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A CLINICAL STUDY ON THE EFFECT OF SHAMAN AUSHADHI ON SERUM CREATININE AND EGFR- A PILOT STUDY

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INTRODUCTION

There are so many causes of increase in serum creatinine like Diabetes mellitus, HTN, glomerular nephritis, polycystic kidney disease, obesity, idiopathic.[2] On the other hand globalisation of dietary habits which may give the extra workload to the excretory system in the human. Preservation of food and agricultural pesticides use is one of the causes for increased workload on kidney. As GFR declines to level as low as 30% of normal, patient may remain asymptomatic with only biochemical evidence, i.e. rise in serum concentration of urea and creatinine. It leads to leg swelling, loss of appetite, vomiting, muscle cramps at night, poor appetite, puffiness around eyes, dry and itchy skin, nocturnal micturation.[1] Dialysis is one of the first lines of treatment in this condition (eGFR<30 ml/min/1.73m^2). Government of India also works on district level, for dialysis centre for the management of such conditions. But it is much cost consuming. All these patients included in study were from low to mid economic group, so those were not affordable to modern convenient medication and treatment. Also, this study aimed to prevent more renal damage by decreasing serum creatinine, albuminuria and increase in eGFR.

The prognosis is not good after dialysis. Therefore, exploration of a safe and alternative therapy is needed. In Ayurvedic text, Renal damage and its parameter are not directly explained. But it can be studied under *Mutraghat, Mutrakruch, Mutravikar*. Many herbo-mineral drugs have been described in *Mutaraghat, Mutrakruch, and Mutravikar of Mutavaha Srotas.*[3][4] Ayurvedic principles of management, comprises two main objectives, one is

decrease in the level of toxins (*Ama*), secondly strengthening the Kidney (*Rasayan*). So, in this study combination of Ayurvedic medicine i.e. *Sarivadi Kwath* (alleviate toxins) and *Shilajit Vataka* was administered orally as *Rasayan*. The significant reduction in serum creatinine level and improvement in GFR was observed in this study.

METHOD

Study Type: Case Series

Study population: 10 patients of increased serum creatinine and decreased eGFR.

Criteria of Diagnosis

1. Serum creatinine
2. eGFR

Assessment Criteria

1. Serum creatinine
2. eGFR

Inclusion Criteria

1. Individuals of both genders, aged 30 to 65 years with increased serum creatinine and eGFR<60 ml/min/1.73m^2 and>30 ml/min/1.73m^2 were included.
2. Additional inclusion criteria were controlled hypertension and controlled other systemic disease.

Exclusion criteria

1. Patients with end stage kidney disease or uncontrolled hypertension, DM, those with participated in another study were excluded.
2. Patients needing dialysis were excluded.
3. Also pregnant and lactating women excluded.

Informed Consent

This study was conducted with written informed consent to participants in this study.

Study Design

This study was conducted from Jan2017 toSept.2018 at Govt. Ayurved College Nagpur. (Fig.1).

During this study patient enrolled in study administered *Sarivadi Kwath* (40ml) and *Shilajit Vataka* (500mg) twice a day for 15days prepared as per Classical method enlisted by Sharangdhar.

Flow chart

Random selection of patient fulfilling criteria of diagnosis and inclusion criteria

First assessment

On preceding day (zero day)

Sarivadi Kwath and *Shilajit Vatak* for 15 days

Followup weekly was taken

Final Assessment after completion of *Shamana Chikitsa*. (after 15 days)

(Fig. 1)

Study therapy

1. *Sarivadi Kwath*- (Table-1) 40ml twice a day for 15 days.

Table. 1: Table showing Sarivadi kwath content and dose.

Sr. No.	Dravya	Matra	Dose	Kala	Anupan
1	*Sariva*	Each sam matra	40ml	Apan kali	Jal
2	*Triphala*				
3	*Patha*				
4	*Punarnava*				
5	*Musta*				

2. *Shilajit Vatak*-500mg /BD for 15days.

Study Evaluation: Primary endpoint was improvement in serum creatinine, eGFR, urine output at the end of 15 days of treatment from zero day.

Statistical Method

Statistical Analysis

Statistical analysis was performed by using software version **(GraphPad InStat Demo-[DATASET1-ISD]** and t-Table.

Parametric variables were described in terms of SD (Standard Deviation).

RESULTS

Study population: Out of 15 screened patients only 10 patients were enrolled in the study and received *Sarivadi Kwath* with their conventional treatment for other diseases.

The study population had mean age of 52 years mainly males. (6 in no. and 60%).

All other baseline physical and clinical parameters were studied on zero day in CKD patients were compared. (Table-2).

There are so many formulas to estimate patients eGFR. **(National Kidney Foundation online calculator used).**

Table. 2: Baseline physical and clinical parameters.

Parameter	**% or total No.**
Age	50years
Male:Female Ratio	3:2
Wt. in Kg(mean)	52kg
BMI kg/m^2(mean)	23
Medical history:	
DM	2
HTN	3
Anaemia	3
Other (Amvat,Pakshvadha)	2

Table. 3: Table Showing the Effect of Therapy on weight, serum creatinine (KFT), eGFR in 10 Patients.

SN	**Parameter in Respective Unit**	**Mean ± SD**		**Mean of Diff. ± SD Score**	**SEd**	**"t"**	**P**
		BT± SD	**AT± SD**				
1	Weight in kg	22.68±**2.984**	22.54±**2.79**	0.1420±**0.37**	0.117	1.211	0.2568
2	Sr.urea	29.09±**6.60**	25.96±**5.84**	3.130±**4.96**	1.57	1.993	0.0774
3	Sr.creatinine	1.53±**0.183**	0.975±**0.331**	0.555±**0.309**	0.0978	5.674	0.0003
4	Sr.uric acid	6.89±**1.22**	6.07±**1.015**	0.8200±**0.999**	0.316	2.594	0.0290
5	Hb%	10.59±**1.358**	11.14±**0.814**	-0.55±**1.411**	0.4463	1.232	0.249
6	**eGFR**	**51.8±8.244**	**93.8±47.23**	**-41.8±44.209**	**13.98**	**2.99**	**0.152**

Table. 4: Table showing effect of treatment on albuminuria in patients.

No. of patients with albuminuria (BT)	**No. of patients with albuminuria (AT)**	**Total % of relief**
4	0	100%

During study it was observed that 2 patients of DM, 3 of HTN, 3 were anaemic. Out of 10 Patients only in 4 patients albuminuria was present.

Patients showed very significant improvement in serum creatinine (P <0.0003) at the end of 15 days treatment as compared to before treatment.

Also, improvement in eGFR (P <0.152) as compare to zero-day values.

There was significant improvement in Serum urea and uric acid at (P< 0.0774 and P<0.0290) respectively.

100% improvement in albuminuria was seen.

Safety-Tolerability

No any side effect or abnormal laboratory results were reported from starting treatment to after treatment.

DISCUSSION

Treatment protocol comprises Hetu Viparit Chikitsa (precipitating factor should be removed). According to modern science dialysis is first line of treatment when the patient having severe clinical signs and symptoms with serum creatinine greater than 10mg/dl or GFR is <15ml/min/1.73m^2.[5,6] As per Ayurved above said condition can be correlated with disease of *Mutravaha Srotas*. According to *Ayurved Vrikka* is made up of *Rakta* and *Medo Prasad Dhatu*. Accumulation of toxic substance causes the increase in serum creatinine, albuminuria and decreased in eGFR. Rakta and Meda *Dhatus, Tridosha* and *Gara Visha were* kept in mind while treating kidney diseases. Taking these Vyadhi Ghatak in to consideration, *Sarivadi Kwath* was used, in which *Sariva is Shit, Madhur, Kaph, Vatajit* and *Vishghna*.[7] So it helps to filter waste products by kidney. *Punarnava* is an important Drug, as it has diuretic, anti-inflammatory, antibacterial activity, rejuvenation, and *Vishnashak* property.[8] It balances *Kaph* and *Vata Dosh*, it also has *Shoth Nashk* property.[9] *Patha* is *Tridoshnashak* and *Vishghna*. *Musta* is Pachak, *Kled Nashak, Vish nashak*.[10] Triphala is Tridosh Nashak. So *Sarivadi Kwath* was used which is *Rakta Prasadak* and it balances the *Meda Dhatu, Tridoshgna* and having *Vishghna, Kled Nashak* property produced by *Rakta and Meda Dushti*. After correction in the *Rakta* and *Meda*, the *Rasayan* and *Balya* drugs may be useful. *Shilajit Vati* was used in this case. *Shilajit* is very important drug in treatment of *Mutravaha Srotas* and in correction of *Pandu*.[11] It is *Kled Nashak* as well as *Rasayan*. Overall effect of combination of drug is *Vishaghna* (anti toxic) and *Tridosh Nashak, Rakta Prasadak* and *Rasayan* wich leads to decrease in serum creatinine and correction of *Pandu*.

CONCLUSION

The observations and results are showing the fruitful effect on subjective and objective parameters in this case study. It is very difficult to conclude on the basis of result of single case study. Foresaid treatment protocol must be evaluated on large scale following proper methodology and must be compared with standard treatment protocol so that society may be benefitted to get rid of suffering of mankind. Thus, principles of management be established on the horizon of Ayurved to relive patients of hampered kidney function with Ayurved prospective.

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