

Rasaushadhi (Herbomineral Formulations) Induced Nephrotoxicity in Children: Safety Concern Case Series

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Abstract

Background: Use of Rasaushadhi (Herbomineral formulations) in children is sensible topic. In last decade, some articles reported in various newspapers about nephrotoxicity of Ayurvedicherbomineral medicines. These issues create negative impression regarding the use of Ayurvedicherbomineral medicines. Ayurveda itself a time tested life science and provide guidelines to stay healthy and preserve the health. Such articles have done considerable damage to the reputation of ayurveda but at same time, it has raised many questions which need to be addressed. To make system more scientific and evidence based study was conducted at Paediatric department of Government institute in 2017. Paediatric department in this institute has used Rasaushadhi in children several times and not noted any problem regarding nephrotoxicity till date.

Aim: Question: Does Rasaushadhi (Herbomineral formulations) cause Nephrotoxicity in children? To determine Rasaushadhi (Herbomineral formulations) is “safe” study was conducted.

Materials and Method: Study was conducted for recurrent and reactive respiratory illness in children and herbomineral five drugs regimen was given to children of age 4 to 14 years for 45 days at 15 days interval. To rule out Nephrotoxicity after the use of Ayurvedicherbomineral formulations kidney function test was done. Patients were clinically observed in 4 follow ups, each follow up was conducted every 15 days. Last (Fourth) telephonic follow up was taken after six months of completion of treatment course to observe any renal obstructive pathology.

Results: Total 13 patients of case series were observed normal kidney function test reports. Last (Fourth) telephonic follow up was also reported normal, no any renal complications reported.

Conclusion: This clinical case series found that use of Ayurvedicherbomineral medicines in paediatric patients is safe and there is no relation with nephrotoxicity or any obstructive renal pathology when used properly.

Keywords: Nephrotoxicity, Rasaushadhi, Herbomineral medicines, Kidney injury, Ayurvedic drug's safety, Paediatric nephrotoxicity, Kidney Function Test.

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Introduction

Ayurveda is not a belief or faith based system. Charakasamhita defines a theory as a conclusion only once it has been established after several investigations in several ways and forms logic.^[1] Rasashastra is a science of minerals aimed at intensively processing

and converting them into biomineral substances, to make them compatible for humans and to use them in an efficient and safe manner for medicinal purposes. Rasaushadhi's have 3 characteristics attributes-

1. Instant effective,
2. Requirement of very small dose,
3. Extensive therapeutic utility irrespective of constitutional variation.^[2]

‘Alpamatropayitwaat Arucera Apraangataha.

Kshipram Arogyadayitwat Ayushodyebhyo Adhiko Rasaha’.

(Vagbhata Rasaratnasamuchyaya.28/1, 1976a).

Rasashastra appeared as a big boon for humanity and a medicaments showed quick effectiveness even in very small doses.^[3] But now a day there is big issue about the use of Rasaushadhi (Herbomineral medicine) in children regarding their safety and impurity. But there are lots of references in *Kashyapasamhita* about use of *Rasaushadhi* in children. *Acharya Kashyapa* has been mentioned herbomineral preparations as internal use or external use in children e.g. *Lohitikagutikain akshirogaa anjana* (external application)^[4], *Shilajatu* internal use in *raktagulma*. In *Brihatrai* and *Laghutraisamhita* of Ayurvedic classic has been mentioned Gold administration in newborn babies.

Nephrotoxicity is characterized as a rapid degradation in the function of the kidney due to toxic effects of medicines and chemicals.^[5] Nephrotoxicity occurs when kidney-specific detoxification and excretion does not work properly due to damage or destruction of the function of the kidney by exogenous or endogenous substances. ^[6] In the past two years, this research study was aimed to make evidence based focus. The clinical case series of total 13 paediatric patients was conducted for 45 days exposure to rasaushadhi (Herbomineral medicines) and checked biomarkers of kidney functions to evaluate whether Rasaushadhi (Herbomineral medicines) cause any damage to kidney.

This study provides an evidence and built confidence in ayurvedic practitioners to use Rasaushadhi (Herbomineral medicines) without any hesitance.

Method

In this case series total 13 patients of 4 to 14

years age of recurrent and reactive airway disease were involved. All patients were diagnosed applying subjective and objective criteria. Patients involved in study received Rasaushadhi (Herbomineral medicines) for 45 days. Patients were clinically observed in 4 follow ups, each follow up was conducted every 15 days. Last (Fourth) telephonic follow up was taken after six months of completion of treatment course to observe any renal obstructive pathology.

Dose: As paediatric dosing system is different from adults. Appropriate dose of medicines given to the patients was calculated as per age according to *Sharangdharsamhita*^[7] and the dose decided after consulting to experts. Five drugs regimen (Table 1) mixed well in powder form and given bid with honey after meal.

Anupana (vehicle): Honey

Consent: Well informed written consent was taken from parents.

Interventions:

Table 1: Rasaushadhi (Herbomineral medicines) {GMP certified pharma company}

Sr. No.	Medicines
1.	Abhrakabhasma
2.	Shwaskuthar rasa
3.	Laxmivilas rasa
4.	Shwasakaschintamani rasa
5.	Sitopaladichurna

Case Series:

Patient-1: 13 years male child; wt.-35.6kg, presented with the complaint of continuous dry cough; had history of Bronchial Asthma for 3yrs. Also had history of taking medications and nebulisation repeatedly and have had seasonal aggravation. Child was diagnosed Reactive Airway Disease and enrolled for study. Total 5 herbomineral Ayurvedic drug combination mentioned in table 1 was given for the period of 45 days with 15 days interval. Patient was clinically observed at follow up after every 15 days. After successfully completion of treatment course of 45 days, Kidney Function Test (KFT) was done at standard pathology lab. Last follow up was taken at 6 month of completion of treatment course to observe any renal complication or obstructive pathology.

Patient-2: 7years male child, wt. - 16.4 kg had complaint of rhinitis with h/o recurrent allergic rhinitis, specific food and seasonal aggravation, repeated medication and nebulisation for same illness. Child was enrolled for study after well informed consent. Herbomineral combination was given. After completion of treatment KFT was done. Last follow up was taken after 6 month on telephone.

Patient-3: 7 years female child; wt.-13.8kg, was presented with c/o breathlessness, cough and cold. Patient had h/o recurrent respiratory illness and allergic rhinitis and received treatment repeatedly for same illness, also had h/o bronchial asthma to grandparent. Patient was admitted in for Panchakarma (Vamana) procedure. Vamana karma was done on next day after that patient was enrolled for study. After successful treatment completion KFT was done, last f/u was taken on phone after 6 month.

Patient-4: 5years female child wt.- 13.1kg; had c/o cough and cold. Patient had h/o seasonal and specific food aggravation and h/o parental allergy. Patient had received medication repeatedly for recurrent respiratory infections (antibiotics and antihistamines). Patient was enrolled for study after well informed consent. 5 herbomineral drugs combination was given and f/u was conducted on time. after successful completion of treatment course LFT was performed at standard lab. Last f/u was taken on phone for any renal complication secondary to herbomineral drug consumption.

Patient-5: 7years female child wt.- 17.4kg had c/o cough and common cold. Patient had h/o allergic respiratory illness, seasonal aggravation and needed repeated medication for allergic respiratory illness. Patient was enrolled for study and given treatment for 45 days at 15 days interval. After course completion KFT was done. Last f/u was taken after 6 month.

Patient – 6: 5years female child wt.-14.6kg; had c/o cough and cold have had h/o specific food aggravation seasonal aggravation, allergy to parent (bronchial asthma to mother) child was diagnosed bronchial asthma by general practitioner. After well informed consent patient was enrolled for study and after completion of course KFT was done.

Patient –7: 13years male child wt. 27 kg; was diagnosed recurrent respiratory illness and enrolled for study after consent. Patient had completed treatment course after that KFT done at same institutional lab to

check biomarkers.

Patient – 8: 11 years male child wt33.4kg had c/o dry cough and had h/o recurrent cough and allergic respiratory illness. Patient had h/o seasonal aggravation and parental asthma. Patient was enrolled for study and 5 herbomineral drugs combination was given for 45 days after 15 days interval. After course completion KFT was done. Last f/u was conducted after 6 month on phone for any urinary obstructive pathology.

Patient -9: 5years female child wt.-15.3 kg; had c/o cough with bouts. Patient had h/o recurrent respiratory illness and repeated medication and nebulisation for same illness. Patient was enrolled for study and 5 herbomineral drugs combination was given. After course completion KFT was done. Last f/u was taken after 6 month.

Patient -10: 4years female child wt.- 12.6kg; had c/o cough, cold, fever and nasal congestion. Patient had h/o recurrent respiratory infections and repeated medication, seasonal aggravation. After well informed consent from parent patient was enrolled for study. Total 5 herbomineral drugs combination was given to patient for 45 days at 15 days interval. After treatment course completion KFT was done at standard private pathology lab. Last f/u was taken on phone to observe any symptom of renal injury or any renal obstructive pathology.

Patient -11: 10years male child wt.-21.6kg; had c/o throat pain, cough and had h/o recurrent respiratory infections (thrice in a month).Also had h/o seasonal aggravation, parental allergy (father) and received repeated medication for same illness. On examination patient had diagnosed tonsil hypertrophy and adenoiditis. Patient was enrolled for study after informed consent. Patient had given 5 herbomineral drugs combination for 45 days. After successful completion of treatment course and on time f/u at 15 days interval KFT was done. Last f/u was done after 6 month.

Patient -12: 14 years male child wt.-50 kg; had c/o cough, common cold and fever. Patient had h/o parental allergy (Mother). Patient was enrolled for study after well informed written consent. 5 drug regimen of rasaushadhi was given to the patient for 45 days at 15 days interval. After successful completion of treatment course KFT was done. Last follow up was taken on phone after 6 months.

Patient -13: 4 year male child wt 13.5kg; had c/o

rhinitis. Patient had h/o recurrent respiratory illness and was taking antibiotics, anti allergic medicines for same illness. Patient had seasonal and specific food aggravation, parental allergy (Mother). Patient was diagnosed atopic rhinitis and enrolled for the study. 5 drug regimen of rasaushadhi was given to the patient for 45 days at 15 days interval. After successful completion of treatment course KFT was done. Last follow up was taken on phone after 6 months./

Results

Patients were observed in 4 follow ups, 3 follow ups from starting were taken at 15 days interval and at 3rd follow up KFT was done, last 4th follow up was taken on phone after 6 months to observe any obstructive pathology secondary to Ayurvedic medicines consumption. At last follow up on phone no any compliant related to renal injury was observed since at all.

Total 13 patients were involved in this case series. After completion of 45 days treatment course Kidney Function Test (KFT) was done and following value of biomarkers were observed.

Table -2 Kidney Function Test (KFT)

Sr.No.	Serum creatinine (mg/dl)	Blood Urea Nitrogen (mg/dl)	Blood urea(mg/dl)	Uric acid
Patient-1	0.9	11.29	24.17	-
Patient-2	0.46	-	40	5.01
Patient-3	0.78	-	21.16	-
Patient-4	0.9	7.94	17	-
Patient-5	0.7	9.81	21	-
Patient-6	0.68	-	18.50	-
Patient-7	0.8	14.49	31	-
Patient-8	0.8	12.15	26	-
Patient-9	0.45	-	26	2.83
Patient-10	0.7	10.75	23	-
Patient-11	0.8	8.64	18.5	-
Patient-12	1.22	-	40	2.59
Patient-13	0.8	9.81	21	-

Discussion

Use of metals and minerals in Ayurvedic drugs remains a most controversial issue for the followers of western medicine. These concerns not always true; mere presence of metal in a formulation will not develop adverse effects. Judicious administration considering all variants as explained in Ayurveda determines the benefit or otherwise. Pioneers of ayurveda have considered in detail about the possible ways by which untoward effects can occurred and provided all guidelines to avoid such occurrence.^[8] Use of various Herbomineral medicines containing metals and minerals in therapeutics is an essential part of Ayurveda but safety and toxicity concern

in the two decades creates debates in conventional community which attempted to damaging the glory of Ayurveda.^[9,10]

Purpose of this study was to see the incidence of kidney injury due to Ayurvedic drug consumption. As Rasaushadhi (Herbomineral medicines) are used by Balroga department and by many of ayurvedic practitioners; and patient got relief from their illness as we expected. In spite of this adverse effect of Rasaushadhi (Herbomineral medicines) remains questionable. To answer such questions study was conducted. This study creates confidence to Ayurvedic practitioners to use herbomineral drugs in paediatric patients.

Conclusion

Proper use of Rasaushadhi (Herbomineral medicines) in paediatric patients is safe. It is clear from this case series use of herbomineral formulations that properly processed Ayurvedic medicines do not produce any toxic potential under judicious administration. Further to affirm the safety of rasaushadhi (herbomineral formulations) longitudinal study in large sample is required.

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