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TANG [HUMANITAS MEDICINE]

Brief Communication

A brief survey on awareness of pharmacovigilance among ayurveda physicians in Sri Lanka

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ABSTRACT

Pharmacovigilance is the study of the safety of drugs under the practical conditions of clinical usage in large communities. Aim of this study was to assess the pharmacovigilance awareness among a focus group of Ayurveda physicians in Sri Lanka who participated for their postgraduate studies. A questionnaire which was suitable for assessing the basic knowledge, attitude and the practice of pharmacovigilance was designed and submitted among group of Ayurveda physicians (n = 30) who participated for postgraduate studies in Institute of Indigenous Medicine, University of Colombo, Sri Lanka. Among participants 30% of the subjects knew the term pharmacovigilance, 20% were aware of the unavailability of the National Pharmacovigilance Program for Ayurveda and Traditional Medicine in Sri Lanka, 70% believe about Adverse Drug Reactions (ADRs) may be occurred from Ayurveda medicine, 60% indicated that Most labeled counterfeit drugs, inappropriate use and standardization problems as the most important causes of ADRs associated with Ayurvedic drugs, 70% physicians accepted their ignorance about pharmacovigilance and admitted that there was a need for better training of this subject and 90% admitted that there should be a national pharmacovigilance programme for Ayurveda medicines in Sri Lanka.We strongly suggest that there is an urgent need for a regular training and the introduce ADRs reporting system among the Ayurveda physicians. Also systematic pharmacovigilance programme is essential to build up for reliable information on the safety and effective practice of Ayurveda medicine in Sri Lanka.

Keywords pharmacovigilance, Ayurveda, adverse reactions

INTRODUCTION

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Further it can be defined as the study of the safety of marketed drugs under the practical conditions of clinical usage in large communities. Recently, World Health Organization (WHO) concerns of pharmacovigilance have been widened and included herbal medicine (Erice, 1997; WHO, 2002). The specific aims of pharmacovigilance are to improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions, to improve public health and safety. Ayurveda and other form of Traditional Medicine (TM) have been practiced in Sri Lanka for more than 3,000 years. Ayurveda, as defined in the Act, encompasses all medical systems indigenous to Asia, including Siddha and Unani in Sri Lanka (Perera, 2012; WHO, 2001). The most important among them is Ayurveda, which also forms part of the national health services provided by the government of Sri Lanka. Number of Ayurveda physicians registered under the Sri Lanka Ayurveda Medical council is around 19,754 as at 31st December, 2010 as per the statistics available. Out of the General physicians Ayurveda counts 84.6%; Siddha system 12.7% and Unani 2.7%. Among the special physicians Ayurveda counts 96.5%; Siddha system 2.9% and Unani 0.6%. Apart from the above registered physicians at the Ayurveda Medical Council, there are more than 8000 Traditional Medical Practitioners practicing medicines who are decedents of reputed families with secret formulae to cure deceases engaged in Public Health Care. About 60 to 70% of the rural population relies on traditional and natural medicine for their primary health care. Ayurveda and other TM systems are used mainly plant and herbal preparations for the treatment of diseases, the former uses about 2000 plant species, the latter about 500. The plants are used singly or as mixtures (Weragoda, 1980). Therefore Herbal drugs are essential components of primary health care system in Sri Lanka (WHO, 2001).

The concept of pharmacovigilance is vibrant and is emphasized repeatedly in all major Sanskrit stanzas related to therapeutics in the main texts (*Samhitas)*. The major goals of pharmacovigilance, namely to improve patient care and safety in relation to drug use, is recurrent themes of Ayurvedic pharmacology (*Dravyaguna Vignana*) and therapeutics (*Chikitsa*) (Pranay et al., 2014; Thatte and Bhalerao, 2008). There is a misunderstanding that Ayurveda medicines are devoid of adverse reactions. However, the classic text book, *viz* the *Charaka Samhita* , describes all the adverse reactions to

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Table 1. Knowledge and attitude about Pharmacovigilance

Questions	Results		
Do you familiar the term pharmacovigilance?	Familiar		Not familiar
	30%		70%
Do Sri Lanka has National pharmacovigilance programme for Ayurveda or traditional medicine?	Not exist		No idea
	20%		80%
Do you believe about adverse drug reactions (ADRs are occurred in Aurveda Medicine?	Believe		Not believe
	70%		30%
What would be the major cause for adverse reactions of Ayurveda Medicine?	A,B &C	B &C	Not reply
A. Due to labeled counterfeit drugs B. Inappropriate use of medicine C. Lack of standardization	60%	10%	30%
Do you need better training of pharmacovigilance?	Yes		Not reply
	70%		30%
Do Ayurveda medicine need national pharmacovigilance programme?	Yes		Not reply
	90%		10%

medicines when they are prepared or used inappropriately (Yadav et al., 2012).

In ancient times, the traditional healers prepared medicines for their patients themselves in their territory. Today, only a few of practitioners follow this production and sale of Ayurvedic drugs has become formalized into a thriving industry. Commercialization of herbal drug industry has brought with it many challenges about safe use of herbal medicines, bringing into focus the need for formal pharmacovigilance programs in Sri Lanka. But still there is no such an initiation to develop pharmacovigilance program for Ayurveda and traditional medical system to report, record and rectify consequences in the national level. This may be due to the strong belief that herbal medicines are safe in therapeutic level. Other reason may be the lack of knowledge about the concept and importance of pharmacovigilance in Ayurveda among Ayurvedic practitioners in Sri Lanka. One of objective of this research was to initiate educational level programme for identifies and addresses challenges that preclude identification and reporting of adverse reactions of herbal medicine. Also another objective of this study was to build up attitudes and awareness of safe use of herbal medicine in Sri Lanka. As a pilot study for develop proper Pharmacogigilanve programme we done this brief survey among postgraduate student of Ayurveda in year 2013 and 2014 batches.

MATERIALS AND METHODS

A questionnaire (Table 1) which was suitable for assessing the basic knowledge, attitude and the practice of pharmacovigilance was designed and submitted among group of Ayurveda physicians (n = 30; female = 21, male = 09) who participated for postgraduate studies in Ayurveda at Institute of Indigenous Medicine, University of Colombo, Sri Lanka.

RESULTS AND DISCUSSION

Our results revealed that 30% of the subjects knew the term pharmacovigilance, 20% were aware of the unavailability of the National Pharmacovigilance Program for Ayurveda and Traditional Medicine in Sri Lanka, 70% believe about Adverse Drug Reactions (ADRs) may be occurred from Ayurveda medicine, 60% indicated that Most labeled counterfeit drugs, inappropriate use and standardization problems as the most important causes of ADRs associated with Ayurvedic drugs, 70% physicians accepted their ignorance about pharmacovigilance and admitted that there was a need for better training of this subject and 90% admitted that there should be a national pharmacovigilance programme for Ayurveda medicines in Sri Lanka (Table 1). According to results Ayurveda medicine system should be improved pharmacovigilance knowledge in physicians for their effective involvement especially in primary health care level.

This study showed slight awareness about the pharmacovigilance among the group of Ayurveda doctors who participated for this initiative survey. Most of physicians realized that ADRs may be occurred in Ayurveda medicine. They believed that there is no proper body to report it. Therefore, it seems necessary to hold awareness programme to realized that ADRs may be occurred in Ayurveda medicine. They believed that there is no proper body to report it. Therefore, it seems necessary to hold awareness programme to improve the ADR reporting and initiating pharmacovigilance programme in national level. Based on observations of Thatte and Bhalerao (5) in Indian context, following are the several interventions that we can way forward in attempting to embrace pharmacovigilance into Ayurveda system in Sri Lanka.

1. Implement a proper national pharmacovigilance program for Ayurveda, Unani, Siddha and Traditional systems of medicine through Ministry of Indigenous Medicine and Department of Ayurveda.
2. Introduce pharmacovigilance concepts into the curriculum of Ayurveda at the under-graduate and post-graduate level.
3. Encourage research on drug safety.
4. Make reporting of adverse reactions to regulators mandatory for Ayurvedic medicine.
5. Encourage public health and safety records of Ayurvedic medicines in Ayurveda health care centers and hospitals.
6. Make unbiased and easily accessible drug information available. The Traditional Knowledge Digital Library launched by the Government of India, is an example of how ancient knowledge available in the ancient scriptures can be made digitally accessible.
7. Create awareness about the science of pharmacovigilance among Ayurvedic physicians, patients and paramedical staff.
8. Development and validation of scales to assess the causality of the reported reactions to Ayurvedic medicines.
9. Give proper train for Ayurvedic experts in the science of pharmacovigilance and include them not only in reporting but also assessment of the adverse reactions.
10. Encourage to develop referral system for Ayurveda and western medicine practice.
11. Improve drug standardization, quality assurance and control in small and large scale drug manufacturing companies including Good Manufacturing Practice (GMP).
12. Proper validation and monitoring of quality and assurance of import Ayurveda drugs in the market.
13. Encourage to make unbiased proper investigation and

validation process before Ayurveda drug registration.
14. Make effective collaboration with stakeholders who engage in Ayurveda and other related sciences towards develop pharmacovigilance (Perera, 2013).

In order to generalize our findings, it is imperative that similar studies to be done in other Ayurveda physicians of the country. In conclusion, we strongly suggest that there is an urgent need for a regular training and the introduce ADRs reporting and evaluating system among the Ayurveda physicians. Also systematic national pharmacovigilance programme is essential to build up for reliable information on the safety and effective practice of Ayurveda medicine in Sri Lanka.

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CONFLICT OF INTEREST

The authors have no conflicting financial interests

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