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Research Article

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Assessment and occurrence of adverse effects after the consumption of Siddha drugs

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Abstract

The Siddha system of medicine is the one of the ancient system of medicine and it is originated nearly 12000 years ago. The Siddha system of medicine is having a specific character and its specialty is that it not only cures the diseases of the body but also cures the diseases of mind. Siddhars are super human beings who defined the age and other laws of nature to which all human beings are subjected to. Siddha system of medicines contains herbals, minerals, metals and animal products. Though the modern medical science facing a lot of changes in its core, Our Siddha system needs more scientifical updations .Now a day's Many researchers did their research works towards Siddha system of Medicine. This study aims to assess the adverse effects after the consumption of Siddha drugs for various Diseases. This study is an observational study and carried out in Ayothidoss Pandithar Hospital, National Institute of Siddha. This study was designed as a Hospital based Cross sectional study to assess the adverse effect of the Siddha medicines after consumption. Study period was three months. Sample size was five hundred patients from National Institute of Siddha OPD (Outpatient Department) Simple Random sampling technique was used to select the patients. Patients with any age group were included.281 male and 219 female patients were interviewed during the time period. After Three months of study we concluded that there were no adverse effects found in the patients during the months from June 2018-August 2018.

Keywords: Siddha, Adverse effects, OPD, Observational Study

Introduction

Siddha system of medicine is the oldest among the Indian system of medicine. It is an ancient system of medicine originating from South India. It is also called as Tamil maruthuvam and Nattu maruthuvam. The word Siddha comes from the word Siddham. Siddha means Knowledge or wisdom. Siddham means an object to be attained on perfection or heavenly wisdom. Siddha system of medicine is a codified medical science developed by Siddhars. One who has attained perfection in life is called SIDDHAR. The Siddhars are 18 in number. They contributed much to be Siddha literatures in palm leaf containing

preparations with plants, mineral sand metals. The word Siddhar denotes one who has achieved some extra ordinary powers-SIDDHI.This achievement was related to the discipline of mind and its superiority over body and was accomplished through yoga and Medicine. The Siddhars propounded the therapeutic properties of plants, metals, minerals and animal products using their wisdom and these formulations are being used by mankind. The drugs dosage, vehicles/adjuvant, indications, duration and diet regimen are precisely defined in Siddha literature. It is well known that all the eyes of the world are turning to the traditional system of medicines, especially Siddha system of medicine to find out a more accepted drug for incurable diseases and minimal unwanted effects of a drug. The efficacy of many Siddha preparations have been established but their safety are not the Siddha physicians should embrace ourselves the Siddha drugs are indeed safe and we should do this by using well established modern and scientific method. Therapeutic activity encompasses successful prevention, diagnosis and treatment of physical and mental status of the body majority of Siddha medicines are now manufactured for global use and they have moved beyond the cultural frame work for which they were originally intended consequently safety of Siddha medicine is a serious issue of intention. Liberal use of heavy metals in Siddha formulations described in ancient Siddha literature also account for some adverse drug reactions. All the drugs (herbals, metals, minerals, animal products) used for the Siddha medicines are purified and processed before medicine preparation and the Siddha medicines are taken along with the correct dose , suitable adjuvant & particular days with pathiyam (Diet regimen) as mentioned in ancient Siddha texts. If any unsuitable or incorrect dosage of medicines or adjuvant and wrong procedure of medicine preparation may be results in adverse effects. Under these situations we need to assess the adverse effects of Siddha medicine is must.

Aim & Objective:

To study adverse effects of Siddha drugs.

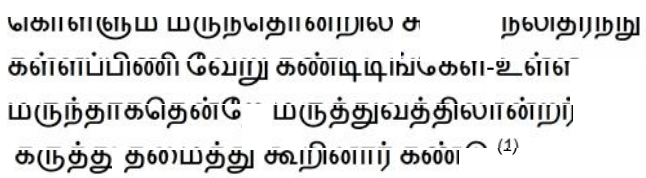
- To document the adverse effects of Siddha drug in NIS OPD.
- To analyze the characteristics of adverse effects.

To study the drug with food interaction

Review of Literature

Siddha aspect:

It is interesting that a reference to ‘adverse events’ has been mentioned in one of the pioneering works in Siddha system of medicine of South India. The prose from the book is reproduced below:



The meaning of the prose is: ‘According to experts, if a drug (medication) cures an illness for which it was prescribed and subsequently causes another illness as result of taking that drug, then even if it is a superior form of drug, it should not be considered as a drug medication’. This prose uses the Tamil term **‘Kallappini’** referring to occurrence of an illness as a ‘consequence’ or **‘Adverse effect’** of the drug that goes beyond its indication. Hence, it is noteworthy to appreciate that the authors of ancient systems of medicine were mindful of unintended effects of medications. Finally, it is important note an imperative message underlying the text. It calls for a physician to have clinical acumen to identify, differentiate and manage the intended and unintended consequences of treatment.

Modern aspect:

The usual term for harm related to a medicine is known as adverse drug reaction (ADR).

Adverse drug reaction:

Definitions

- An **adverse drug reaction (ADR)** is an *unintended and noxious effect* that is attributable to a medicine when it has been given within the normal range of doses used in man[2]

- An **adverse event (AE)** is an undesirable occurrence that occurs in the context of drug treatment but which *may or may not* be causally related to a medicine[2]

Classification system:

ADRs have traditionally been classified into two broad categories, as follows

- Type A (Augmented) reactions
- Type B (Bizarre) reactions

Type A reactions are generally:

- Dose related
- Predictable from drug pharmacology
- Common

- Normally reversible
- May be manageable with dose adjustment.

Type B reactions are generally:

- Not dose related
- Unpredictable from drug pharmacology
- Uncommon
- May be serious or irreversible
- Indicative that the drug needs to be stopped

Additional categories of ADRs have also suggested, as follows

- Type C (Chronic)
- Type D (Delayed)
- Type E (End of use) – Withdrawal reaction

System of classification was proposed by Aronson and Ferner based on **dose-relatedness, time course** and **susceptibility** this is known as 'DoTS'.

Summary of DoTS categories

Dose	Time	Susceptibility
Toxic Collateral Hyper susceptibility	Independent Dependent -rapid administration -first dose -early,intermediate,late -delayed -withdrawal	Age Gender Ethnic origin Genetic Disease

In terms of dose-relatedness 'toxic' means that reactions occur as a result of drug levels being too high, 'collateral' means that reactions occur at drug level which are in the usual therapeutic range and 'hyper susceptibility' means that reactions may occur even at very low, sub-therapeutic doses. The terms early, intermediate, and late have not been precisely defined; the main difference between 'late' and 'delayed' reactions is that the latter may occur long after treatment is stopped. A withdrawal reaction means one that is specifically precipitated by stopping the drug [(3)]

Materials and Methods

This study was carried out in National Institute of Siddha, Chennai with is an apex Institute for Siddha medicine. This study is an observational study. This study was designed as a hospital based cross sectional study to evaluate the adverse effects. The period of study was from June to August 2018. A total of 500 patients were interviewed during the three month period interviewed using a structured questionnaire. Interview was carried out in Nanju maruthuvam outpatient department under the supervision of Head of Department conducted the interview in a separate enclosure to ensure the privacy of patients. Interview was carried out in local language. Patient taking only Siddha medicine and patients who are willing to give information was included. Patient taking other than Siddha medicines and patient who are not willing to give information was excluded. The purpose of the study was explained to them and informed consent was obtained orally. A pre designed questionnaire was given. They were asked to answer the relevant questions. The questions were focused on getting details about the common adverse effects that they were affected and diet and food regimen and how to manage the adverse effects. Since the study pertains to data collection from the patient knowledge and no identification disclosure in the study, Director, National Institute of Siddha in the capacity of Member-Secretary, IEC has granted permission to conduct the study. This study enrolled in Clinical Trial Registry India Reg.no.CTRI/2018/06/014412. 8 to 10 patients were covered at daily OPD by simple random sampling method .Patient who had been interviewed would not be interviewed again.

Statistical Analysis:

All collected data were entered in MS Access software using a pre-designed form for data entry and STATA software was used to perform statistical analysis. Basic descriptive statistics include frequency distribution and cross-tabulations were performed.

Results and Discussion

Table: 1 Total number of the Patients

Gender	Total no. of patients	Percentage
Male	281	56%
Female	219	46%
	500	100%

Table: 2 Age distribution of the patients both male and female

Age(years)	Males(n-281)	Females(n-219)	Total(n-500)
10-20	06 (2.1%)	06 (2.7%)	12 (2.4%)
21-30	30 (10.6%)	19 (8.6%)	49 (9.8%)
31-40	41 (14.5%)	37 (16.8%)	78 (15.6%)
41-50	53 (18.8%)	71 (32.4%)	124 (24.8%)
51-60	56 (19.9%)	53 (24.2%)	109 (21.8%)
61-70	73 (25.9%)	30 (13.6%)	103 (20.6%)
71-80	19 (6.7%)	03 (1.7%)	22 (4.4%)
81-90	03 (1.5%)	00 (0%)	03 (0.6%)

Table: 1 shows that total number of patients included in this study there were 281(56%) Male and 219(44%) Female patients covered for the interview. Table: 2 reveals that the age group of patients mostly from 61-70 yrs of age group of 73(25.9%) males .51-60 yrs of age group of 56(19.9%) males and 53(24.2%) females. 41-50 yrs of age group of 71(32.4%) females and 53(18.8%) males were interviewed.

Figure: 1 Gender %

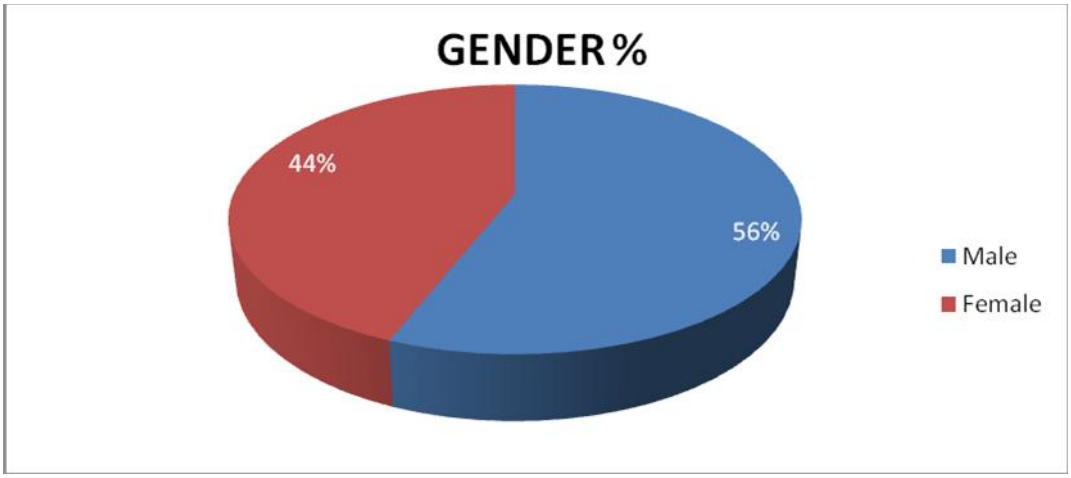


Figure 1 shows that the proportion of the genders there were 281(56%) Male and 219(44%) Female patients covered for the interview.

Figure: 2 Distribution of age both Male and Female

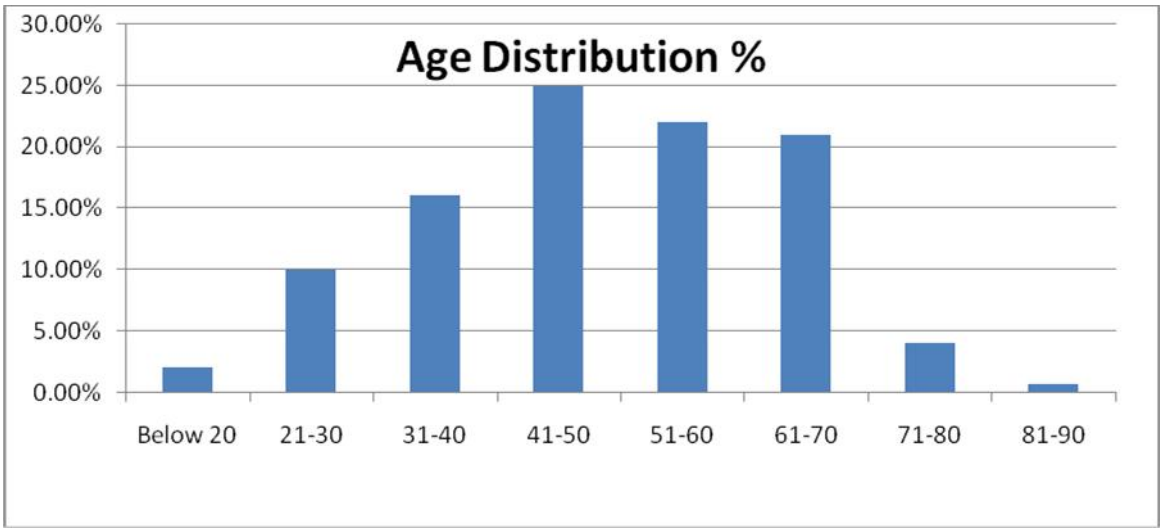


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Figure: 3 Distribution of frequency of diseases

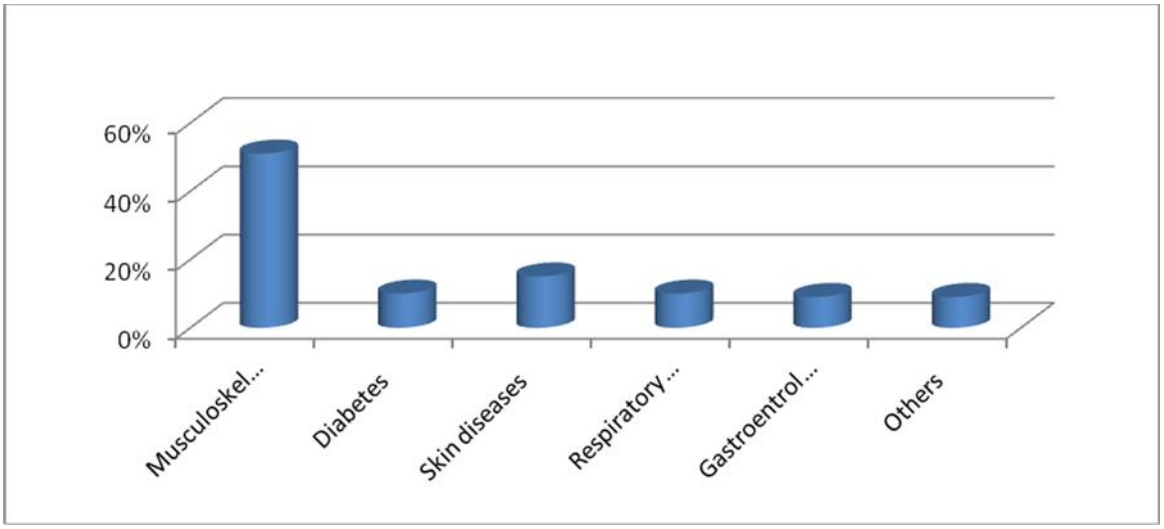

Figure: 3 represents Most number of affected among the all the other patient like musculoskeletal disorders including Arthritis were the reason for i.e.257 (51%) More females found to have Arthritis than males. The other diseases reported were Diabetes (10%) Skin diseases (15%) Respiratory diseases (10%) Gastroenterology (9%). All the patients taking Siddha medicines for the various diseases in National Institute of Siddha, at least for the past five days are represented in this figure.

Observation

All the patients taking Siddha medicines in National Institute of Siddha, at least for the past five days the common adverse drug reactions mentioned are Oral ulcer, Redness, Rashes, Itching, Abdominal pain, Vomiting, Loose stools and they have to be found no significant adverse drug reactions during taking medicines .This study results in there is no significant adverse effects found in the patients of National Institute of Siddha during the time period of June 2018-August 2018.

Conclusion

This study was carried out in three months for the assessment of adverse effects of Siddha drugs using NIS patients selected randomly and asking questions through proper oral consent. The study results in there are no significant adverse effects takes place during these three months June 2018-August 2018

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