

Literature Evidence Of Pharmacovigilance In Siddha SystemM.V. Aishwharyah^{1*}, K.Balagurusamy²

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Abstract

The purpose of pharmacovigilance is to detect, assess, and understand, and to prevent the adverse effects or any other possible drug-related problems. Herbal medicines have been regarded as safe to be consumed as over the counter medicines by the public considering their natural origin. Several herbal formulations have been scientifically proven to be antidiabetics, bronchodilator, hepatoprotectives, antioxidants etc. The commonest myth of the complete safety irrespective of their processing, dosage and physician's advice has misled the people to self medicate causing disappointing side-effects or unwanted after effects. Hence there is an emergent need for an increasing awareness for pharmacovigilance practice in relation to their use alone or in combination with synthetic drugs and to monitor the safety of these conventional medicines. The traditional Siddha texts also highlights the possible toxic effects of the raw materials of plant, metal or mineral origin when they are substandardly purified, processed, stored and failure of dietary restriction (*Pathiyam*). This review is a documentation of the literature evidences on drug toxicity and its symptoms in order to create awareness on pharmacovigilance of Siddha medicines.

Keywords: Adverse Reaction, Siddha Medicines, Pharmacovigilance, Natural Medicines, Mineral drugs

Introduction

The traditional Siddha system of medicine is an age old science practised widely in TamilNadu, India. The Siddhars who were the founders of this system were supreme divine humans who by their wisdom have indicated various plants, metals and minerals for the human ailments to attain the state of heavenly bliss. The Siddha system cannot remove itself from the application of pharmacovigilance due to the fact that Siddhars are also aware of the adverse effect of these natural sources when they are not properly prepared and processed and have indicated the toxic effects in the

literature. Although the term pharmacovigilance is actually not featured in Siddha texts, it is vibrant throughout literature.^[1]

Offlate, Pharmacovigilance and its associated tools have been developing in relation to synthetic drugs to optimize the safety of herbal and herbomineral formulations. Safety monitoring of herbal medicines is improved by modifying existing methodology.^[2] This paper deals with the adverse drug reactions in Siddha system, and the need for pharmacovigilance of herbal medicines and future suggestions.

Siddha Literature Review On Adverse Effects Of Selected Herbs, Metals And Minerals

According to Siddha literature, drug preparation starts right from purification process, to preparation, dosing and diet restriction. Failure to the adherence of any of these guidelines may result in adverse events. At the same time, purified herbs, minerals and metal compounds have been scientifically evaluated to be safe without causing any adverse events. For example purified Pooram (Mercurous chloride) as per Siddha literature shows the nanoconversion with presence of heavy metals within the limits. Poora parpam revealed the evidence based result for the presence of nano particles within the formulation. Nano particles have multiple mechanisms in biological environment such as cellular penetration, alteration in physiology, regulation of enzyme function, restoring cell environment and functional property.^[3] Therefore it is highly essential to follow a strict adherence to the prescribed procedures as per Siddha literature.

Table-1 Commonly Used Mineral Compounds And Their Adverse Effects On Improper Preparation And Misuse^[4]

S.No	Mineral Compounds	Symptoms Of Adverse Effects
1.	Hydragyrum subchloride (<i>Pooram</i>)	Ulcerative gastritis, ulcerative gingivitis, ulcerative stomatitis, ulcerative glossitis, foul smell in saliva, dysphagia, pimples and prickly heat, lumbago, ulcerative uvulitis, orchitis
2	Cinnabar (<i>Lingam</i>)	Ulcerative gastritis, ulcerative stomatitis, ulcerative uvulitis, ulcerative enteritis, ulcerative laryngitis, aphasia, halitosis, burning sensation in the stomach, toddy or vinegar like saliva and dysphagia.
3	Litharge (<i>Mirudharsingi</i>)	Stomatitis, dryness of throat, gastric ulceration, pruritis with ulcers

4	Camphor (<i>Karpooram</i>)	Burning sensation in the stomach and internal organs, haemetemesis with camphor odour, headache and heaviness of head, bodyache, Malaise, convulsion, hallucination, ataxia, inflammation of gastrointestinal tract
5	Lead (<i>Vangam</i>)	Blackish or bluish discoloration of teeth gums, acute abdominal pain, constipation, bloating, jaundice, dyspnea, urticarial rashes
6	Copper (<i>Chembu</i>)	Cough, hiccough, giddiness, increased salivary secretion, irritation in the chest, throat pain
7	Copper Sulphate (<i>Thurusu</i>)	Metallic taste, nausea, excessive salivation, haematemesis with bad odour, gastritis, flatulence, dysentery, contents of the vomitus stench like fish odour dryness in throat, morbid thirst, anuria, cerebrovascularataxia, anorexia, excessive lacrimation
8	Arsenic (<i>Vellai paadanam</i>)	Papules, puffiness of the face, bitter taste, swelling in nose, ulcer in upper palate, 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, giddiness, tetany like spasm, delirium, anasarca
9	Arsenic trisulphidum	Bleeding in nail beds, ulcer with scab and pus, burning sensation in stomach, change in voice, epistaxis, lack of appetite, itching, difficulty in breathing, Illusion, swelling in lower abdomen, pain in hip and chest.
10	Mica (<i>Abiragam</i>)	Cough and wheezing sound arises from chest like an asthma, congestion in chest, flatulence, distension of abdomen
11	Calcium carbonate (<i>Chunnambu</i>)	Lime is used along with betel leaves and areca nut. If it is consumed excess it causes oral ulcers, burning sensation of stomach, gastritis, stomatitis, glossitis, pharyngitis, vomiting and diarrhoea

Table-2 Traditional Herbs And Their Adverse Effects On Improper Preparation And Misuse^[5-6]

S.No	Mineral Compounds	Symptoms Of Adverse Effects
1.	Abrus precatorius (<i>Kuntrimony</i>)	Vomiting abdominal colic, burning sensation in the stomach, diarrhoea, anorexia, body ache
2	Calotropis gigantea (<i>Erukku</i>)	Ulceration in the mouth and stomach. Nausea, vomiting, diarrhoea, gastritis, upward gaze, unconsciousness, exhaustion, perspiration, spasmodic pain in

		calf muscles, diminished vision, bitter taste, blackish discolouration of teeth, syncope
3	Plumbago (<i>Chithira Moola ver</i>)	Inflammation and ulceration. If it consumed in excess, it induces irritation and gastritis.
4	Datura alba (<i>Umathai</i>)	Dryness of mouth, difficulty in speaking, dilatation of cutaneous of blood vessels, dilatation of the pupil, dull vision, delirium, drowsiness, dysphagia
5	Strchnos nux vomica (<i>Etti kottai</i>)	If it is used for a long period it leads to nervous debility and causes sterility in women and spermatolysis.
6	Papaver somniferum (<i>Abini</i>)	Giddiness, indigestion, vomiting, dyspnoea, constricted pupil, occasional dilation of pupil, facial paralysis, Laziness, constipation, pallor of the face, cyanosis, hyperhydrosis, convulsions' psychiatric illness with mental disorders.
7	Aconitum ferox (<i>Naabi</i>)	Generalized pruritis, body pain, discolorization of the body, abdominal Colic, vomiting, anorexia. Heavyness of the lower abdomen, feeble pulse, hallucination, syncope, disturbed sleep, blood stained diarrhoea with pain.
9	Nicotiana Tabacum (<i> Pugai Elai</i>)	Cardiac problem, Anasarea, anaemia and spermatolysis. Rapid pulse followed by feeble pulse alternatively, Dyspnoea, giddiness, unconsciousness, lassitude, exhaustion, vomiting, diarrhea, abdominal colic, blurred vision, anemia, fatigue, anasarca, disease of the liver.
10	Gum myrrh (<i>Raktha polam</i>)	Ulcer, erythema, Inflammatory swelling, burning sensation, inflammation of gastro intestinal tract, vomiting and altered taste.
11	Semecarpus anacardium (<i>Seran kottai</i>)	Blisters and redness in lips, mouth, tongue, throat, stomach, altered, fatty changes in liver if taken orally. If latex comes in contact extremely in skin, redness and blisters in the skin

Need For Pharmacovigilance Of Traditional Medicines

An AR is defined as a noxious and unintended response to a marketed health product, which occurs at doses normally used or tested for the diagnosis, treatment, or prevention of a disease or the modification of an organic function.^[7] More than 60 to 70% of modern medicines in the world market are directly or indirectly derived from plant products.^[8] Therefore we need to move forward in attempting to provoke pharmacovigilance in herbals and mineral formulation. Introducing

pharmacovigilance concepts into the curriculum of herbals at the undergraduate and postgraduate level and reporting of adverse reactions to regulatory mandatory for traditional formulations would pave way for the essential to standardize the traditional formulations. Yet another interesting part of Siddha literature is that for the mentioned adverse effects, the antidotes have also been prescribed^[6]

Conclusion

The wide use and easy availability of herbal medicines, has made adverse reactions to traditional medicines as an issue of concern. This review is to highlight the ancient literature on its sound emphasis on safety and quality of traditional medicine. The various symptoms of adverse effects of the commonly used plants and minerals provides an awareness that self medication should be avoided and strict adherence to purification, preparation, dosage and diet should be followed as prescribed by the qualified traditional practitioner.

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