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Pharmacovigilance of Herbal Medicine: Herbavigilance

Hale Zerrin Toklu

Department of Pharmacology and Therapeutics, College of Medicine, University of Florida, FL, USA

Corresponding author: Hale Zerrin Toklu, Department of Pharmacology and Therapeutics, University of Florida, 1200 Newell Drive, P.O. Box 100267, Gainesville, FL 32610-0267, USA, Tel: +1 352 392-3395, E-mail: haletoklu@yahoo.com

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Abstract

Many patients use herbs/herbal supplements as an alternative and or adjunct to their prescribed medicine. Herbal products are preferred by population, because they are natural. Moreover they are believed to be “safe” and “have less side effects” than “synthetic drugs”. On the other hand, plants contain a number of active ingredients that produce physiological effect in the body. If an herb/herbal product is claimed to have beneficial effect on a certain health condition, then it must be capable to change the physiological system; i.e., exert a pharmacological response. Therefore, it may possess side effects as well.

Keywords: Herbal; Pharmacovigilance; Herbavigilance; Adverse effect; Adverse reactions; Safety; Herb-drug interactions; Pharmacist; Medicine; Public health; Herb; Evidence based medicine

Pharmacovigilance and Herbavigilance

Pharmacovigilance is the science and activity relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products [1]. The word "pharmacovigilance" is derived from pharmakon (drug in Greek) and vigilare (keep an eye on/monitor in Latin). As such, pharmacovigilance mainly focuses on adverse drug reactions (ADR), which are defined as any response to a drug which is noxious and unintended, including lack of efficacy. In this aspect, pharmacovigilance basically targets safety of medicine. Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients [2,3]. World Health Organization (WHO), FDA (US Food and Drug Administration) and European Medicines Agency (EMA) introduced legislation on pharmacovigilance [1,4,5] to promote good vigilance practice standards with increased transparency of pharmacovigilance data; thus paving the way for pharmacoepidemiological studies [6].

Many patients use herbs/herbal supplements as an alternative and or adjunct to their prescribed medicine. Herbal products are used by 20% of the population in US [5]. Herbal products are preferred by people, because they are natural; and they are believed to be “safe” and “have less side effects” than the “synthetic drugs”. On the other hand, plants contain a number of active ingredients that produce the physiological effect in the body. If an herb/herbal product is claimed to have beneficial effect on a certain health condition, then it must be capable to change the physiological system; i.e., exert a pharmacological response. Therefore, it may likely possess side effects as well. For example, if one would prepare herbal tea from digitalis leaves, they may have the signs of toxicity, although it is natural and herbal.

Herbal supplements should be commercially available after being standardized according to a particular active compound. Hence, there are number of problems regarding the use of these herbal products (Figure 1). Other than the effects of the biologically active constituents of the plant, side effects may be due to the herb-drug interactions or contaminants [7]. Because of all the above mentioned reasons, here are numerous case reports on PubMed due to adverse effects of herbal supplements, especially with the combination ones. However, most of them cannot be identified due to insufficient knowledge about the content of the mixture. A study from Canada showed that most of the herbal products tested were of poor quality, including considerable product substitution, contamination and use of fillers, or substances that are not listed in the label. In this study they analyzed 44 herbal products representing 12 companies and 30 different species of herbs, and 50 leaf samples collected from 42 herbal species [8]. The supplements used in government-funded clinical studies are analyzed for purity and standardized for dose. Supplement manufacturers are required to perform such analyses for FDA. Yet, according to a report aired in January 2016 by PBS's investigative series Frontline, few of the thousands of supplement manufacturers do so, and the FDA lacks the staff and resources to analyze supplements or to compel manufacturers to comply [9].

Regarding a product, not all the medical evidence has the same power. It is important to use the well designed, objective studies as a reliable source of evidence. The number of patients, their health condition, other accompanying disease conditions, inclusion/exclusion criteria, methodology, statistical analysis, bias and conclusions should be carefully evaluated. Evidence based medicine is a final decision making process for implementing the best treatment plan for the patient according to the external medical evidence that is compatible with national health policy and patient factors. On the other hand, use of these herbal products do not have concrete evidence for their efficacy for certain diseases, hence can be harmful. Thus, they mostly do not rely on “evidence based medicine” criteria [10].

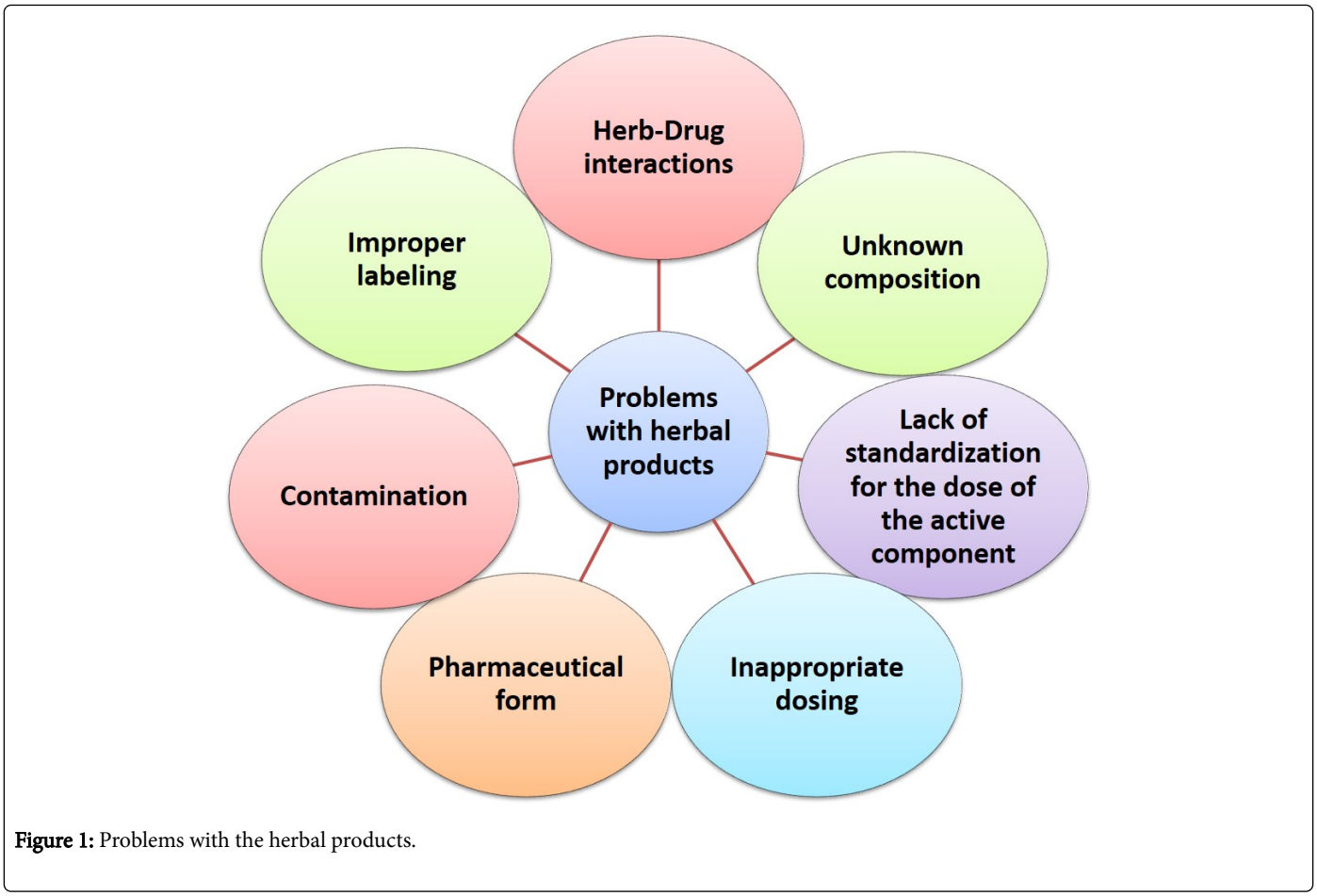

Figure 1: Problems with the herbal products.

The US Drug-Induced Liver Injury Network remains an important resource for analyzing drug induced-liver injury and continues to provide new information about idiosyncratic liver injury. Herbal and dietary supplements represent an increasing proportion of hepatotoxicity cases seen in the USA and abroad. It's important to identify better means of diagnosing and predicting toxicity, adverse effects and interactions of these products in order to improve the safety of current and future drugs [11].

Pharmacists' role in detecting and reporting adverse effects with herbal products

Pharmacists have a distinct role in identifying and reporting adverse effects due to herbal products; because they are literally experts on drugs of any origin either natural or synthetic. In most countries, pharmacists go through an extensive education on medicinal plants which are used in traditional folk medicine, as well as the synthetic medicines [12]. Therefore, pharmacists already have the knowledge to detect safety signals of drugs of any origin. Moreover, according to the 2012 FIP Pharmacist Workforce Report, global sample reveals that, on average, 55% of pharmacists were found to work in community pharmacy environments, 18% in hospitals, 10% in industry, 5% in research and academia, and 5% in regulation [13]. Roughly, 73% of pharmacists work in hospital or pharmacy settings, where they can face events based on adverse drug reactions or other drug related problems. Therefore, their involvement in pharmacovigilance systems is crucial [14].

A study with 1618 patients showed that the patients had insufficient knowledge about their prescribed drugs, although they had been using them for a while [15]. Also, ignorant use of herbs and herbal medicine concomitantly with the prescription drugs, is another problem [16]. Since many herbal products contain active ingredients that can interact with prescription medicines, WHO prepared a guideline on monitoring of herbal medicine in the pharmacovigilance systems [3]. The use of herbal products is not limited to cure of ailments, but they are also used for their potential ergogenic effects especially among athletes [17].

Discussion and Conclusion

A "herbavigilance" system needs to be established in order to assess the adverse effects that are caused by herbal products. For detecting the pharmacovigilance signals, information received from patients and healthcare providers plays a critical role in providing the necessary data. Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and guidance.

References

1. World Health Organization (2012) Safety monitoring of medicinal products: reporting system for the general public.
2. Stephens MDB (2004) Stephens' Detection of New Adverse Drug Reactions. In: Talbot J, Patrick W, West Sussex (eds.) John Wiley & Sons Ltd., pp: 1-88.

3. World Health Organization (2004) Guidelines on safety monitoring of herbal medicines in pharmacovigilance systems.
4. FDA's Sentinel Initiative (2013) US Food and Drug Administration. Silver Spring.
5. Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010. Official Journal of the European Union dated 31.12.2010. L 348/74-99.
6. Gulmez SE (2013) The new pharmacovigilance legislation and impact on observational studies. Marmara Pharm J 17: 61-64.
7. Bent S (2008) Herbal medicine in the United States: review of efficacy, safety, and regulation: grand rounds at University of California, San Francisco Medical Center. J Gen Intern Med 23: 854-859.
8. Newmaster SG, Grguric M, Shanmughanandhan D, Ramalingam S, Ragupathy S (2013) DNA barcoding detects contamination and substitution in North American herbal products. BMC Med 11: 222.
9. http://www.pbs.org/wgbh/frontline/film/supplements-and-safety/
10. Toklu HZ (2015) Promoting evidence-based practice in pharmacies. Integrated Pharmacy Research and Practice 4: 127-131
11. Sarges P, Steinberg JM, Lewis JH (2016) Drug-Induced Liver Injury: Highlights from a Review of the 2015 Literature. Drug Saf 39: 561575.
12. Toklu HZ (2015) Pharmaceutical Education vs. Pharmacy Practice: Do We Really Teach What They Need For Practicing? J Pharma Care Health Sys 3: e001.
13. FIP Global Pharmacy (2012) Workforce Report (eds.) Diane Gal Hague, Netherlands.
14. Toklu HZ, Mensah E (2016) Why do we need pharmacists in pharmacovigilance systems? Online J Public Health Inform (accepted).
15. Akıcı A, Kalaca S, Ugurlu MU, Toklu HZ, Iskender E, et al (2004) Patient knowledge about drugs prescribed at primary healthcare facilities. Pharmacoepidemiol. Drug Saf 13: 871-876.
16. Ozkum D, Akı O, Toklu HZ (2013) Herbal medicine use among diabetes mellitus patients in Northern Cyprus. J Med Plant Res. 7: 1652-1664.
17. Yavuz HU, Ozkum D (2014) Herbs potentially enhancing sports performance. Curr Topics Nutr Res 12: 25-34