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Research Methodology for Ayurveda and Traditional Systems of Medicines: Practical Difficulties and Way Ahead

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The conceptual framework in which Nature and Science are interpreted depends on historical, cultural, social and economic factors. It is very well known that when comparing western and eastern perceptions of the world, different approaches are found: traditionally, for the West the attention is directed "outward" while for the East it is "inward", this leads to reaching a balance respectively "outside" and "inside". The perception of the "outside" is naturally limited by sensorial boundaries and it ends up in a fragmented view of reality, while the attention toward an inner primordial origin leads to holistic perception of reality. The practical result of the "outward" attitude is evident in the field of Modern Science, dominated by western culture, where scientists see Nature as made of separated items. These different substrates lead us to the diverse approaches to health and disease such as those of Modern Biomedicine and Traditional Medicines like Ayurveda.

However, nature is one, notwithstanding the diverse human viewpoints, and a complete picture will result only from the collaboration of multiple perspectives.

The tradition of Ayurveda testifies the existence of a deep disposition to Research since ancient times.[1] In this regard, the discussion exposed in the classical texts was essentially articulated on the validation of the knowledge processes as well as on the manifestation of diseases, the real efficacy of therapy and the development of new formulations and protocols.[2,3] However, it was nothing like the Research as an organized activity, as it is intended today in the bio-medical field, this concept is something new for Ayurveda. Nevertheless, it is important to clarify that modern Research, characterized by the scientific method, is an overall new concept which has been developed in the West only during the last four centuries. In this framework Biomedicine, for the undoubtedly great progress focusing on organs and systems, but also for the huge economic interests that have accrued,[4-6] has become the medical system of reference of the modern world, and its reductionist based thinking is dominant today in the medical scientific community.

In recent years initiatives of study, research and dissemination of Ayurveda's vision and philosophy have proliferated not only in India but in the whole world. Research in Ayurveda is flourishing and, according to PubMed, the largest database of scientific papers in the world, in the last seven years, almost 60% of total articles on Ayurveda produced from 1945 to the present have been published.[7] Not to mention the number of articles published in journals indexed in other Databases than PubMed such as DHARAONLINE or AYUSH Research Portal.[8-9]

However, very few of them have provided valid information useful to reveal the underpinning value of Ayurvedic principles and their applicability to modern environment. Most of these studies have been performed mainly according to the requirements of modern Research in Biomedicine, without any necessary adjustment based on epistemological diversities, Moreover, most of these studies have been done

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in vitro or *in vivo*, with just a few clinical trials.[10] Besides, Research activities in Ayurveda currently don't follow a well-defined strategy, the majority of the studies is sparse and misdirected, and they are in large part guided by the urge of proving the efficacy of Ayurveda according to the epistemological framework of Modern Biomedicine. Furthermore, a relevant part of the studies are focused on ethnobotany and ethnopharmacology, in the strenuous search for information that could lead to the discovery of new chemical entities.[1]

The assignation of the 2015 Nobel Prize in Physiology and Medicine to Prof. Youyou Tu for the identification of an anti-malarial drug derived from a herb used in a traditional Chinese Medicine, is actually a signal of a potential danger. The event has been considered by many official legitimization for Traditional Medicine, however this is not true. It is rather the opposite, because this finding has been made using the conventional scientific method of drug discovery, neglecting the complex Chinese Medicine's pharmacology, its epistemology and approach to health and disease.[11] This could drive into a mislead enthusiasm in pursuing a reductionistic pathway even in the Traditional Medicine environment. This risk is very present also for Ayurveda. As a matter of fact, research based on the isolation of active principles and the search for the "golden bullet" drug is a widespread attitude present in the ayurvedic to shape community, which is reinforced by the glamour of modern science findings. This behavior, neglecting the very essence of Ayurveda's Dravyaguna, which uses complex algorithms to combine herbs and other materials in order to obtain a synergic effect, could lead to the progressive loss of the holistic perspective of Ayurvedic epistemology.

However, in the last years a new wave of Research in Ayurveda is emerging and a novel approach is taking shape with the aim to establish a dialogue with Modern Medicine.[12-15]

As an example, the recent molecular biology studies on the concept of individual constitution (*Prakrti*) on which Ayurveda focuses its diagnostic, therapeutic and preventive logic[16] are of considerable importance. The evaluation of *Prakrti* takes into account the constant interaction between environmental, physical and epigenetic components which contribute to shaping the individual phenotype. The full and proper understanding of the deep concept of *Prakrti* is therefore of vital importance for conveying and sharing Ayurveda's principles to Modern Medicine and Science. Several studies have recently highlighted the relationship between the *Prakrti* and the expression of particular genes, identifying the corresponding genomic basis.[17] It has been also analyzed the relationship between the *Prakrti* and the psychological personality characteristics measured according to Western methods.[18] Other interesting trends, that witness this novel cross-epistemological approach, span from the clinical use of physical and rehabilitation treatments to the management of chronic diseases and aging, from the elaboration of new models of health and disease to public health management.[19-22] Taken together, these findings will allow not only to successfully integrate the diagnostic mode of Ayurveda in the prevention and treatment of mental and social health, but also to develop a new vision of human functioning useful also to Modern Medicine. However, a conceptual coordination of these efforts and studies is needed. It is of crucial importance to individuate a novel strategy of Research and to develop a methodology which, while fulfilling the request of organization and coherence of modern Science, will follow the epistemological premises of Ayurveda. This will allow a real synergic interface between BioMedicine and Modern Science. However, it is important to have well clear in mind that the application of modern Research methodology in Ayurveda is a very difficult and complex task, since it is rooted on a different epistemological and ontological model.

Research in Ayurveda is needed for several reasons: to complete the information that has been lost during the millennia, to better understand its principles and underpinning mechanism of action, to verify its applicability in present times and to understand if the synergy with Modern Biomedicine and Science can lead to broader advancements in Research, inspiring new directions. The latter, in my opinion, is the most innovative and promising issue.

The epistemology of Ayurveda and its ontological vision of the universe is of high complexity and derives from

all the diverse *Darshana* of Indian Traditional System of Knowledge. It deeply differs from the epistemology of Modern Science and Biomedicine. They are two systems which are coherent in themselves, with their diverse point of view of reality and they cannot be overlapped.

It is thus very important to understand why the application of reductionistic biomedical thought to Ayurveda is detrimental to its essence, and paradoxically prevents its deeper knowledge and possible applications. Reductionism defines the logical structure and methodology of Modern Science: according to this view the "reality" is explained as constituted of independent objects, consequently the capacity of controlling objects means controlling "reality". The essence of Knowledge is thus intended as formed by multiple units of information, whose single identification is considered as success. However, these units of information are kept separated by definition since reality is seen as formed by isolated fundamental components and not by objects interacting with each other. This hampers the perception of the dynamism of processes and of the whole interconnected framework of reality. The thinking underpinning Ayurveda is relational and systemic, every part is in continuous interrelation to each other and to the whole. "All in one and one in all."

Consequently, if the study of Ayurveda is performed according to the methods of Modern Biomedicine it will be distorted, it will be reduced, as it currently happens in many research studies, to a mere verification of the efficacy of certain preparations for specific conditions, or to the possibility of including only some of the ayurvedic techniques, pulled out from their conceptual context, in the current medical practice. In no way, by the very nature of Modern Science, the holistic essence of reality will be considered: in this view the ontological system at the basis of Ayurveda does not have any place, unless it is bent into the biomedical theoretical framework as well as methodology, denying its own identity as well as epistemological foundations. Research in Ayurveda must serve the knowledge of this ancient science, it should not be intended to confirm the limits of modern science and it should be performed according to the ayurvedic logical structure and not to that of BioMedicine.

This is not to say that modern BioMedicine is wrong, on the contrary it is extremely efficacious especially in acute conditions and emergencies. I personally believe that the two systems are based on different epistemology and they shouldn't be mixed up in a confused manner. Let me tell you a nice story I heard in India, in order to better I understand my point. One fine day a child told his father that the teacher said that Sun rises at East, the father nodded and then said smiling that actually the Sun rises in a place that we call East. The child was confused and decided to ask his Grandfather his opinion. The old man patiently listened to the story and then told the young boy that in reality the Sun never rises or set. Who is right? All of them: it depends on the knowledge and on the level of observation. If I have to sail a ship I need to understand where the cardinal points are and knowing the sunrise and sunset sites is useful information, I don't mind about the motion of the planets which instead are important if, for example, I want to understand the dynamic of eclipses. The same happens for Ayurveda and Modern Medicine, they are related to different levels and they need coherent means to be studied and understood.

In Statistics, the concept of validity is the extent to which a concept, conclusion or measurement is well-founded and corresponds accurately to what we feel is the real world. An argument is sound and valid only if the premises are true, thus the conclusion is guaranteed to be true. According to this concept, we need premises that fit together into a certain pattern that yields the conclusion. If we deny the ontological system at the basis of Ayurveda, we cannot expect true and innovative conclusion in our studies.

Nonetheless, Ayurveda and Modern Science need to meet for the benefit of mankind. From their encounter a new, more complete perception of reality can emerge, it will be like understanding the relativity of sunset, sunrise and planet motion compared to the wholeness of the system. The debate between diverse epistemologies is the harbinger of new paradigms. The chaotic flow generated by the contact of two diverse conceptual environments when properly mediated, is potentially proficient and can generate a higher level of coherence between the systems engendering novel perspectives. However, due to the intrinsic turbulence of this cultural

contact, it is a very delicate operation and it is of crucial importance to find the more appropriate way to nurture it. For this process I tend to use the word "integration" very rarely and with attention.

In the last 20 years "integration" is an emerging concept in the field of biomedicine, since its limitations in offering solutions to many chronic illnesses have stimulated the search for treatment strategies beyond the boundaries of conventional health care. Many efforts have been made in this direction however we are far away from achieving the goal. One of the most important reasons for this unsuccessful result is the heterogeneous understanding of the concept of integration, which is influenced by cultural perceptions. Moreover, the rules about the development of this integration process have never been clear.[23-25] The "integration" of different medical systems and/or knowledge systems will be successful only if it is meant as a synergy, and not a merging, between the diverse approaches, leading to the development of inter-connections and the harmonious functioning of both systems. Unfortunately, "integration" is currently used as synonymous with "assimilation" and the majority of the integrative approaches rely on the concept of other medical systems confluence into the Biomedical model.[26,27] Since the participation of the two systems is not equal, this assimilation process, wrongly described as integration, leads to the eventual dissolution of other knowledge systems. There is a real risk of "neo-colonization" of Complementary and Alternative Medicines (CAMs) and Traditional Medicine.[28-31]

It is thus very important to keep this risk in mind while proposing novel perspective of collaboration between knowledge systems and relative health care approaches.

In this regards, some attempts have been made so far to promote the understanding of "integration" as synergic interaction, collaboration, rather than assimilation,[12-15,20,34] in order to preserve epistemological and conceptual diversity and to nurture a comprehensive view of Medicine and Science. This collaborative approach, based on a process of cross-cultural translation, would imply the effort to "reformulate" fundamental epistemological concepts in order to make them reciprocally understandable. This "reformulation" process could foster the discovery of convergences and similarities, as well as differences between knowledge systems, that in the long run could lead to the global enrichment of the overall medical understanding. It will generate a complex and comprehensive view of health, which will ignite the emergence of new paradigm in science as well as medicine.

It is very well known that Ayurveda suggests to observe Nature using the concept of *Loka purusha saamya*, the analogy of Man and Universe, and this approach can be used in order to find optimal solutions to complex problems.

Nature is characterized by "Complexity", where the many components of the system continuously interact with each other in multiple ways and collaboratively, creating higher levels of complexity and culminating in a superior order called of "Emergence", a novel state of the system, greater than the sum of its parts. In the economy of an organism, an higher level of complexity leads to emergent adaptive behavior while a lower complexity corresponds to a lower capacity of adaptation.[1] Adaptation is the key to evolution, survival and ultimately to Health. Concept beautifully expressed by Susruta "As the moon, the sun and air support the cosmos with releasing, receiving and dispersing, likewise *Kapha* and *Pitta* support the body".[32] As a matter of fact, chronic diseases show a lower level of complexity with difficulties in adaptation. In conclusion, we may infer that the collaboration between Ayurveda and Modern Medicine will increase the complexity of the general knowledge system leading to the emergence of a novel paradigm of science. Moreover, collaboration requires the phenomena of synchronization, rhythmogenesis and coherence, as observed in brain networks,[33] where a dynamic substrate of continuous cross-talk is at the basis for cognitive functions such as learning and memory.

This proposal, where diverse epistemologies are bridged together, goes under the definition of "Collaborative Medicine and Science" (Co.M.S.), that we recently introduced.[34] The basic assumption of this novel conceptual framework of Research is quite obvious, and it is that we do not need to prove that Ayurveda works, because it does, history confirms it. It will be a waste of time and resources proving its effectiveness according to the parameters and framework of Modern Biomedicine,

activity which I also think quite humiliating and harmful for Ayurveda. Co.M.S. will instead coordinate and direct the research toward a coherent pathway, with the aim to understand Ayurveda, answering to three main questions: What, How and Why. What is working, How it is working, Why it is working. The answers to these questions will change the way we look at the world. This approach will bring to a paradigm shift not only in Medicine but in all Science. It is important not to limit the application of Ayurveda to medical field since its theoretical foundations, if properly contextualized and translated, have the potential to involve the entire scientific domains.

The Co.M.S. strategy will kindle future research and activities to interface Ayurveda and Modern Science and Biomedicine through three main approaches which are closely interrelated: 1. Reformulation and contextualization of the Ayurveda fundamentals, 2. Ayurveda modelling 3. Localization of Ayurveda.

1. Reformulation and contextualization of the Ayurveda fundamentals

This is a necessary step, the knowledge and wisdom of Ayurveda is deeply rooted in the classical texts. However, in my opinion, this incredible mine of knowledge is not exploited to its full potential. Many people, especially in the West use only English translations most of which are dated, incorrect or predominantly literary translations in which the true scientific significance is lost. Moreover, the very concept of translation of classical texts from Sanskrit poses substantial difficulties due to the cognitive system at the base of the Sanskrit language which is different from the Western one. In India, the situation still poses some problems since most of the times these texts are used only as references, with no real deep understanding and above all without making any effort for their contextualization. Today's world presents an inherent complexity that must be taken into account for the application of the classical texts indications. The relationship with modern science depends on this ability to reformulate the epistemological foundations of Ayurveda in sharable concepts. This "reformulation" could foster the discovery of convergences and similarities, as well as the differences between knowledge systems and in the long run could lead to the global enrichment of the overall medical knowledge. Finding commonalities will allow the creation of a sort of "Rosetta Stone" which will be crucial for mutual understanding and for going beyond the limits of current scientific understanding. This process could ultimately result in authentic integration, implying the harmonious and synergic co-existence of more than one system, rather than the merging of other systems into a dominant one. In the field of Medicine it will generate a complex and comprehensive view of health, which will ignite the emergence of new paradigms. Finding commonalities between *Padartha Vijnana, Mahabhuta, Guna*, *Agni* and the modern concepts of reality, matter, mind, time, energy are some of the fundamental challenges.

2. Ayurveda Modeling

It is an application of scientific, conceptual as well as graphic modeling. It is an activity that is necessary to overcome the communication gap arising out of cultural diversity of the knowledge systems. The modern scientist will have access to deeper concepts of Ayurveda with reference to existing and commonly accepted knowledge. Ayurveda Modeling will describe and formalize in a logical and objective way the principles used in Ayurveda to interpret reality. It will allow simulation, visualization, manipulation and intuitive understanding of the entities, processes or phenomenons being represented. This will enhance individual and mutual understanding and create a reference point for sharing and collaboration. As an example, the recent representation that we made of Ayurveda through Complex Adaptive Systems offers a breakthrough vision of an Ayurvedic concept in terms congruent with Modern Medicine and Science.[20,35]

3. Ayurveda Localization

Ayurveda, as the very meaning of the word indicates, is the science that deals with life in general and as such can be applied everywhere there is life, not only in India. However, if life is the same everywhere, the conditions in which it affirms and evolves are different according to diverse ecosystems and sociocultural milieus, leading to manifold expression of living beings and their socio-behavioural schemes. A traditional medicine is deeply rooted in the essence of Nature but it emerges according to the conditioning of the environment. Ayurveda in

its pragmatic form is emerged according to the Indian domain, nevertheless also in India there are substantial differences, for example between North and South. This is the reason why the simple and general globalization of Ayurveda, as crude transportation of its practice through latitudes is not completely effective and accepted. Thus the principles of Nature, well defined and described by Ayurveda, have to be "extracted" from the Indian location and found and discovered in other local environments and Traditions. This task will be largely achieved through the previously described activity of reformulation and contextualization. Thus, the generalized principles of Ayurveda that will derive from "Localization" could be transported all over the world, applied regionally and used to interpret the local manifestation and expression of Nature. This will enable a versatile application of the principles of Ayurveda in diverse parts of the world, creating systems of healing that are suited to the local conditions and individual variations. Localization of Ayurveda is a fundamental concept for the realization of the primary goal of Ayurveda itself: the availability of its principles and benefits to everyone and everywhere.

As stated in Charaka Samhita, Ayurveda never had a beginning nor it will have and end, as a logical consequence it does not need to be preserved. What instead needs preservation is the human knowledge of Ayurveda, our interpretation of it. A coherent Research keeping in mind Tradition goes in that direction, taking into account the need for Tapas that remains the basis of man's life. It is necessary for human beings to get to know and accept themselves and their position in Nature. This is a historical moment often dominated by confusion, fragmentation and uncertainty, and the proper research and diffusion of Ayurveda will surely help in finding a new cohesion in the vision of Nature and ultimately in the arising of higher human awareness.

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