Research Article

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THE SAFETY OF AYURVEDIC HERBO-MINERAL FORMULATIONS ON RENAL FUNCTION: AN OBSERVATIONAL STUDY

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ABSTRACT

In the recent past, many claims have appeared regarding the safety/toxicity of Ayurvedic medicines in various contexts, as it trembles the faith of patients and value of Ayurveda. A need has raised for Ayurvedic researchers to ascertain the safety of the medicines and validate the utility of Ayurvedic treatment. The study was aimed at establishing the safety/toxicity of Ayurvedic herbo-mineral formulations by measuring serum urea and creatinine levels before and after the Ayurvedic intervention. An observational study was carried out at the out-patient department of the clinical section of National Ayurveda Dietetics Research Institute (NADRI), Bangalore. Patients availing uninterrupted Ayurvedic Herbo-mineral treatment for a period of four weeks and above were chosen. Out of 242 patients who were subjected to serum urea and creatinine to evaluate the renal safety profile, 20 patients were randomly selected in the age group between 30 – 80 years, irrespective of the disease. The levels of serum urea and creatinine before and after Ayurvedic intervention were noted to be within the normal range. Statistical analysis has shown P value for serum urea <0.0006 and serum creatinine <0.0001. The study revealed that the consumption of Ayurvedic herbo-mineral formulation did not affect urea and creatinine values, when compared before and after Ayurvedic intervention. There were no adverse drug reactions or side effects reported during the study.

Keywords: Serum Urea, Serum Creatinine, Herbo-Mineral, Toxicity, Safety profile, Ayurveda.

INTRODUCTION

Modern civilization is inclining towards Ayurveda for metabolic and chronic diseases. In the recent past, many claims have sprung up with regards to the toxicity of the Ayurvedic medicines in various contexts. Amitava Dasgupta, has reviewed that herbal medicines can cause significant toxic effects and even death, contrary to the popular belief that natural medicines are safe and devoid of side effects. Herbal medicines include Chinese herbal products, Ayurvedic medicines etc. Several herbal products interfere with immunoassays used for monitoring the concentrations of therapeutic drugs. Herbal medicines also can cause toxic effects, leading to abnormal test results. Therefore, the common belief that anything natural is safe is not correct[1].

A study by Dr Robert Saper warns that, users of Ayurvedic medicine may be at risk for heavy metal toxicity, and testing of Ayurvedic Herbal Medical Products for toxic heavy metals should be mandatory. The American medical research community has sounded a heavy metal warning against Ayurvedic medicaments. Herbal products from the Indian system of medicine sold in the US contain dangerous levels of lead, mercury and arsenic. In a study published in the prestigious Journal of American Medical Association (JAMA), researchers from the Harvard Medical School reported that Herbal Medicinal Products (HMPs) sold as remedies for treatment of ailments such as arthritis and diabetes contained toxic heavy metals with levels high enough to cause poisoning[2,3].

Currently, an issue is raised with respect to increasing reports of ADR related to herbal medicines labeled as Alternative medicine and Ayurveda[4,5].

Today, a need to establish the safety of Ayurvedic medicines has been a challenge posed to the Ayurvedic fraternity. A Bheshaja (drug) forms the prime limb among the Chiktsa Chatushpada (four fold treatment). Bheshaja includes drugs of herbal, mineral and animal origin. Each drug (medicine) is procured after proper identification, authentication and is processed in view of its purification thus enhancing the therapeutic properties[6].

Though safety is supreme, drug trials in real life are highlighting efficacy more than safety. Hence this study

was envisaged, keeping in view, the safety of Ayurvedic medicines as it is equally important in the treatment of disorders requiring long-term management[7].

Creatinine and Urea have been found to be reliable indicators of kidney function. Measurement of the above mentioned two parameters is widely regarded as a test of renal function.

The aim of our study was to measure serum urea and creatinine levels before and after Ayurvedic intervention to establish the safety/toxicity of Ayurvedic herbo-mineral formulations on renal function. The present study was conducted based on the above background.

MATERIALS AND METHODS

242 patients availing Ayurvedic treatment for various systemic diseases at the clinical section of National Ayurveda Dietetics Research Institute, (CCRAS) Bangalore were routinely subjected to serum urea and serum creatinine test. Out of 242 patients, 20 patients who were on Ayurvedic (herbo-mineral) medications for four weeks and above, aged between 30 – 80 years were selected. The normal biochemical values of renal functions, without any history of liver and kidney disorders was considered as an inclusion criteria. The main parameters under study were urea and creatinine levels. Estimation of serum urea was estimated by Berthelot's method[8] while creatinine was estimated by alkaline Jaffe's Picrate method[9].

Table 1 shows the patient details, levels of urea and creatinine, medicaments administered and duration of treatment of the 20 patients.

The medicines screened for their safety / toxicity profile are listed in Table 2.

Statistical Analysis

Data were analyzed using Student's paired t-test using the Prism Graph pad software. The results were expressed as Mean ± Standard Deviation and P value <0.001 was considered as statistically significant.

RESULTS

The values of serum urea and creatinine, as observed before and after the Ayurvedic intervention showed a significant decrease in some subjects. There was no difference in the parameters observed in a few subjects. In some subjects, the levels were found to have increased but however, stayed within the normal limits.
The levels of serum urea and serum creatinine before and after Ayurvedic intervention were noted to be within the normal range. Statistical analysis has shown serum urea with P value <0.0006 and serum creatinine P value <0.0001. Table 3

Moreover, it was also found that the individual values of observed serum creatinine were relatively lower than their pre test values. There were no adverse drug reactions or side effects reported during the study

Table 1: Patient details, medicaments administered and duration of treatment

Sl. No	Age	Sex	Urea BT	Urea AT	Creatinine BT	Creatinine AT	Medicines consumed	Treatment duration (months)
1	54	M	18	23	0.9	1	Agnitundi vati Smritisagara rasa Lashunadi vati	7
2	48	F	15	13	1	1.2	Chandra prabha vati	3
3	66	F	30	18	0.8	0.5	Mahayogaraja guggulu Lashunadi vati	6
4	54	M	29	26	1.1	1.1	Chandra prabha vati	1
5	69	M	16	15	0.5	1.1	Chandra prabha vati	6
6	48	F	22	19	1.4	0.9	Chandra prabha vati	8
7	56	F	15	21	0.6	0.5	Shvasa kutara rasa Tribhuvana keerthi rasa Shirah shula vajradi rasa	4
8	45	M	16	22	1.2	1	Chandra prabha vati	3
9	42	M	20	17	1	1.2	Chandra prabha vati	7
10	36	M	14	20	0.6	0.5	Chandra prabha vati	4
11	62	F	16	21	0.9	0.9	Chandra prabha vati	1
12	51	M	31	35	1	1.1	Chandra prabha vati	4
13	30	M	15	17	1	1.1	Maha shankha vati Sutashekhara rasa	1
14	56	M	14	15	0.6	0.6	Dhatri loha lashunadi vati Smruti sagara rasa	7
15	56	M	23	20	1	0.8	Chandra prabha vati	7
16	72	M	31	28	1.5	1.3	Chandra prabha vati Arogya vardhini vati	3
17	37	M	20	19	1.9	1.9	Maha shankha vati Sutashekhara rasa Dhatri louha	2
18	61	M	18	18	0.5	0.5	Chandra prabha vati	8
19	54	F	19	25	0.9	1	Chandra prabha vati	4
20	63	M	28	26	1.3	1.1	Chandra prabha vati	2

Table 2: List of medicines screened in the study

Sl. No.	Name of the medicines	Main Ingredients	Indication
1.	Agnitundi vati	Parada,Gandaka, Vatsanabha (*Aconitum ferox*) Visamusti (*Strychnos nuxvomica*)	Agnimandya, Amajwara
2.	Arogya vardini vati	Parada, Gandhaka , Lohabhasma, Tamra Bhasma, Abhraka Bhasma	Kusta,Yakrit Vikara.
3.	Chandra prabha vati	Loha bhasma, Shilajithu , Guggulu	Prameha , Pandu
4.	Dhatri loha	Lohabhasma, Amalaki (*Emblica officinalis*) Guduchi (*Tinospora cordifolia*)	Parinamasula, Kamala
5.	Lashunadi vati	Gandhaka, Lashuna (*Allium sativum*)	Ajirna, Atisara, Visuchika
6.	Maha shanka vati	Shankabhasma, Kajjali, Vatsanabha, Panchalavana.	Bhagandara, Pandu, Prameha
7.	Maha yograj guggulu	Trikatu, Sindura, Mandura, Abhraka,Lloha Bhasma	Prameha, Kusta
8.	Shirashula vajra vati	Parada, Gandaka, Loha, Tamra, Guggulu.	Shirashula
9.	Smritisagara rasa	Kajjali, Haratala, Shilajatu, Tamrabhasma.	Manasaroga, Anidra,
10.	Sutashekara rasa	Parada, Swarnabhasma, Tankana	Amlapitta, Chardi, Gulma
11.	Swasakutara rasa	Parada , Gandhaka, tankana, Manashila,	Agnimandhya,Swasa, Kasa
12.	Tribhuvan keerthi rasa	Hingula, Tankan	Vata Kaphaja Jwara

*Above medicines were procured from IMPCL [Indian Medicines Pharmaceutical Corporation Limited (A Government of India Enterprise)]

Table 3: Comparison of the biochemical parameters (mean ±SD) before and after treatment and statistical analysis

Parameters	Mean ± SD		T value	P value	Significance
	Before	after			
Serum Urea (mmol/l)	20.5±6.065	20.9 ± 5.19	0.38	<0.0006	****
Serum Creatinine (µmol/l)	0.98±0.35	0.96±0.34	0.39	<0.0001	****

DISCUSSION

Few qualitative inferences can be drawn on the basis of the available results of this study and also observations made during the study. In the present study, though the serum urea level was changed in each sample before and after the Ayurvedic intervention, the change was not to an extent that could cross the normal range. It is very important note that serum creatinine levels significantly reduced after the Ayurvedic intervention when compared with the base line data. During this observational study, none of the patients complained of any adverse drug reaction (ADR)/ side effects.

The drugs screened for renal safety were 34 in number, mostly herbo-mineral and a few herbal single or compound drugs. Some of the major metallic constituents of the drugs were Mandoora Bhasma (Calcined Iron slag), Loha bhasma (Calcined iron), Tamra bhasma (Calcined copper), Abhraka bhasma (Calcined mica), Haratala (Purified orpiment - Arsenic sulphide), Manashila (Calcined red orpiment), Shilajatu (Asphaltum), Parada (Purified Mercury), Hingula (Purified Cinnabar), Gandhaka (Purified sulphur), Kajjali (Mercuric sulphide).

Though, most of the preparations contained metallic/mineral components, there were no changes in the safety profile as they complied to GMP standards. However, the toxicity of the metallic preparations as mentioned in the other contexts, could be due to the following reasons

- Drug interaction (Viruddadravyaprayoga)
- Iatrogenic (Vaidhyakruta)
- Overdose (Atimatradravyaprayoga)
- Administration of unwholesome drugs (Ahitatamadravyas)
- Administration of medicine in diverse pathological stages (Avastanusaradravyaprayoga)
- Therapeutic procedural complications (Panchakarmavyapad)
- Improper use of Rasaushadi (Medicines of mineral origin) [10]

By performing modern chemical tests on the Ayurvedic formulations, results indicate the presence of certain heavy metals in these formulations. Ayurvedic science has also cautioned about the toxic nature of these compounds. Hence, Ayurveda advocates different purificatory procedures to the metallic and toxic compounds prior to their addition to the formulations. This facilitates the transformation of these compounds to safe, non-toxic form thus allowing internal administration. According to Ayurveda, the formulations contain heavy metals for producing different effects like enhancement of bio availability of herbs, as a carrier for active principles and as catalysts. The metals which have been transformed to non toxic forms are safe for internal use. After performing the desired action these metals are eliminated from the body through the excretory system[8]. Herbal/ Natural/ Food supplement/ Nutraceutical drugs are sold under the umbrella of Ayurveda to cater to the needs and demands of public. However, the OTC drugs may not comply to the desired GMP standards. The fault lies in the manufacturing process and not in the system of Ayurvedic medicine. Here arises the need for standardization. The need for standardization are:

- Global acceptance
- Documentation
- Reproducibility
- Industrial scale production
- Prevent adulteration and contamination
- Assess the quality of raw materials and finished products.
- Estimate the amount of active principle.
- Achieve batch to batch consistency of finished product[11].

This study ascertains that the herbo-mineral medications are safer for both short-term and long term consumption as far as the renal functions are concerned. The results provide a positive conclusion that the Ayurvedic herbo mineral medicines are safe. There is no conflict or confusion in this regard, that the study has established a safety profile to the medicines evaluated, contrary to the claims regarding toxicity of Ayurvedic medicines.

CONCLUSION

To sum up, herbo-mineral medications are safer for both short-term and long term, if each drug (medicine) is procured after proper identification, authentification and are prepared under proper guidance of wise physicians. Further exploration with larger samples appears necessary to seal the issue.

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