Review Article

Need of Pharmacovigilance in Siddha System of Medicine

A. Alif Fathima[1]*, M.P. Abdul Kader Jeylani[2], S. Balamani[3], U.Kavitha[4]

[1]P.G. Scholar, [2]Professor, [3]Lecturer, [4]Program Assistant, Peripheral Pharmacovigilance Center
Govt. Siddha Medical College, Palayamkottai

ABSTRACT

Pharmacovigilance is defined as the detection, assessment, and prevention of Adverse Drug Reactions (ADR) in humans. Ministry of AYUSH, Government of India, New Delhi has initiated the Pharmacovigilance Program for ASU & H drugs. The main aim of Pharmacovigilance is to improve patients care & safety in relation to the use of medicines. The Siddha system of medicine is mainly practiced in South India. It is one of the earliest traditional medicine systems in the world which treats not only the body but also the mind and the soul. Although the term Pharmacovigilance is actually not featured in Siddha texts, it is vibrant throughout literature. This paper deals with the chances of occurrence of ADR in Siddha Medicine and its prevention. ADR may occur from birth of the drug to clinical application which involves various disciplines. No doubt, standard ingredients processed through standardized production method would give standard finished products which prevent ADR. Also, Right drug at Right dose for Right person with Right diet and Right Vehicle will prevent ADR. Therayar, ancient Siddhar explained the possible complications of medicines i.e. ADR along with their antidote and precaution.

Keywords: *Siddha Medicine, Pharmacovigilance, Adverse Drug Reaction.*

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Corresponding Author

A. Alif Fathima
Govt. Siddha Medical College, Palayamkottai
E-mail: aliffathima1992@g mail.com

INTRODUCTION

PHARMACOVIGILANCE

According to WHO: Pharmacovigilance is the science and activities relating to the Detection, Assessment, Comprehending and Mitigating the Negative Consequences of Medications. Pharmacovigilance is the systematic process of gathering, monitoring, investigating, assessing, and evaluating data from healthcare professionals and patients regarding the negative effects of drugs and biological products. As to the World Health Organisation (WHO), an adverse medication reaction refers to a harmful and

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unanticipated response that occurs at the typical dosage used in humans for preventing, diagnosing, or treating diseases, or for altering normal bodily functions. Adverse drug reactions are a significant contributor to illness and death in humans.[1]

PHARMACOVIGILANCE IN SIDDHA SYSTEM OF MEDICINE

The Ministry of AYUSH has introduced new Central Sector scheme for promoting Pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs.[2] Siddha therapeutic drugs are designed to cure, treat and prevent diseases. Uniqueness in Siddha system of medicine is Siddha physicians who are proficient to diagnose the disease, prepare the medicine and treat the patient.[3]

CHANCES OF ADR IN SIDDHA SYSTEM

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 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.[3]

COLLECTION / PRODUCTION OF RAW DRUGS

According to the Siddha writings, it is specified that the herbs must be cultivated in fertile and favourable soil, in a state of good health, without any damage or threat from predators. Additionally, it specifies that herbs cultivated in infertile soil, cemetery sites, wetlands, and sandy areas, along food pathways, consumed by moths/termites, impacted by forest fires, and diminished by extreme cold are unsuitable for therapeutic use. Regrettably, in actuality, these preconditions are often not upheld due to numerous factors. Various significant elements, such as age, plant habitats, variations in collecting time and altitude, and post-harvest conditions, can indeed modify the active compounds.[4] The season of collection of raw drugs and geographical area of collection have great impact in the expression of pharmacological activity. According to Ancient Tamil Classics, the geographical areas (*Kurinji*- Mountainous region, *Mullai*- Forest areas, *Marutham*- Cultivation area, *Neithal*- Sea shore and *Palai*- Desert area) have features that are ethnic to that area. Commonly the plants collected in Marutham and Kurinji area are highly nutritive and possess medicinal value; but the herb in other areas imbalances three humours and paves the way for certain pathological conditions.[5]

SYSTEMATIC IDENTIFICATION

The systematic and anatomical components of plants have a crucial significance in the context of plants and plant products in ISM. For instance, various plants are grouped together under a same name. Various plants and plant products from distinct genera and families are assigned a single name.Four

It is essential to accurately identify medications derived from minerals or animals, in addition to herbal drugs. The medication chinakkaram, which was utilised by ancient physicians, consisted of potassium aluminium sulphate. The medicine now on the market is ammonium aluminium sulphate.[4]

ADULTERATION

Adulteration is a practice of substituting the original crude drug partially or fully with other substances which is either free from or inferior in therapeutic and chemical properties or addition of low grade or spoiled drugs or entirely different drug similar to that of original drug substituted with an intention of enhancement of profits. It is invariably found that the Adverse Event Reports are not due to the presence of an intended herb but rather due to the presence of an unintended herb.[9]

SUBSTITUTION

Substitutes, such as Maramanjal Coscinium fenestratum (Menispermaceae) and Berberis aristata (Berberidaceae), are officially allowed whenever possible. Both of these substitutes contain berberin as the main component, although the amount may vary.[4]

METHODS OF DETOXIFICATION AND PURIFICATION

Prior to commencing the preparation process, it is essential for the medicine to undergo a standard purification method, if required, as there exist multiple purification processes.Four Suddhi is a distinctive detoxification method used to purify and boost the potency of different types of raw pharmaceuticals used in Siddha formulations. Its purpose is to lessen the poisonous elements and effects of these drugs while also increasing their medicinal characteristics. For instance, Nabi, Aconitum sp., is a toxic substance that is utilised as a medicinal medication after purification, typically by soaking it in cow's urine. Through these procedures, the active components no longer exhibit their heart-depressing effects, but instead become stimulants with a slight cardiotonic property.[4]

Bharatha mathiyaana Palavaippu charakkun sirsila
Seereya moolithanum seyamaana suddiindri
Thaerunal marunthu Serthu thindrida
maranamendraarum.

- **Pararaasasekar**
-

If the drug is taken without purification, this results in death.[6]

METHODS OF MANUFACTURE

The Siddha system of medicine has implemented its own essential principles in the field of pharmaceuticals. It encompasses a wide range of internal medications and external therapies. The methodologies and tools employed

for the formulation of Siddha medications are thoroughly elucidated in the literature.The creation of a formulation requires a series of stages, including powdering, heating, boiling, drying, grinding, calcinations, sublimation, filtration, and others. Each step necessitates the careful and delicate treatment of the active ingredients to ensure that their efficacy remains intact.Four The modification in the medication processing technique is also exerting a significant detrimental effect on the formulations. The medications may have harmful effects as a result of misprocessing. For instance, if pollutants such as Thodam are not effectively eliminated during the preparation of Rasam, it might result in many health conditions including skin disorders, haemorrhoids, neurological disorders, respiratory problems, and in rare cases, even death..[5]

Pakkuva paagathaiuru panchinmarunthum pirazha
Pakkuva paagathup parumarunthum – Meikurungaal
Akkaalamum paranum Aazhimarunthun Sedan
Sukkalamum porunthungaan.

- **Pathaartha Guna Chinthamani**

If the drug has not attained its perfect quality, it equals to the poison of Adhiseshan (Serpentine Demigod) poison.[7,13]

Paagamodatattik kulirntha paani erasayananal
Vegavilegan kudineer meisurasam – Yaegumeraa
Meentha venchsanathigalai meela orukkaazhatti
Maantha nanjum vaerirukumo

- **Pathaartha Guna Chinthamani**
-

If Medicines once prepared, it should not be reheated. if it is heated again, it will become poisonous.[7]

DOSE

Claude Bernard was great Physiologist once said "Everything is poisonous, Nothing is poisonous" all depends on dose that we used. Poison can be used as a medicine in proper dose. No drug is poisonous, and No drugs is safe it means Safety and efficacy of a drug depends on the dose of drug.[1]

Avizhtha kadumaiyanal agan thalarung
Kaviralar Polae irukkung Kankal Upasaanthi
Seivathu Moothandamur Ser Ver Neipaantha
Mei kudineerae yamaiyum

- **Therayar Venba**

Siddha Literatures describe that if a medicine is taken at higher dose, ADR such as weakness, red eye will develop.[6]

PRESCRIPTION

The ideology underlying the customised formulations in Siddha medicine aims to avoid side effects and after effects. Indiscriminate administration of synthetic compounds can exacerbate the imbalance of the physical system, whereas natural products containing a balanced ratio of the five elements positively support the physical system. Therefore, the adoption of Western practices in our traditional medicine may lead to serious repercussions, such as the occurrence of negative medication reactions similar to those observed in contemporary medicine.[8]

Avizhtha uphasaanthi Yaar ariya poraar
Navilum athanaal undaagum nanmai kavalaiyara
Karravarkunch sarrae Kalangumana mathanal
Arramarach sei illayam.

- **Therayar Venba**

Siddha Doctor must know the therapeutic effect as well as treatment for ADR if it produce.[6]

ADR TYPE F

Konda viresanathaar koru malangaliya
Thandidinum vanthi pinnagidinum – Pandithanae
Neetathae meendum nigazhu mathanveerai
Otta orusanthi yodhu.

- **Kannusaamiyam**

If an individual takes a purgative medicine, it results in therapeutic failure or it leads to vomiting. Then the Physician should not repeat the same medicine instead treat with some herbal decoction.[10]

PATHIYAM (DO'S & DON'T DO'S)

Pathiyam ponaal palan pomarunthugalum
Sutthi ini noigal anugume – Pathiyangal
Undaanal unda uruthi Avizhthangat
Kendaalum unmai ithe.

During medication Diet should be followed according to the medicine, otherwise the disease will lead to severe.[11]

FOOD INTERACTION

A food can turn toxic when it combines with certain other food items and such combinations should be avoided. For instance, milk and fish should not be taken together. On the contrary, certain combinations of food have proved extremely useful in removing the ill effects. For example, jack fruit taken along with ghee or honey and groundnut along with palm jaggery is considered as an ideal combination. Siddha system recommends dietary regimen to enhance the therapeutic activities of drugs. In certain clinical conditions, to avoid drug-diet interaction, usage Of bitter gourd, sesbania leaf, yellow pumpkin, fish and dry fish and garnishing of Food should be avoided.[12,14]

ADJUVANT

Adjuvant (Tunai Marunthu), vehicle (Anupanam) and dietary regimen (Pathiyam) also play a role in Pharmacodynamics. Many drugs are prescribed for various ailments based on the clinical manifestation, Body constitution and age. The same drug / formulation, by

merely changing the vehicle, can possibly change the signalling pathways of medicine and probably target different receptors resulting in different therapeutic effects.[14] Lack of knowledge in the use of anupanam is the main cause for the failure of many Siddha practitioners at the bed side.[15]

COMMON ADR

Kollum marunthondril koorum nalitheernthu
Kallappini verukandidin kel ulla
Marunthaga thendrae maruthuvathil landror
Karunthamaithu koorinar Kandu

When the medicine is administrated for a particular disease, if it produce adverse effect, then the medicine should be stopped.[10]

Adverse Drug Reaction may be Sweating, Tiredness, Palpitation may present.[13]

DRUG MISUSE

Vaenda marunthendru Veenu karuthuvathu
Poondagu meikkup porunthiyathu meendum
Saeritha arinthathanai thinnil siruthu
Mariththu vidaamal vazhvar.

The patient has to take the medicines only if it is needed for a healthy life. Avoid to take unwanted medicines.[11]

DISCUSSION

Siddhars have used minerals mostly in chronic conditions and as life saving agents. They have described the possible adverse effects in a drug preparation when the Standard Operating Procedure (SOP) is not followed. A proper purification process (suthi) and strict adherence to the SOP laid down by Siddhars in preparing the medicine, correct dosage, adjuvant and duration of administration will ensure Safety of Siddha formulations. Thus, perfectly processed drugs can be safely used as Therapeutic agents. Nanju Maruthuvam (Siddha Toxicology) clearly explains the possible adverse drug reaction of Siddha drugs or toxicities and their management in detail.[14,16,17]

CONCLUSION

This research examines the likelihood of adverse drug reactions (ADRs) in Siddha Medicine and explores methods of prevention. Adverse drug reactions (ADR) can manifest at any stage, from the medicine's inception to its clinical implementation, including multiple fields of study. Undoubtedly, utilising conventional materials processed using a uniform production procedure would result in standardised final goods that effectively mitigate adverse drug reactions (ADRs). Administering the appropriate medication, in the correct dosage, to the suitable individual, along with a proper diet and mode of administration, will effectively mitigate the occurrence of adverse drug reactions (ADRs). The adverse occurrences reported by the PV system have the potential to provide advantages to the community because they are close to both the population and public health practitioners.

The advancement of efficacious pharmaceuticals significantly enhances the physical health and overall welfare of folks. Nevertheless, there is a necessity to boost photovoltaic (PV) systems in order to more efficiently oversee and address safety concerns related to medications, hence augmenting their impact on public health. Therefore, ensuring pharmacovigilance for the safety of medical products is a shared obligation of the industry, drug regulators, physicians, and other healthcare professionals. The primary goal is to facilitate the recovery of patients and, ideally, prevent illnesses from occurring.

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