

EDITORIAL

HERBAL MEDICINE IN KENYA: EVIDENCE OF SAFETY AND EFFICACY

Herbal medicines, which formed the basis of health care throughout the world since the earliest days of mankind, are still widely used. Indeed, medicinal plants have been a common source of medicaments, either in the form of traditional preparations or as pure active principles. Examples of plant derived drugs widely used in western medicine are found in quinine, antimalarial from *Cinchona* sp; digitoxin, cardiotonic from *Digitalis purpurea* L; vincristine, antitumour from *Catharanthus roseus* L; colchicine, anti-gout from *Colchicum autumnale* L; reserpine, a hypotensive agent from *Rauwolfia* spp. atropine, anticholinergic L; from *Atropa balladonna* L; codein, antitussive/analgesic from *Papaver somniferum* L; morphine, analgesic from *Papaver somniferum* L, among others(1).

Traditional medicine involves the use of herbal medicine, animal parts and minerals. However, herbal medicines are the most widely used of the three. Herbal medicines contain as active ingredients, aerial or underground parts of plants, or other plant material, or combinations thereof, whether in the crude state or as plant preparations(2). The basic principle of herbal medicine is a mixture of ancient tradition applied to modern conditions without, in many cases, the benefit of modern science and technology(3). However, traditional practices are now being coupled with up-to-date scientific methodology and processed dosage forms are now being produced, Pharmaceutical formulations are required as a means of producing standardised galenical products for use and for commercial purposes. Examples of herbal preparations exploited for commercial purposes include Feverfew Leaf capsules for migraines; Devils claw capsules for rheumatism, Echinacea root capsules, anti-infective, Ginger root capsules for nausea and vomiting, Ginko leaf capsules for improved peripheral circulation; and Willow bark capsules, anti-inflammatory, just to mention a few. Some of these herbal formulations are available on the Kenyan market, though a regulatory mechanism for their registration is not yet in place. The regulatory authorities can only assume that the products have undergone proof of safety and efficacy in the countries of origin. Some unprocessed dosage forms found in health shops are regarded as natural food supplements and proof of safety and efficacy is not a requirement.

In recent years the importance of the utilisation of herbal medicine in primary health care system has been emphasized in Africa as well as other countries. In Kenya, herbs are traditionally consumed in various ways, most commonly in the form of infusion or decoction prepared from the dried plant material. In this case, the only testimony of efficacy and safety is the prolonged and apparently uneventful use.

Ethnomedical information obtained from relevant literature sources and through collaboration with

traditional medical practitioners is a useful tool in evaluation of safe use of herbal medicines. A history of safe and apparently successful traditional use of herbal medicines provides an initial indication of safety. A general rule in the assessment of safety and efficacy of herbal medicines is that traditional experience in the use and the medical, historical and ethnological background of these products shall be taken into account, through detailed descriptions in the medical or pharmaceutical literature or documented account of their application(4). The need for scientific rationalization of the use of traditional herbal remedies in contemporary clinical therapy has necessitated the requirement for the assessment and control of labelled herbal medicines. In view of this, WHO has formulated guidelines(5) concerning basic elements of legislation and registration of herbal remedies. These guidelines contain basic criteria for assessment of quality, safety and efficacy of herbal medicines and important requirements for labelling and package insert for consumers' information. The requirements for pharmaceutical assessment cover issues such as identification, galenical forms, analysis and stability. Safety assessment covers at least the documented experience of safety and toxicological studies, where indicated. The assessment of efficacy and intended use includes evaluation of traditional use through appraisal of literature and evidence to support the indication claim. Based on these guidelines the Kenya regulatory authority is in the process of drafting a regulatory document for herbal medicine regulation and registration.

Meanwhile, research and evaluations to guarantee the availability of safe, effective and standardised galenical products is in progress in the various institution in Kenya dealing with natural products. The many and various forms of herbal medicine have evolved against widely different ethnological, cultural, climatic, geographic and even philosophical background. The evaluation of these products and ensuring their safety and efficacy through registration and regulation present important challenges. There are several types of evidence that it is desirable to obtain before a therapy is advocated. The evidence of safety and efficacy are the most critical.

Evidence that a therapy has few, if any, significant adverse effects and will not cause harm must be considered important in all medicines including herbal medicine. However, there are two potential complications, which confound this seemingly simple statement: what level of safety should be demanded and what type of evidence of safety is acceptable? In determining what level of safety should be sought, the risk/benefit ratio of the therapy in question must be considered. If the potential benefits of a therapy are likely to be very

significant, or even life-saving, then the level of risk a patient may be willing to take with the therapy is likely to be higher than the level of risk they are willing to accept for the benefit of temporary symptom relief or the cure of minor complaint. In determining what evidence of safety is acceptable it is important to consider what weight should be given to a history of safe traditional use. With herbal medicine such evidence is common and is often given reasonable weight by herbal medicine advocates and to some extent by policy makers. However, minimum standards of safety need to be defined in order to protect the public from unscrupulous traders. Currently, the safety and efficacy of herbal therapies are important concerns for the Kenyan health care authorities and the provision of safe and effective phytopharmaceuticals, including laws and regulations to help maintain public confidence in the use of herbal therapy is becoming a national health care priority.

Despite the use of herbal medicines over many centuries, only a relatively small number of plant species has been studied for possible medical application. Safety and efficacy data are available for an even smaller number of plants, their extracts and active ingredients and preparations containing them(6). The evidence for the efficacy of herbal medicine is mixed, many herbs have established activities while others do not; among those which are active many are claimed to have numerous other actions for which evidence is lacking. Problems sometimes arise when mixtures of herbs are used. Even when these have proven efficacy it may be difficult to standardise and control. More research is needed on the efficacy of most herbal remedies, and indeed institutions in Kenya dealing with natural products such as Kenya Medical Research Institute (KEMRI) and University of Nairobi, continue to carry out research in order to build up an evidence base.

At Kenya Medical Research Institute, traditional medicine research programme focuses on the rationalisation of the use of traditional herbal remedies in contemporary clinical therapy. In particular, it uses a multidisciplinary approach, which includes ethnomedical, ethnobotanical, pharmaceutical, medicinal phytochemical sciences, and pharmacology and toxicology in correlation with the clinical sciences to determine the usefulness of phytopharmaceuticals in modern therapy. The use of carefully selected biological models combined with pharmacoepidemiologically selected medicinal plants have resulted in the identification of herbal medicines that may have therapeutic effect. Appropriate biological assays using cell culture models, isolated organs and tissues or in vivo animal models help in the establishment of efficacy claims. Observational studies also offer great advantages in the establishment of proof of efficacy of a herbal preparation. Not only does this method avoid extrapolation of results in animals to man, but it limits the number of tests to be carried out to prove safety

and efficacy of a herbal medicine. In our laboratories we have carried out observational studies to support indicated claims of a traditional anti-asthmatic formulation. In this study we decided to observe a traditional medicine practitioner carry out his treatment of asthma on confirmed asthmatics attending a chest clinic who had given informed consent to participate. Pulmonary function tests were carried out on these patients prior to administration of the medicine, then daily for two days and thereafter every month. The results indicated that great improvements were obtained using the traditional medicine(7).

Some medicinal plants are currently being screened for antiviral activity against herpes simplex virus (HSV) and human immunodeficiency virus (HIV). HIV activity has been demonstrated in vitro(8) and anti HSV activity has been demonstrated both in vitro and also in animal model(9). A herbal medicine claimed by traditional medical practitioners to treat malaria has demonstrated in vitro activity against *Plasmodium falciparum* and clinical trials on efficacy and safety are going on. More studies on other plant products are to be planned. Only by doing so, shall we get enough information on safety and efficacy. The future of herbal products in Kenya should be, to follow scientific methods to standardize them in order to assure the public of the quality, safety and efficacy.

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