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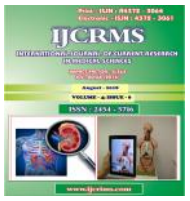

Review Article

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Literature review of Siddha drugs on Pharmacovigilance

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Abstract

Since centuries mankind has been using siddha system of medicine. Despite siddha medicines have clinical efficacy in innumerable diseases still striving for global acceptance because of lack in modern scientific ethos. People and siddha physicians repudiated to accept that siddha medicine may cause adverse effects which is unexposed. Now a days adverse drug reaction is explained in the term **Pharmacovigilance**. There is no absolute equivalent term for adverse effect and pharmacovigilance in siddha text.The technical term adverse drug reaction may be featured as **'NanjuKurigunam'** in siddha text. Publications regarding adverse reactions in Siddha system of medicine is minimally low rather than clinical efficacy of siddha drugs. Hence this is a small venture to discuss about pharmacovigilance in siddha system of medicine.

Keywords: Pharmacovigilance, Siddha, Nanju kurigunam.

Introduction

Pharmacovigilance (PV) is the branch dealing with adverse drug reactions (ADRs), their recognition, and reporting. Pharmacovigilance (PV) plays a key role in the healthcare system through assessment, monitoring and discovery of interactions amongst drugs and their effects in human[1].

According to World Health Organisation(WHO) Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem[2]. The idea of pharmacovigilance took shape mainly after 1961, after thalidomide tragedy was reported [3]. After the need for drug monitoring was well established worldwide, WHO's Programme for International Drug Monitoring began in 1968, with Uppsala Monitoring Centre (UMC) in Sweden being the collaborating centre for this global initiative.After understanding the need for a better Adverse Drug Reaction reporting system in India the Department of AYUSH, Ministry of Health and Family Welfare, Government of India launched the Pharmacovigilence programme of India (PvPI) in 2010 named National Pharmaco-vigilance Consultative Committee for ASU drugs (NPCC-ASU).

Pharmacovigilance in siddha system of medicine:

Siddha therapeutic drugs are designed to cure, treat and prevent diseases. Uniqueness in siddha system of medicine is siddha physicians are proficient to diagnose the disease, prepare the medicine and treat the patient. Now a days many pharmaceutical companies have been grown up for the manufacturing of medicine. There are so many steps involved in drug preparation begins from raw drug collection. There is a defined protocol for each step of drug preparation and drug intake. Adverse drug reaction may occur if the drug was not properly prepared or any improper schedule of drug intake. **.** According to WHO adverse reaction is defined as follows 'A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function'[4].

There is false impression about siddha medicine that it may or may not cause adverse effects but there is no clear picture regarding adverse effects. Adverse drug reaction content are scattered in Siddha literature. Adverse drug reaction is mentioned in Siddha text for specific drugs along with treatment in the term of **Nanju Murivu.**

In day to day practise we may came across some adverse reaction with the drug but failed to accept it. But in Various Siddha text, it is clearly mentioned the adverse reaction may occur due to improper preparation of the drug or improper schedule of drug intake. Drug intake includes Dose, duration, season, adjuvant and pathiyam. Some of the examples are given below.

Drug	Pathiyam /Purification	Suspected Adverse reaction
Lead [5]	Avoid foxtail,kodo,abin,tamarind,sesbania sesban, cucurbita maxima, vigna unguiculata,Coitus.	Blackish or bluish discolouration of teeth gums, acute abdomen, pain, constipation ,bloating, hyper relaxed muscles jaundice, dyspnoea, urticarial rashes may occur.
Copper [6]	Add ghee, butter,milk, appam,adai,aval, sugar,pori,payaru,banana.	Cough, hiccough, giddiness, increased salivary secretion, irritation in the chest, throat pain ,sounds like elephant may occur.
Red sulphide of mercury[7]	Add Milk and rice	Ulcer in mouth, uvula,throat,large intestine. Restriction of intake of spicy foods .Difficulty in speaking intake of foods ,liquids will be present. Halitosis, distaste, burning sensation in the stomach .saliva will be sticky and white in colour like palm toddy,vinegar.
Hydragyram sub chloride[8]**:**	Avoid salt and tamarind .Take cows milk once in a day. After 7 days take fried salt, cajanus cajan. On 15th day take head bath with ocimum sanctum and then take oil bath.	Papules and pimple like rashes, ulcer in depression of the chest,restricted intake of spicy food,orchitis,ulcer in uvula,diarrhoea,dysentery.
Hydragyrum perchloride[9]	Avoid salt and tamarind .Take cows milk once in a day. After 7 days take fried salt, cajanus cajan. On 15th day take head bath with ocimum sanctum and then take oil bath.	It causes toxcicity in blood,increased salivation,inflammation and ulceration of mouth, throat,stomach.vomiting ,diarrrohoea,dysentery,difficulty in swallowing of saliva,swelling of the face,fissure in the skin with oozing,thirst,hiccough,giddiness,fainting,fits.

Arsenic trisulphidum[10]: Bleeding in nailbeds,ulcer with scab and pus,burning sensation in stomach,change in voice,epitaxis,distaste,lack of appetite,itching and redness in hairbed,difficulty in breathing,illusion,swelling in lower abdomen.pain in hip and chest.	Avoid tamarind and salt.	Bleeding in nailbeds,ulcer with scab and pus,burning sensation in stomach,change in voice,epitaxis,distaste,lack of appetite, itching and redness in hairbed, difficulty in breathing, illusion, swelling in lower abdomen. pain in hip and chest.
Arsenic [11]		Papules ,puffiness of the face, ,bitter taste,swelling in nose,ulcer in upper palate,lip,kalimbu taste, increased salivation ,nausea,pain in throat,difficulty in swallowing,burning sensation in stomach,vomiting and diarrhoea, blood stained vomitus and stools,bad odour in vomitus,thirst,anuria,gidiiness,tetany like spasm,delirium,sometimes anasarca leading to death.
Mica[12]	Avoid tamarind ,tobacco,,coitus,brassica juncea,alcohol,sesbania sesban	Death may occur if pathiyam of coitus not followed properly rather than other things
Semecarpus anacardium[13.]	If not properly purified	Blisters and redness in lips,mouth,tongue,throat,stomach,Altered fatty changes in liver if taken orally. If latex come in contact externally in skin ,redness and blisters will be present in the skin.

Types of adverse reaction:

Historically, ADRs have been classified as type A or type B. All ADRs are not fit in to type A and type B. Again they are classified in to another two types. These types we may apply in Siddha system also[14].

Type A:

Type A reactions are predictable from the known pharmacology of a drug and are associated with high morbidity and low mortality.

Example:

The dose of Vanga parpam (Lead parpam) is weight of the one fourth weight of Cajanus cajan. If it exceeds the dose it may cause adverse reaction[15].

Type B:

Type B reactions are idiosyncratic, bizarre or novel responses that cannot be predicted from the known pharmacology of a drug and are associated with low morbidity and high mortality.

Example:

Adjuvant, intake of the drug during a specific season, pathiyam if not followed properly type B adverse reaction may occur.

Type C (chronic/cumulative):

It generally gives cumulative effect.

Example:

The duration of intake of poora parpam is only 7 days. if taken for more than indicated duration it may cause cumulative effect[16].

During the intake of annabedhi chenduram purgation therapy have to be incorporated once in 10 days. More than 10 days of intake leads to constipation and this gives cumulative effect[17].

Type D (delayed/onset):

It is carcinogenic and genotoxic.

Discussion:

Certain guidelines are described in Siddha text to prevent adverse effects which are mentioned below.

Guide lines to be followed in Siddha pharmaceutical preparations:

Collection
Identification
Purification.
Isolation.
Synthesis.
Standardisation.

Guide lines to be followed:

Line of treatment will enhance the therapeutic effect:
Oilbath.
Purgation or Emetic or Nasiyam therapy accordingly.
Internal medicines.
External therapies.

Guidelines for oil bath:

Oil bath is done usually with Gingley oil. During oil bath a person has to apply oil from head to toe and bath with herbal powder mentioned below. Within 3 hours from Sun rise is most suitable time to take oil bath. In general Saturday is ideal for oil bath for men and Friday for women.

Take *Curcuma zedoaria* (Round zeodoary), pepper, neem seeds, outer skin of *Terminalia chebula* (*Chebulic myrobalan*) and kernel of *Emblica officinalis* (Indian gooseberry). Grind these ingredients with cow's milk (Kaarampasu). Boil them well. It is applied externally on the head prior to head bath.

Avoid coitus and cucurbita maxima, macratyloma uniflorum, brassica juncea, vinegar, sorghum bicolour in diet. Add cows ghee, milk, sugar, wheat, powdered rice.

Dose:

Prescribed dose have to be taken.

Adjuvant :

To enhance the therapeutic efficacy drugs should be taken along with prescribed adjuvants.

Duration and season:

Some medicines like Linga parpam ,Abiraka chenduram have to be taken in a specific season and specific duration which is already mentioned.

Pathiyam :

It is related to DO'S and DONT'S related to diet and habits.

Reporting adverse reaction for siddha drugs:

Reporting procedures for India's pharmacovigilance program for ASU drugs[18]

India's National Program of Pharmacovigilance for ASU drugs was adopted under the following blueprint in accordance with recommendations of the expert group made at its meeting on 28-29 August, 2008.

What to report?

The National Pharmacovigilance Programme for ASU drugs (NPP ASU) shall encourage reporting of all suspected drug related adverse events, including those suspected to have been caused by interaction with any other drugs or food incompatibilities. Reporting of seemingly insignificant or common adverse reactions may be important, since it could highlight a widespread prescribing problem.

The program particularly solicits reports of

- all adverse reactions suspected to have been caused by ASU drugs either alone or in conjunction with other drugs
- all suspected drug interactions
- reactions to any other drugs suspected of significantly affecting a patient's management, including reactions suspected for events in the following categories
- death
- life threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent, or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage.

The prescribed 'Adverse Drug Event Reporting Form for ASU Drugs' shall be used for the purpose of the National Pharmacovigilance Programme for ASU.

Who can Report?

Any health care professional may report suspected adverse drug events. The program does not accept reports from lay members of the public, nor others than health care professionals. Others can report through the physician under whom they have undergone treatment.

Where to report?

Reporting should be done in a prescribed format through a local pharmaco-vigilance center.

Direction of submitted information:

Information in the forms is to be handled in all confidentiality. Peripheral pharmacovigilancecenters forward the form to their Intermediary pharmacovigilance centers where causality analysis is carried out. The information is then forwarded to the National Pharmacovigilance Resource Centre, where it is consolidated, statistically analyzed, and forwarded to the Ministry of AYUSH.

Conclusion

By reporting adverse reaction in Siddha drugs we can ensure drug safety ultimately leads to drug development and universal acceptance .

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