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## Importance of homoeopathic posology in relation to pharmacovigilance: A review

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### Abstract

Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines. It is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, with a view to identify new information about hazards associated with medicines and preventing harm to patients. The results confirm effectiveness of the drug in clinical practice. Present study helps to know the risk and benefits of drug as there is a belief that medicines are diluted in Homoeopathy and it will not produce any unwanted aggravation. Doses are responsible for cure as it depends upon susceptibility, potency, and repetition of doses. Hahnemann did much experimental research through clinical trial and concluded to minimize the quantity of dose for best results. Homoeopathy therapeutic dose is capable of only producing a slight temporary aggravation or intensification of already existing symptoms, never of producing new symptoms. Clinicians must aware of distinction between Homoeopathic aggravation and Adverse drug reaction and serve public health accordingly without any harm.

**Methodology:** An intense literature search was made using electronic data bases, hand searching, journals, web pages, reviewing bibliography resources, available publications, Major scientific databases namely Pubmed, Science Direct and Springer were searched. The search words used were Pharmacovigilance, Safety of AYUSH drugs, Adverse Drug action, Posology, Doses in Homoeopathy.

**Results:** Thirty studies were included in the review. Most of research is carried on placebo control studies and Homoeopathic aggravations. Some studies concluded the presence of adverse events but their effects are very transient. Studies revealed that dose depends upon susceptibility of patient. Apart from drug adverse events studies showed light on different things like study of drug in different potencies and their effectiveness in different doses and these also should be validated scientifically and accepted by scientific fraternity.

**Conclusion:** Considering the importance of dose and there effect which may produce aggravation or adverse events which may be serious or transient, future research should focus on pharmacovigilance to aware clinicians on its risks and advise their patients accordingly.

**Keywords:** pharmacovigilance, dose, adverse event, drug action, potentiation, adverse drug reaction, susceptibility, WHO, Ayush

### 1. Introduction

Subject background: Homoeopathy is largest used alternative system of medicine which was invented by Christian Friedrich Samuel Hahnemann more than 200 years ago. Posology means doctrine of doses of medicine. The word dose is derived from Greek language 'dosis' which means 'giving the quantity of drug'. In Homoeopathic posology 'dose' means particular preparation of medicine, quantity, form of preparation of medicine and number of particular preparation of medicine. WHO says Pharmacovigilance as science and activities which is related to detecting, assessing, understanding and preventing of any adverse drug effects or any other possible drug related problems. The word pharmacovigilance consists of 'pharmakon' means drug and vigilare means to alert, meaning of word suggests to keep alert or keen observing action of medicine. The main objective of pharmacovigilance is drug safety, medicine safety and overall safe guarding public health.

Till 2007 in India, adverse drug reactions related to Indian systems of medicine were reported through National Pharmacovigilance Programme. In the year 2008, in regard to WHO guidelines for the safety issues of herbal medicines and to bring awareness on pharmacovigilance system for AYUSH drugs, Department of AYUSH, Ministry of Health & Family Welfare, Government of India, launched the National Pharmacovigilance Programme to report the adverse drug reaction for Ayurveda, Siddha and Unani (ASU) drugs in year 2008.

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In collaboration with WHO, a protocol of National Pharmacovigilance Programme for ASU drugs published by Department of AYUSH to provide proper documentation, monitoring, regulation and control of the activities in relation to pharmacovigilance. It was then followed by new scheme by Ministry of AYUSH in year 2017-18 as Central Sector Scheme for promoting pharmacovigilance of Ayurveda, Unani, Siddha and Homoeopathy (ASU&H) drugs. A three-tier network namely National Pharmacovigilance Centre (NPC), Intermediary Pharmacovigilance Centres (IPC) and Peripheral Pharmacovigilance Centres (PPC) has been established under this scheme. As per WHO Adverse drug reaction (ADR) means a reaction to a drug which is noxious, unintended and occurs at doses normally used on humans for the, diagnosis, prophylaxis or for therapy of any disease or for modification of any physiological function. Adverse drug event (ADE) is any untoward event that will occur during treatment with a pharmaceutical product but that does not have a direct causal relation to the treatment pharmacological effects depend upon amount of medicine used in quantity and repletion of medicine in doses.

### Need of study

There is a naïve assumption that medicines in Homoeopathy are diluted and prepared from natural sources it must be safe. The present review suggest us neglected issue of the distinction between Homeopathic aggravation, adverse reactions and adverse effects.

**Objectives:** To detect the problems related to use of Homoeopathic medicine and to provide safety to public. To assess benefit, harm effectiveness of medicine, risk of medicine etc Encouraging safety, cost effective medicine to public, understanding and educating the public about importance of doses and their application and different effects produced in different individuals which was clearly explained by Hahnemann

### Methodology

#### Materials and Methods

An intense literature search was made using electronic data bases, hand searching, journals, web pages, reviewing bibliography resources, available publications, Major scientific databases namely PubMed, Science Direct and Springer were searched. The search words used were 'Pharmacovigilance, 'Safety of AYUSH drugs', 'Pharmacovigilance in ASU & H drugs, Adverse drug reaction, Posology, Doses in homoeopathy.

### Study selection

All titles, abstracts and complete articles were independently reviewed to eliminate duplications.

**Inclusion criteria:** Publications of English language are used

**Exclusion criteria:** Unpublished data such as dissertations were not included.

### Data extraction

The database search was carried out to find relevant scientific papers published up. The database search yielded 30 records, which reveals there are some aggravations after

using medicine in some cases which were not serious but still studies are needed for further relevant data about adverse drug reactions. Need more support from clinicians, educational institutions for data report about adverse effects and aggravations.

### Discussion

Pharmacovigilance is an arm for patient care and surveillance aiming for getting the best outcome from treatment with medicines. No one purposely wants to harm patients, but unfortunately for different reasons if any medicine will produce harm then pharmacovigilance helps to study the adverse reactions and stop further harm.

Wide variety of plants, animals, minerals, nosodes, sarcodes, imponderabilia are sources of Homoeopathic remedies which are collected and preserved according to rules given in pharmacopoeia. Many plants like Nux vomica, Coffea cruda, Tabacum are used as medicines which contain alkaloids like Strychnine, Brucine, Caffeine, Nicotine etc. if Medicines are prepared directly from these sources it could produce harm to patients and healthy human beings but in Homoeopathy medicines are prepared in unique way. At first mother tinctures, mother solutions and mother substance are prepared and from it higher potencies are prepared through potentiation process which is speciality of Homoeopathy

Many pharmacological effects depend on both the concentration of the drug at the site of action and the time course of its appearance there. For example, a toxicity of methotrexate is greater when a low dose is given repeatedly than when the same total amount is given as a single dose. The risk of an adverse drug reaction differs among members of an exposed population. In some cases the risk of an adverse reaction will be present in susceptible subjects and absent in others

An adverse drug reaction (ADR) is a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product. This can be through the normal use of the medicine but also be as a result of misuse, abuse or medication error, overdose, off-label use or during occupational exposure. AE is any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment which Results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, sometimes results in persistent or significant disability/incapacity, Results in congenital anomaly or birth Defect. A serious adverse event is any untoward medical occurrence in any dose. To understand the concept of what constitutes a dose, it is essential to throw some light on the concept of the history of homoeopathy, and upon the development of the problem of dosage.

### Homoeopathic concept of doses

H.A Roberts mentions in his book 'The Principles and Art of Cure by Homoeopathy', Hahnemann's final views and practice in regard to the dose which were arrived at gradually, through long years of careful experiment and observation. His discovery of the principle of potentiation came about gradually as he experimented in the reduction of his doses, in order to arrive at a point where severe aggravations would not occur.

Hahnemann believes that a substance which can able to produce disease can able to cure disease and started proving medicines on healthy human beings .curative power of drugs lie in the power they possess of changing the state of man’s health .Drug after drug was tested by Hahnemann by himself and on his family and friends .After six years of careful study and observations he formulated principle ‘ similia similibus curantur’. As each man differs from another man in their individual aspects so each drug differs from another in their pharmacological properties. Hahnemann at beginning used large doses, in 1786 he used large and repeated doses of mercury , in 1796 he prescribed Veratrum alb, for bronchial asthma 3 grains every morning for 4 weeks. In 1813 he stated that smallest dose is sufficient to cure disease, there will be severe aggravation on large doses of medicine. Hahnemann observed undesirable medicinal aggravation even after well selected medicine is administered. He did many experimental research through clinical trial and concluded to minimize the quantity of dose for best results in first edition of Organon, Hahnemann said that by diminishing size of dose he can able to avoid aggravation and accessory effects of drugs . In introduction chapter vol 1 of chronic diseases he says that experience taught him to give higher potencies. In 6th edition of Organon of medicine he showed path for 50 millesimal scale potencies in which drugstrength is 1/50000

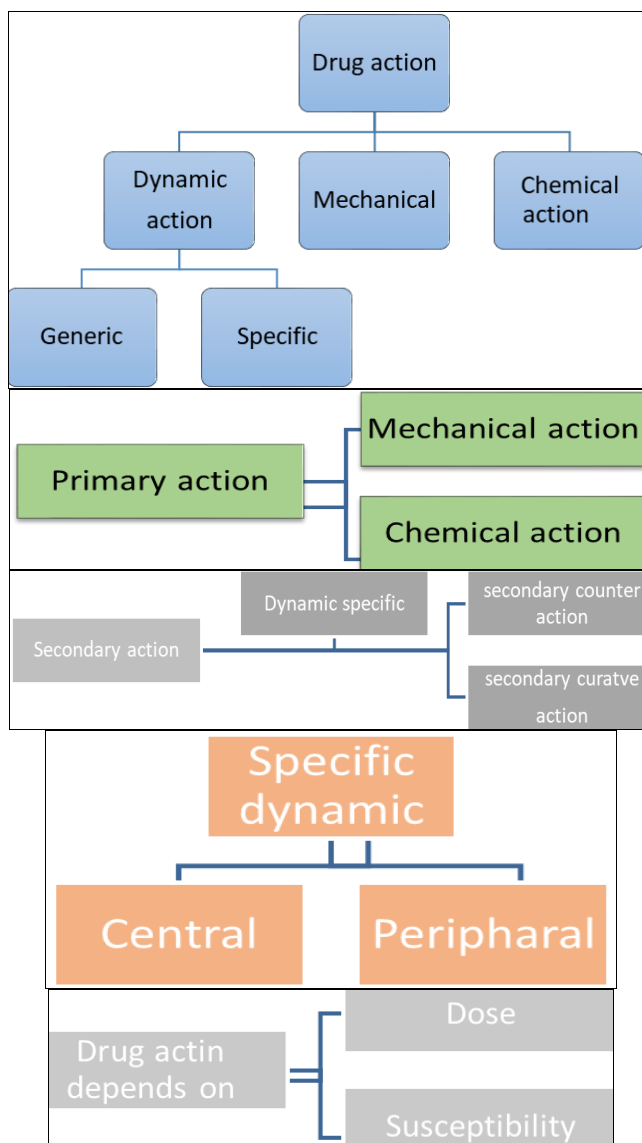
of original drug.

According to pharmacovigilanc there is a three dimensional classification system based on dose relatedness, timing, and patient susceptibility (DoTS) for adverse reactions Roberts mentioned in the chapter ‘Dose’ that the Homeopathic doctrine of dosage was based upon the discovery of the opposite action of large and small doses of medicine. Describing the Law of Mutual Action he gave an example of Ipecac, which in 3 large doses causes nausea and vomiting and in small doses, under certain conditions, will cure the same, Opium in large doses will cause a deep sleep or narcosis, and in small doses, under certain, conditions, will cure the same. Further he had given the distinction between physiological, therapeutic, and pathogenetic action of drugs. According to him the action of a drug may be pathogenetic (toxic), or therapeutic (curative), depending upon the size and strength of the dose, the susceptibility of the patient and the principle upon which it is given.

**Mode of action of doses**

Drug action depends upon dose and general receptive capacity of body mechanism.

Drug action is sum total of action imparted on an individual living human being and total of reaction that it can induce in vital force of same.



The symptoms which drug produce upon healthy organism vary according to dose. According to Arndt – Schultz law a substance which acts as a toxin in high concentrations acts as a stimulant in low concentrations. This phenomenon is known as hormesis. Small doses stimulate, moderate doses inhibit and large doses kill. Central symptoms in specific dynamic appears when large doses are taken and peripheral on taking small doses without any interruption for example, Mercury in certain doses shows its action on alimentary canal and its appendages (central symptoms), in smaller doses it produces symptoms on skin, glands (peripheral). Arsenic in certain doses shows chemical action, in smaller doses shows generic dynamic symptoms in still smaller doses specific dynamic symptoms of central variety and in yet smaller doses shows peripheral specific symptoms which are the symptoms of gradual poisoning. These varieties of symptoms are dependent upon dose. In moderate or small doses primary symptoms appear early, in large doses shows permanent alterations of tissues, sometimes symptoms of agony in fatal cases. T.F. Allen says the results of different doses vary. Hahnemann who has immense experience as a drug prover had been well aware of fact that symptoms which appear as contradictory depends upon dose. For this reason he recommends use of small doses in proving. For example appearance or nonappearance opposes series of symptoms of Nux vomica like constipation and diarrhea depends upon dose in which drug was proved. It can be understood only if repeated experiments are done with different doses on many provers. Hering says that the symptoms which arise in proving of higher potencies are similar to later effects of stronger doses.

### Conclusion

Considering the importance of dose and their effect which may produce aggravation or adverse events which may be serious or transient, future research should focus on pharmacovigilance to aware clinicians on its risks and advise their patients accordingly. The fast-growing popularity of Homeopathy and increasing use of self-medication of Homoeopathic medicines shows the need of pharmacovigilance of Homoeopathic remedies for patient safety. The present review provides the researchers information on the status of pharmacovigilance in Homoeopathic medicines and can guide them in planning future studies. In addition a pharmacovigilance centre may contribute to and participate in postgraduate educational programs. Findings or hypotheses from the pharmacovigilance system may be of potential interest for further study with regard to mechanisms, reaction frequency, and so on, to academic pharmacological institutions. Reports may include from clinical studies, spontaneous reports from healthcare professionals or patients or other intermediaries, reports from literature sources, plays great role for patient safety and measures.

### Conflict of Interest

Not available

### Financial Support

Not available

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