

Adulteration and Contamination of Ayurvedic Herbal Medications

Krishnaprasad R, Pillay VV, Rajesh RR, Vishnupriya N

ABSTRACT

For long, indigenous systems of medicine of India such as Ayurveda and Unani have been credited with the development of naturally derived medicines that were presumed to be relatively free from adverse effects. Increasingly however, there is evidence to suggest that some of these medicines may not be entirely safe, particularly those originating from makeshift manufacturers. This paper presents the findings of a study involving some common Ayurvedic medicines, which revealed the presence of heavy metals and synthetic steroids that were in some cases responsible for significant morbidity among those who consumed them.

Key Words: Ayurveda, herbal medicine, heavy metals, steroids

Introduction

The Ayurvedic system of medicine is based on ancient knowledge contained in Atharvaveda, one of the Hindu religious texts. It deals with a holistic approach to individual and social health, encompassing preventive and curative aspects. In fact, Ayurveda is a way of life based on strict emphasis on diet, life-style, and Yoga practices suitable for an individual according to his/her constitution. In most cities of India, and even some overseas countries, ayurvedic herbal medicines (AHMs) are becoming increasingly popular as an effective and relatively safe alternative to allopathic drugs. However, AHMs are not regulated as medicines, and because of this they are freely available to everyone. This raises serious safety concerns as to their actual effects on the human body, particularly those AHMs which are manufactured by small, cottage industrialists.

It is increasingly becoming evident that some ayurvedic herbal medicines contain toxic heavy metals or undeclared prescription drugs. Although adulteration with drugs is fraudulent, the inclusion of heavy metals could be either accidental or intentional for alleged medicinal purposes.

In this article we review the cases that have been admitted to AIMS, Cochin where the symptoms could be traced to the toxic effects of metals in AHMs, or due to the adulteration of AHMs.

Materials and Methods

This audit was conducted on samples brought to The Department of Analytical Toxicology, Amrita Institute of Medical Sciences & Research (AIMS), Cochin. The laboratory attached to the department performs mainly toxicological analysis on blood, urine and gastric washings. Analyses of drug samples are also carried out. The laboratory is equipped with a Shimadzu HPLC system with a photo diode array detector. Along with HPLC analysis, UV Spectroscopy and colorimetric methods

**Dept of Analytical Toxicology, Amrita Institute of Medical Sciences & Research,
Cochin 682026**

are also used to identify the drugs and poisons. Heavy metal analysis was carried out by limit tests¹ on the herbal products, followed by atomic absorption spectroscopy. Examination of the blood, urine or drug samples for prescription drugs was done by chromatography and colorimetric reactions. Briefly, the AHMs were screened for common prescription drugs by color tests. An ethereal extract of the samples was evaporated and redissolved in minimal volume of methanol. This was spotted on to TLC plates. The silica gel G 250 mm thick plate was developed with a suitable mobile phase depending on the result of the screening reactions.²

Results

Of the 200 cases examined, 24 cases were directly traceable to AHM use. This represents 12% of the total number of cases analyzed. Blood, urine and AHM analysis of these 24 cases was carried out. 23 of the 24 cases, i.e., 96% tested positive for metals. The highest number tested positive for lead, followed by mercury (**Fig 1**). Arsenic was found in two samples and antimony in one. The concentrations of the metals in the AHM were of the order of milligrams per deciliter, suggesting intentional addition rather than contamination. Blood and urine concentrations of the metals ranged from the toxic range to normal levels depending on the duration of use of the AHM. In eight cases, the AHM samples tested positive for prescription drugs. This accounts for 30 % of the total number. The pattern of prescription drugs found is shown in **Fig 2**. Corticosteroids were the commonest, comprising betamethasone, dexamethasone, prednisolone, and hydrocortisone. Interestingly, two of the sample tested positive for metronidazole and tinidazole.

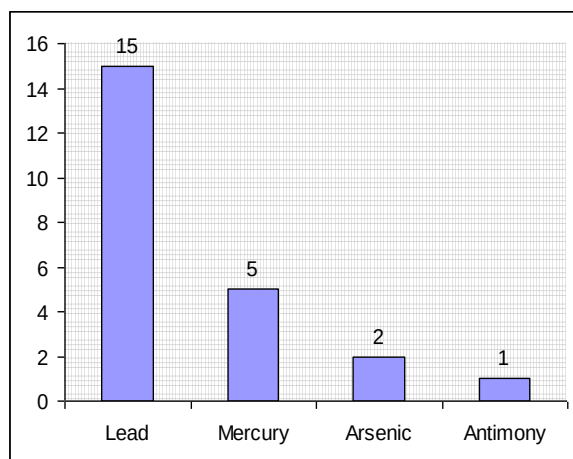


Fig.1 Bar chart showing the heavy metals detected

Discussion

Our experience shows that the two most common metals found in AHMs are lead and mercury, either found singly or together. Only two samples showed the presence of arsenic. The concentrations were of the order of milligrams per deciliter. Traditional ayurvedic literature is rich with examples of the therapeutic properties of these metals. Their usage ranges from the treatment of male impotence to general health tonics.³ The patients in our study were taking these formulations

for chronic disorders such as arthritis and asthma. Regular chronic use of these drugs resulted in the signs and symptoms of lead poisoning in some of them. The most common symptom experienced was abdominal discomfort. All the patients had anemia, ranging from mild forms to full-blown hypochromic microcytic anemia. Three of the patients with microcytic hypochromic anemia also were positive for urinary coproporphyrinogen III. None of the patients showed any neurological manifestations. Serum lead levels estimated by Atomic Absorption Spectroscopy showed levels higher than the normal.⁴

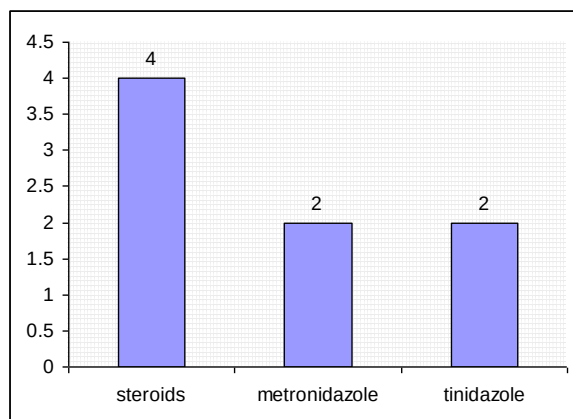


Fig.2 Bar chart showing the prescription drugs detected

The second most commonly encountered metal was mercury. This was usually in association with lead. None of the patients showed any signs or symptoms of mercury poisoning. Interestingly, in one patient the signs and symptoms suggested lead poisoning, but the serum lead was in the normal range. Analysis of the ayurvedic medication consumed in this case showed very high amounts of mercury.⁵

Steroids were the most common prescription drugs detected. They included betamethasone, dexamethasone, prednisolone, and hydrocortisone. In three of the cases, the AHMs were being consumed for more than two years. One of the patients, a child, presented with nephrotic syndrome secondary to steroid overdose. The AHM was being administered as a cure for asthma.

Two powder samples analyzed showed the presence of the antiprotozoal drugs metronidazole and/or tinidazole. These powders were being marketed as cures for alcoholism. This novel use is apparently based on the disulfiram-like reaction seen with this family of drugs when consumed concomitantly with alcohol. Indigenous medical systems such as Ayurveda and Unani have a long and rich history of herbal medicine usage, and heavy metals have been a regular and deliberate constituent of such traditional Indian remedies. Indian schools of medicine emphasize the importance of metals such as lead, copper, gold, iron, mercury, silver, tin and zinc for the proper functioning of the human body. Ayurvedic textbooks, for example, while taking note of the toxicity

of heavy metals, recommend special physicochemical processes that, according to ancient Indian belief, "detoxify" such toxic heavy metals (e.g., by heating them until they glow). Strictly speaking, these constituents are thus not contaminants but ingredients deliberately included for a specific curative purpose. Thus, to use the term "contamination" with respect to the presence of heavy metals in such remedies might be misleading. Contamination of AHMs by heavy metals is likely when faulty manufacturing processes are used.

Although contamination can be accidental, adulteration is by definition, fraudulent. The reasons why some AHMs contain prescription drugs are speculative. Manufacturers probably include such ingredients to render their products more clinically effective. If this is the case, it seems obvious that the inclusion of prescription drugs is fraudulent and illegal. The adulterants employed include a wide range of pharmaceuticals. Steroids appear to be a perennial favourite. The lax licensing system in India allows over the counter purchase of corticosteroids such as prednisolone, which are powdered and added to the AHM. The resulting clinical consequences are often serious and sometimes life threatening: agranulocytosis, Cushing's syndrome, coma, and excessive increase of the international normalized ratio (INR) have all been reported.

In other cases, the adulterants caused no symptoms at all and the problem was discovered only through routine check-ups or through the remarkably good clinical response, which turned out to be due not to the AHM, but to the undeclared prescription drug. Many consumers are motivated to try AHMs through a misconception that these remedies are inherently safe. Most of the individuals using herbal medicines do not reveal this fact to their physicians. This non-communication further aggravates the problem because doctors fail to diagnose adverse effects caused by medicines of which they are not aware. Consequently, most diagnoses are made retrospectively after the laboratory detects the contaminant.

Yet another problem relates to the fact that the majority of people taking herbal remedies combine them with conventional (allopathic) drugs. This opens the possibility of herb-drug interactions.

So, the question that must be addressed urgently is: how can the risk to patients be minimized from the indiscriminate use of indigenous medicines? Part of the answer lies in ensuring that appropriate strategy involving various agencies should be in place. The consumer should be informed that "natural" does not necessarily mean "safe," and that adverse effects as a result of AHMs are an undeniable reality. It is imperative that regulating authorities should evolve measures to control this sector of healthcare more effectively.

REFERENCES

1. Flanagan RJ, Braithwaite RA. Basic Analytical Toxicology. Geneva: World Health Organization; 1995.
2. Moffat AC, editor. Clarke's Isolation and identification of Drugs. 2nd ed. London: The Pharmaceutical Press.
3. Pandey RS, Tamrakar BP. Pharmaceutics of Metals in Ayurveda. New Delhi: Vedams Books Pvt Ltd; 1998.
4. Burtis CA, Ashwood ER, editors. Tietz Text book of Clinical Chemistry, 3rd ed. Philadelphia: WB Saunders; 1998.
5. Woods JS. Altered porphyrin metabolism as a biomarker of mercury exposure. Can J Physiol Pharmacol. 1996; 74: 210-215.