

A Prospective Observational Case Series of Liver Injury in Paediatric Patients Secondary to Consumption of Ayurvedic Herbomineral Formulations.

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Abstract

Background: Ayurvedic medicines especially herbomineral formulations are combinations of metals and herbs but not in a raw form. There are very good positive things in society about these herbomineral medicines and lots of misconceptions in modern world and modern scientist. They are much confused that how ayurvedic doctors can use metals in medicines; because they feel that metals are toxic to human body, metal can cause hepatotoxicity and nephrotoxicity. This is on scientific level totally confusion and misunderstanding in the mind of allopathy people. Why this confusion arises...? Actually they must little bit understand about ayurvedic science. This science never suggests to use these metals in the raw form. They are converting these metals totally nano particle level so original metal has been lost its molecular structure and it is completely new ayurvedic bhasmas are only oxides of metal. First purify the metal and after purification with lots of complicated biochemical processing, converting them into such molecule that molecule does not have a single raw metal molecule. This must be understood that final product is completely different than raw metal used. If try to study this things then nobody will challenge to ayurvedic science.

Aim: Observe the incidence of hepatic injury in paediatric patients due to herbomineral drug consumption.

Material and Method: In this prospective case series 5 drugs regimen of herbomineral medicine was given to 14 paediatric patients of age group 4 years to 14 years who were diagnosed as reactive and recurrent respiratory disease. The total duration of drug delivery was 90 days. After successful completion of treatment course Liver Function Test (LFT) of each patient was done and conclusion was drawn.

Outcomes: Total 14 patients, biomarkers of Liver Function Test were observed normal and at last follow up every patient was clinically fine.

Conclusion: Use of herbomineral medicines in paediatric patients is safe and it does not cause hepatotoxicity.

Keywords: Hepatotoxicity, Liver injury, Herbomineral formulation, Paediatric, Drug Induced Liver Injury, Ayurvedic Medicines. Liver Function Test, Nephrotoxicity.

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Introduction

Ayurveda believes in eradicating the disease right from its root and propound drugs that cause no complications. The metabolism of drugs depends upon the Bhautikagni's (enzymes) in liver and the Dhatvagni's in the cells or tissues.^[1,2] In order to produce main desired

effect a drug must be present in appropriate concentration at the site of action. The optimum concentration of the drug depend upon the dose administered and the extent and rate of its digestion, absorption, localisation or bioinformation and excretion.^[3] Despite rapid advancing theories in modern pharmacology; much a remains to be said about drug versus disease, pharmacokinetics, biotransformation, selective affinity of drugs to a particular cell or system.^[4] Ayurveda believes in treatment without complications and therefore the Ayurvedic drugs as remain administered show s no encouraging pharmacodynamic or chemiotherapeutic actions, they show only the pharmacotherapeutic actions well.^[5]

The use of herbomineral Ayurvedic formulations is sensible and objectionable topic from the site of western science followers but at the same time the use of these medicines is interesting in Ayurvedic practitioners as they get desired effects among the patients. Various articles regarding the nephrotoxicity and hepatotoxicity secondary to consumption of Ayurvedic herbomineral and metallic medicines are found at internet. To address such issues the study was conducted to make evidence based knowledge and to claim the safe use of herbomineral medicines in paediatric population.

This prospective clinical trial was done with well informed consent in paediatric patients under the age group of 4 to 14 years which were diagnosed as Reactive and recurrent respiratory diseases and herbomineral five drug regimen was given for 3 months. Study was conducted at government Ayurvedic college osmanabad, Maharashtra in 2017-2018. Patients were observed for Hepatic pathological changes by applying biomarkers of Liver Functions.

This study provides evidence to use of Ayurvedic herbomineral medicines in children without causing harm to liver and also build confidence regarding the use of Ayurvedic herbomineral medicines among Ayurvedic practitioners and society also.

Material and Method

Study design

Study type: Observational, Prospective Clinical Trial.

0.- 14 participants of age group 4 years to 14 years.

Study duration: 1 year.

Group and cohorts: Single group/cohort diagnosed reactive and recurrent respiratory disease.

Sampling Method: Non-probability sample.

Study population- Children's in the age group of 4 to 14 years suffering from Reactive and recurrent respiratory diseases was involved in study and given 5 herbomineral drugs regimen for same illness.

Criteria: Inclusion criteria – children in the age group of 4 to 14 years presenting with complaints of recurrent respiratory illness episodes wheeze associated respiratory illness, reactive airway disease. Exclusion criteria - children suffering from tuberculosis, congenital heart disease and malformations, child suffering from any hepatic disease and any life threatening conditions.

Intervention: 5 herbomineral drugs regimen from standard and GMP certified Pharma Company.

1. Swaskaschintamani rasa^[6]
2. Swaskuthar rasa^[7]
3. Laxmivilas rasa^[8]
4. Abraka bhasma (shataputi)^[9]
5. Sitopaladi churna.^[10]

Dose: Dose was decided as per age according to Sharangadhara samhita^[11] and after discussed with higher authority of concerned subjects (Rasashastra department and paediatric department of institute). Above mentioned 5 drug regimens in powder form, 500 mg up to 7 years and 1 gm to above 7 years children BID after meal.

Anupana (vehicle): Honey

Duration of drug delivery: 5 drug combination was given for 3 months at one month interval.

Consent: Child was enrolled in study after taking well informed written consent from parents.

Follow up- total 4 follow ups were conducted at one month interval. At last follow up Liver Function test of each patient was done at authentic pathology laboratory.

Case Series:

Table 1: Case series/case details

Case	Age in years	Sex	Weight in Kg	Present complaints	History	Diagnosis	Treatment	Written Consent
Pt -1	14	M	35.6	Dry cough, cold, chest pain	Specific food and seasonal aggravation, repeated medication and nebulisation.	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt -2	7	M	16.4	Rhinitis	Repeatedly received medication and nebulisation.	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt-3	7	M	13.8	Breathlessness, cough, cold	Asthama in grandparents, repeated medication and nebulisation.	Reactive airway disease	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt-4	5	F	13.1	Cough, cold	Seasonal and specific food aggravation, parental allergy, repeated medication and nebulization	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt-5	7	F	15	Rhinitis	Specific food aggravation, repeated use of nebulisation.	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt -6	5	F	14.6	Cough and cold	Parental allergy, specific food and .seasonal agrgravation	Reactive airway disease	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt-7	13	M	27	Continuous rhinitis	Specific food and seasonal aggravation, repeated medication for same illness.	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt -8	11	M	33.4	Continuous dry cough	Grand Parental allergy, specific food and seasonal aggravation	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt -9	5	F	15.3	Cough with bouts	Seasonal and specific food aggravation, parental allergy, repeated medication and nebulisation	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt -10	4	F	12.6	Tonsillitis, fever, cough, cold.	Specific food and seasonal aggravation, repeated medications for same illness.	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt -11	10	M	21.6	Running nose	Seasonal and specific food aggravation, parental allergy, repeated medication and nebulisation.	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt -12	14	M	50.2	Cough, cold, fever	Seasonal aggravation, repeated medication, parental allergic rhinitis.	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt -13	4	M	13.5	Rhinitis	Seasonal and specific food aggravation, parental allerg.	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes
Pt -14	5	M	12.5	Cough, cold	Seasonal and specific food aggravation, parental allergy, repeated medication and nebulisation	Recurrent respiratory disease/illness	Swaskaschintamani rasa, swaskuthar rasa, lsxmivilas rasa, abhraka bhasma, sitopaladi churna.	Yes

Results

The present observational clinical trial was carried out to observe the liver injury after giving Ayurvedic herbomineral medicines to paediatric patients had same

diagnosis. After successful completion of 3 months treatment course Liver Function Test was done and following results were obtained.

Table 2: Liver Function Test (LFT) Patient's Value

Sr.No.	Bilirubin Total (mg/dl)	Direct (mg/dl)	Indirect (mg/dl)	S.G.O.T. (U/L)	S.G.P.T. (U/L)	Total Proteins (g/dl)	Albumin	Globulin	Alkaline Phosphate (U/L)
Patient-1	1.00	0.6	0.4	23	12	6.7	4.4	2.3	214
Patient-2	0.35	0.35	0.00	31	18.3	-	-	-	-
Patient-3	0.86	0.19	0.67	41	25.6	6.7	3.6	3.2	101.3
Patient-4	1.0	0.6	0.4	37	28	6.7	3.6	3.1	-
Patient-5	1.2	0.7	0.5	38	20	5.8	4.2	1.6	-
Patient-6	0.87	0.34	0.53	40.3	39.2	-	-	-	115
Patient-7	0.9	0.3	0.6	28	19	6.4	3.5	2.9	-
Patient-8	1.0	0.4	0.6	41	33	7.0	3.5	3.50	-
Patient-9	1.96	1.37	0.59	31	23.3	-	-	-	-
Patient-10	1.0	0.6	0.4	38.9	22.1	6.7	4.2	2.5	-
Patient-11	0.54	0.24	0.30	39.7	20.6	7.27	4.25	3.02	-
Patient-12	0.48	0.46	0.02	19	11.3	-	-	-	-
Patient-13	0.9	0.5	0.4	30	22	7.9	4.5	3.40	-
Patient-14	0.5	0.2	0.3	35.1	16.5	6.24	3.64	2.6	-

Discussion

Generally speaking, Ayurvedic drugs possess no toxicity nor do they cause any complication and therefore, the Ayurvedic treatment never causes iatrogenic diseases (diseases caused by misguided treatment). But if the disease has not been properly diagnosed and only symptomatic treatment is given the duration of treatment is unnecessarily increased and obviously, this has socio-economic repercussions. Even though drugs have got active principles which with they work, they have some other fractions which counteract their bad effects, if any. Therefore Ayurveda advocates that drug should be used as a whole so that the desired effects may be had without any side effects.^[12]

In Ayurvedic medicines the calculated proportion of ingredients in different formulations has a scientific meaning behind it. Disturbance in that proportion causes incompatibility. Once these explanations are accepted, it should be admitted that Ayurveda treats the patient while other systems of medicine treat the disease. To a lay and ignorant man, it is difficult to understand a disease without patient and a patient without disease.

There are some Ayurvedic metallic preparations, but they are fully and perfectly purified before administration. The finished product of Ayurvedic formularies does not cause any toxic or side effects. In some of the formulations antidotes are added to avoid any possibility of toxic effects. Majority of Ayurvedic drugs show only the pharmacotherapeutic actions and do not cause any complication.^[13]

Some articles published in journal regarding hepatic toxicity^[14] and nephrotoxicity secondary to consumption of Ayurvedic medicines are observed and to address such articles the study was conducted. Paediatric department of this institute several times used Herbomineral medicines in children and does not noted any adverse effect of such medicines till date. Actual study was conducted over the paediatric patients suffered from recurrent respiratory illness and reactive airway disease^[15], and herbomineral medicines (5 drug regimen) for 3 months. Along with this, to observe hepatotoxicity secondary to these combinations Liver Function Test was carried out after successful completion of treatment. And results was found no any pathological changes in the biomarkers

of liver function after given the herbomineral 5 drugs combination for 3 months in appropriate dose.

Conclusions

The present study, In this 14 patients observational clinical trial it was observed that use of Ayurvedic herbomineral medicines is safe and there is no relation to hepatotoxicity secondary to consumption of Ayurvedic herbomineral formulations.

Concluded as:

1. The aim of treatment is to cure the disease and to restore the health. Proper selection of drugs brings desired effects. Keeping all the pharmacological aspects in view, a drug should be chosen and employed to cure a disease.
2. Drug administration should be preceded by perfect diagnosis of disease and followed by expected results only.
3. the social implication of medicine is to see that man remains healthy and happy, and also useful to society. except in case where life itself is in danger, any drug causing iatrogenic disease should be socially and ethically contrabanded.

The Ayurvedic drugs fulfil all above requirements and therefore, satisfy the social obligation of medicine.

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