditional medicine, clinical questions and keywords should be used. They agree that to design a clinical question, PICO criteria should be applied. In this regard, participant number 12 mentioned: "diagnostic foundations of disease in traditional and allopathic medicine are approximately the same, and the principles of diagnosis in each of them rely on patient examination, and patient signs and clinical symptoms while differences are related to treatment methods for which PICO is authentic." Participant No.9 said: "Certainly, when we ask a question, for example in allergic rhinitis, patients show some symptoms of the disease which are not treated by routine methods. Therefore, to find alternatives we should concentrate on researchable issues. And, our search should include keywords converted to their equivalent in Iranian traditional medicine. Finally, it could be concluded that the disease is cold or hot which are Iranian traditional medicine major keywords. It is worth mentioning that we can keep these keywords and ask Iranian traditional medicine scholars to present a new protocol that is applicable in the modern world."

Critical appraisal criteria

Participant No.2 believed that the principles of Fiqh (jurisprudence) should be explored. He mentioned, "Fiqh confirms that to produce positive results, the Book (Holy Quran), tradition, consensus, and wisdom must support prescriptions approved by Iranian traditional medicine scholars." Participant No.9 believed: "There are some inconsistencies about complicated and problematic cases for which Ijtihad is absolutely necessary (whose approach to solving the existing inconsistencies is to apply rationality, to use available traditional medicine resources and asking human beings with highest capacities). That is the same as the method used in seminary schools for many years in jurisprudence, logic and other fields of medicine." participant No.10 believed "Those who are more knowledgeable can find the most effective answers presented by an expert."

Resource search criteria

Resource evaluation criteria include a scientific credit of an author, authorship, time and venue of writing a book or compilation of an encyclopedia. Participant No.12 said, "The very author and his level of knowledge and reputation highly affect compilation of subject matters." Participant No.13 said "If an individual had expertise in a specific field of knowledge such as orthopedics, ophthalmology, *etc*., and if he had written a

book on that specific topic, his prescription would be accepted." Participant No.2 explained the leading role of authors: "The masterpieces of those great scholars whose registered practices are of paramount importance are such as, narration of Al-Marza by Rhazes or the book entitled The Great Mysteries". Participant No.6 believed that the accurate prescription could be found according to the books of clinicians (e.g. Rhazes, Bahaodoleh, *etc.*). Here, it is valuable to refer to some contemporary scholars like Dr. Ahmadiyeh, Dr. Khosravi, Dr. Mostafavi Kashani who as medical graduates are fully aware of the principles of Iranian traditional medicine and has amalgamated modern and traditional expertise."

Regarding the significance of the period of writing, participant No.10 believed "Since a generation is changed, recent books are much more important than the old ones."Participant No.12 confirmed this saying and mentioned that "Transposition (priority and recency) of these books are very important and those written currently are considered complete, because author has added his personal experiences and views to the subject matter previously mentioned in the old books." Considering the book authorship, university lecturers believed that living place condition and common diseases influenced the books written by ancient scholars. In this regard, participant No.12 added "The Iranian books differ from Indian, Syrian or Egyptian ones because inhabitants of those regions differ from Iran inhabitants in terms of temperament, living conditions, *etc*. Therefore, to apply changes in prescriptions and grades of drugs deems necessary."

Considering, writing an encyclopedia, participant No.7 believed that encyclopedias are significantly more important than books written on a specific subject matter. For example, Zakhireh Kharazmshahi is a much more invaluable reference than a concise book which almost lacks all sciences."

Clinical prescription appraisal criteria

The next theme is an evaluation of prescriptions, diagnosis, and treatment. In other words, to evaluate books and resources, their contents should be evaluated in terms of availability of prescribed components, non-toxicity of prescribed medicine, the least number of components in a mixed drug, subject matter frequency in various books and using test keywords. In this respect, participant No.5 said, "Let's see if there is anyone of these components or if the toxicity of these components has been proved or not? I prefer to use the plain ones." In regard to subject matter frequency, participant No.7 believed that the therapeutic method of drug use should frequently be mentioned in various books, for example, properties of using Golghand. In addition, for application of test keywords, participant No.13 believed "the experienced prescription is the one who has basic efficacies and is exclusively based on the empirical practice of our physicians and is called " Mojarab", " Mojarab mojarab", " Bi Adil", *etc*."

Table 1. Rules and regulations of Iranian traditional medicine evidence

Rules and Regulations	Clinical questions design and clinical question-based search
	Critical appraisal criteria
	Resource search criteria
	Clinical prescriptions appraisal criteria

Discussion

The study participants believed that rules and regulations of evidence utility in Iranian traditional and allopathic medicine are nearly the same, which include four stages of designing a clinical question, searching resources, critical appraisal of the evidence and their application according to the patient condition. Regarding the design of a clinical question, participants believed that its design is similar to that of allopathic medicine and resembles the PICO model. That is to say, patient and type of the proposed intervention should be specified. In other words, the patient condition should be compared with a criterion. However, such a comparison may be carried out with other medicines or traditional therapeutic, diagnostic methods.

Since no specific database is available for Iranian traditional medicine, to search the best resources they should be searched manually through specified reliable keywords. In this case, researchers need an acceptable knowledge of traditional medicine common texts and glossaries and search strategies expertise. In addition, different research findings have emphasized the necessity to develop a specialized database for specific books and resources of Iranian traditional medicine to avoid ineffective web search, to avoid waste of time, to access valid and reliable evidence easily, and to ensure quality of the available evidence.

Last but not the least, the results of the search should be adapted to patient condition and his tendencies, existing facilities, and physician experience. Considering the above-mentioned issues, the best and most effective, reasonable and cheap diagnosis or therapeutic method should be selected for each specific disease.

For a critical appraisal of the evidence, Iranian traditional medicine applies principles of Fiqh (jurisprudence). Previously, medicine as a science was taught in schools of medicine and in many aspects was similar to other sciences such as Fiqh, philosophy, logic and doctrine, which were taught in seminary schools for many years by the most distinguished and prominent scholars of Iranian traditional medicine and religion (e.g. Avicenna, Aghili Khorasani, *etc*.). They considered the application of the four-category principles of the Book (Holy Quran), tradition, consensus and reason (wisdom) as the main criteria to access accurate knowledge.

Moreover, general principles should be applied to all sciences. The criteria of evidence evaluation in Iranian traditional medicine include two general parts of the evaluation of traditional medicine books and resources as well as evaluation of prescriptions and available therapeutic methods. It is estimated that approximately 17,000 Iranian traditional medicine book titles are accessible. In addition, hand-written versions of these books, authored by various scholars are also available. However, there are some partial inconsistencies among these hand-written versions which may lead to apparent changes in the meaning as well. Meanwhile, some experts believe that difference and contradiction among traditional medicine books are much less than other sciences and allopathic medicine. Basically, if the proposed criteria of Iranian traditional medicine scholars to evaluate books and resources of traditional medicine are ignored, to access accurate knowledge from among these huge volumes of information is an arduous task.

In regard to authorship criteria, it means that if a copy of a book is written by a famous author, it is of more importance than other copies written by an unknown individual. It goes without saying that the book written by one who has medical and specific subject matter knowledge is more valuable than those written by a layman who enjoys beautiful handwriting but lacks the field-specific knowledge.

In addition, scientific prestige and credit of author is an important criterion to evaluate texts. It is obvious that a subject explained by one of the scientists and famous university lecturers of Iranian traditional medicine such as Avicenna or Rhazes has more significance than the one explained in a book written by a physician or an author with dubious credit and prestige.

Considering test specificity of the subject matter is another important issue. Reviewing texts reveals that in some cases the author places special emphasis on the practicality of the test and reiterates that he has applied the test for many times.

We believe that evidence-based books are much more important than non-evidenced ones, and their degree of importance varies from those based on sporadic listening and knowledge.

To elaborate the issues consider the following examples

-Al-Khavayni in "Hedayat al-Mota'alemin" mentioned "all subject matters in my book are based on experiences and evidence" (6).

-Rhazes in "Al-Havi" certifies " On the basis of what I have heard and seen, Bhang seed, Lofah root, Lake mud, Frankincense(Kondor), Aghaghia, Rejle seed, Badroog seed, Pomegranate flower (Golnar) and Camphor could be mixed to make a tablet" (7).

-Another example with a specific emphasis on the specifications of patients is the one mentioned by Rhazes: "Hussein Vazah caught flu followed by high fever, bilious vomiting, tongue dryness and coughing ..." (8).

An example of cases presented by others is:

In "Al-Havi" (*P*.156), Rhazes observed accuracy and authenticity in speech and quotes a subject which has not been tested before. He said, "I have heard that someone certifies the accuracy of this remark in various narrations with equal importance" (9).

An example of analogy is:

Avicenna in 'Qanun" while pointing to a remark of a physician on fetus body organs formation, has some objections and mentioned "One has considered liver as the sole body organ created firstly in a fetus, because body needs food at the very beginning, and certainly no one can survive without food consumption. Liver distributes food in the body, and it is logical that liver be created first "This researcher has conducted his research mistakenly. The scientists and researchers not only disagreed with him on this issue but also adopted an opposing approach (10). He has not explained how he conducted research on the fetus but it is obvious that embryology as a science existed then, and scientists and researchers conducted numerous research activities in that field.

Time and venue of writing a book and an author lifespan also play leading roles in the degree of its significance. The members of Iranian traditional medicine community believe that since treatments of Iranian traditional medicine differ from one region to the other and from one individual to another one, from time to time some books were written that gained more importance. In the same direction, to update Iranian traditional medicine according to the current conditions and variables, they believe that research activities should be carried out on the basis of its principles and basics.

In cases that a book is identified as reliable and attributable, its contents, prescriptions, and diagnostic and therapeutic methods should also be appraised. In Iranian traditional medicine, there are several methods or therapeutic prescriptions proposed to cure a disease. In these cases, the most complete and inexpensive method should be selected. In this project, university lecturers believed in the availability of medicines mentioned in the related prescriptions. In view of the fact that these books are ancient, Iran territory was widespread (ranging from India to Andalusia) and physicians were traveling in various cities.

In ancient times, region-specific medicines were more accessible than the current situation. Also, inhabitance of the authors in specific parts of Iran and using plants native to their inhabitance to treat diseases was popular. Nowadays, some of these medicines are not available, and some others are expensive such as Singh Plant, which is native to India and China and does not grow in Iran. In some other cases, the name of a plant is changed during centuries. Under these circumstances, even if the plant is native to Iran, it is unknown with the name which has been referred to in the ancient books; therefore, it is considered as unavailable. In conclusion, to prevent patient confusion, before prescription of any drugs, these issues should be taken into serious consideration.

Moreover, drug toxicity or safety is of importance. Specific drugs or medicines were used previously and nowadays; their toxicity has been proved due to the remarkable progress of science. These drugs, for example, Colchicum (known as a toxic or poisonous plant), should not be consumed because of their toxicity. However, the recent studies proved that its poisonous effects exceed its recommended dose in "Makhzan al-Adviya" and other Iranian traditional medicine books (in other words its maximum recommended dose in Iranian traditional medicine resources is less than its poisonous dose) (11). However, Iranian traditional medicine scholars are fully aware of side effects of this medicine and to reduce its poisonous effect they prescribed another method or material named Mosleh.

Using the least possible components in a drug is emphasized in Iranian traditional medicine, and it is considered as one of the major principles of acceptance of a prescription. In this regard, Rhazes said, "To treat a disease by a diet has priority over a drug prescription and prescription of plain drugs is superior to the prescription of mixed ones" (12).

Successiveness or frequency of a prescription in various books is also emphasized. A solid evidence to use a prescription or a treatment method is to find its explanation in various books related to different centuries. Generally speaking, repetition of a treatment or a drug prescription means that its consumption is allowed; otherwise, it should be avoided. In regard to identifying the drugs used for several centuries, World Health Organization (WHO) approved this principle (13).

Using the emphatic words such as experienced (Mojarab), much experienced, unparallel and unique (Bi Adil) is another significant point which is mentioned in the assessment of the prescriptions and some of their examples are observed in most Iranian traditional medicine books. Each one of these has a specific meaning that indicates their level of importance. For example, an "unparalleled" prescription is more important than the "experienced" one.

Avicenna in "Qanun" said "If plain drugs are mixed with each other and their effects remain unchanged, they are called "tested." In other words, if a drug is investigated through different research activities, it is called "tested" (14).

Although evidence-based practice in Iranian traditional medicine follows the principles of western EBM, it has its specific rules, regulations and criteria that should be strictly followed by Iranian traditional medicine researchers and practitioners. In this regard, critical appraisal of books and resources according to the proposed criteria is highly recommended. Moreover, to develop a digital library and a traditional medicine database to provide reliable electronic versions of these invaluable resources are recommended which in turn prevents patent registration of Iranian traditional medicine knowledge by foreigners.

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