

Herbal medicine: no research to evaluate clinical evidence

Opinion

In the past decades herbal medicine seemed clearly to have a good scientific basis, compared with other CAM methods: There was a solid basis of pharmaceutical quality, especially in those German speaking countries, in which herbal medicines were treated as medicinal products under a strict drug law. There was already a huge amount of pharmacological research about active ingredients and their mechanisms of action. Claims have been postulated based on these mechanisms of actions combined with knowledge of traditions and clinical use. A few manufacturers of herbal drugs sponsored clinical studies for their herbal products, at least for those with sophisticated formulas like combinations of several herbs or those which contained certain herbal extracts (in that times the question was raised by old-fashioned herbalist, whether a modern extract would really contain all active compounds). For simple and cheap forms of herbal medicines, e.g. herbal teas clinical trials were extremely rare and this poor situations never changed up to nowadays.

Pharmacognosy was a specialty of botanic till the 1960ies, then the name was switched to 'pharmaceutical biology' and developing to one of 4 core branches of the pharmaceutical departments. They took charge of all aspects of pharmaceutical quality. This included pharmacological research to elucidate, which substances out of that many in a plant would contribute to the efficacy. These substances or just certain substances specific for a plant could be then used as marker substance for following the concentration process during extraction process and also for showing stability of the final product.

Pharmacological investigations of whole plants, certain fractions or isolated substances have been performed also by pharmaceutical biologists (starting with crude pharmacological test batteries) or by pharmacologists. Clinical research, however, had no own branch in medicine and was performed by some broad minded clinicians in their respective medical specialties. When in the 1990 the first few professorships for natural healing resp. CAM were installed in Europe, some of these took charge of herbal medicine. While others (e.g. Berlin, Zürich, Essen, Rostock, and Munich) conducted some clinical trials, Exeter contributed only in form of reviews. (It is still worth notifying, that the staff (e.g. number of professors) of one single of the bigger institutes for Pharmaceutical Biology exceeds the research-related part of all CAM-departments in Europe combined!

Since clinical research of herbal drugs needs no special methodology, the special characteristic of herbal medicine comes mainly from Pharmacy and less from Medicine. Specialness of herbal medicines is commonly based on the hypothesis, that many active substances in a herb should act in a complex synergistic way in the form of a multi-target-therapy. This should then lead to a soft "action and also to less side effects. The benefit-risk-ration should be better than specific one- substance-one target medications. This explanation bears some romantic and idealistic ideas, which can obviously not

cover those herbs, which have only one pharmacological target. The WHO, however, recommends herbal preparations just as cheap substances in certain (poor) areas and this seems neither scientifically convincing nor ethically valid! There is not much literature about theory of herbal medicine and an international consensus on a scientific basis of herbal medicine is still missing!

One might ask the question, why there is this lack of scientific basis of a special therapy, which - at least compared to other CAM-procedures - has really a significant economic importance? Is the answer so simple, that all that many pharmaceutical biologists and medical doctors just forgot to create a scientific basis for herbal medicine? I think there are huge agenda of scientists, who prefer to have wide and fuzzy definitions of herbal medicine. A great part of biomedical research at all – that is preclinical research is somewhat linked to herbs and plants. Politicians of all nations as well as managers of big chemical/pharmaceutical companies like their picture, that they support research on pharmacology of unknown or known plants. They create the impression, that this might be good for herbal medicine, either to find new plants for clinical use or to support old known plants and improve them into new formulations. They keep quiet about the real aim that is to find new patentable substances, which is not at all the aim of herbal medicine.

So worldwide there are now thousands of labs with thousands of pharmacists, chemists, biologists etc., isolating new substances and looking for their affects in vitro. Together they form a „scientific mafia“ with the aim, to get even more money for the expensive lab equipment, materials and staff: if you have doubts about that „mafia“ just compare the sales of industry of lab equipment with sales of herbal drug industry....

Now, the results of that huge amounts of money and work in the preclinical labs did not lead to many new developments within the

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past decades – neither chemical drugs more new herbal drug. New techniques like gen-chips promise wider screening than before, but future might show not more success in future. The few positive examples needed decades till could be used clinically. Freedom of science means, that each researcher can chose his own strategies and so maximum number of publications its he criteria for career in science. Every publication corresponds to the whole picture like a little part of a huge puzzle, and researchers often start a now puzzle by investigating the next substance and next herb with their test battery. For clinical use of a new chemical drug the full puzzle should be completed, another program is needed for registration of a new herbal drug, which corresponds to another puzzle format than that for chemical drugs. Researchers produce publications without being aware, whether they would contribute for development of a chemical or an herbal drug. They are in a situation like a child, trying to lay a puzzle, but not recognizing that his puzzle pieces are indeed from 2 different puzzles.

Indeed if we screen publications by attribute 'herbal', we find thousands of publications, nearly all preclinical studies and only few clinical trials (even using filters for clinical studies still results in much more preclinical publications). Nowadays in the time of evidence based medicine, the scientific basis for many well-known and widely used herbs is even worse than 30years ago, when there was at least some plausibility according pharmacology mandatory for filing a positive monography of the Kommission E. In the puzzle of any herb today mainly clinical trials are missing. But sponsors for clinical trials are rare and those few medical researchers are then forced to work on systematic review instead.

Systematic reviews about only a few and older clinical trials can never result with a positive conclusion! Common cold is a very important area of herbal medicine. But in dependence, to which medical specialization the same patients attends, different diagnoses will be named: the GP would name common cold, the ear, nose and throat doctor would call rhinitis or trachealis, the pulmonologist would call bronchitis. So each systematic review about one of these more or less specific diagnoses would cover only part of the existing clinical trials. Clinical trials on the other hand, look often for specific outcome parameters and fail to give information about the course of general symptoms of a common cold. So often one can only guess, that the complex study bears not much more information than the old wording: a common cold lasts 2weeks with help of a doctor and 14days without. In practice I experience a fast relief of symptoms with different kinds of herbal treatments at least, so that patients could do their jobs earlier and more easily. Studies about prevention of worsening of common cold to bronchitis or pulmonitis are needed, since that you cannot extrapolate from observation in practice.

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