INTERNATIONAL
AYURVEDIC MEDICAL
JOURNAL

IAMJ

International Ayurvedic Medical Journal, (*ISSN: 2320 5091)* (April, 2017) 5 (4)

EVALUATION OF GUDAARDRAKARASAYANA ON THE RENAL FUNCTION TEST IN CHRONIC KIDNEY DISEASE

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ABSTRACT

Background: Chronic Kidney Disease (CKD) is the condition where there will be reduction of the functional unit of the kidney "Nephron". The clinical symptoms such as oedema and laboratory complications of CKD become more apparent with Glomerular Filtration Rate (GFR) decline and disease progress to the stage 3 & 4. This condition of the oedema in the renal pathology can be paralleled with the pathology of the *Shotha*. **Aims:** Evaluation of *GudaArdrakaRasayana* on the Renal Function Test in Chronic Kidney **Settings:** SDM Hospital of Ayurveda, Udupi, Karnataka. Year: April 2012 and April 2015 **Design:** This study was conducted as a prospective, Single Centre and open label trial with Pretest and Postest design with administration of *Guda Ardraka Rasyana* with dose of 48 grams in divided dose in empty stomach with luke warm water as adjuvant for a period of 1 month with a follow up of 15 days. **Methods and Materials:** Patients aged between 20 and 65 years who were clinically diagnosed in SDM College of AYurveda, Udupi between April 2012 and April 2015 were included in the study. Who present themselves with persistent uremia (>50 mg/dL), Increased Serum Creatinine (>1.4 mg/dL), Uricemia (>7.0 mg/dL) and who were does not fall under exclusion criteria. **Analysis Used:** Student t test for samples was used to compare the baseline characteristics, for Assessment $p<0.05$ was considered significant. **Results:** Mean serum Urea concentration which was 53.8 mg/dL came down to 44.6 mg/dL, with P = 0.279 and t=1.151 indicating Renal function change significance but could not overcome the effect from the chance. Serum Creatinine decreased significantly from the baseline value 3.02 mg/dL to 2.53 mg/dL with p value 0.035 and t value 2.482. Serum Uric acid concentration had decreased from mean value 6.140 mg/dL to 5.710 mg/dL with 7% average reduction in Uricemia from the baseline. **Conclusion:** *GudaArdrakaRasayana* treatment sig-

nificantly reduced Serum Urea, Creatinine, Uric Acid Concentration and increasing the excretion, by maintaining or improving the glomerular filtration in patients with CKD.

1. Studies with a longer follow-up, larger sample size and patients in various stages of CKD are required to confirm effect of *Guda Ardraka Rasayana* on Increases the glomerular Filtration and induce long-term renoprotection in CKD.

Keywords: Chronic Kidney Disease, Uremic syndrome, Glomerular Filtration Rate

INTRODUCTION

Kidney, a vital multipurpose organ which serves many function, most of the people are familiar with one important function i.e. getting rid of the substances that are the waste product of metabolism. Not only this it also plays a very important role in maintaining the balance in the fluid compartments, osmolality , concentration of the electrolyte there by maintaining the arterial pressure as well as acid base balance. Apart from these functions it also secretes hormone “erythropoietin” which stimulates production of the red blood cells (1)

Chronic Kidney Disease is the condition where there will be reduction of the functional unit of the kidney “Nephron” (2). This is progressive and irreversible pathology which can be caused due to two broad set of the mechanisms1) initiating mechanism 2) progressive mechanism. The former is determined by the genetic abnormality ofthe kidney development or the integrity, immune complex deposition and inflammation, Toxins. The later can be explained by thereduction in the number of nephrons leads to the increased blood flow, increased GFR and increased urine output in the initial phase subsequently result in maladaptive hypertrophy and sclerosis (3). Blood Urea and creatinine are the waste products of the metabolism which are cleared through glomerular filtration. These metabolic waste products accumulate almost in proportion to the number of the nephron destroyed. Therefore if GFR decreases creatinine excretion also decreases (4). Urate is one among some of the solute which also depends upon GFR for its excretion.

Although accumulation of the Serum urea and creatinine along with many toxins in renal failure are implicated for the uremic syndrome. Thus serum concentration of urea and creatinine should be viewed as being readily measured and impaired Kidney function represents a vast over simplification of the uremic state (5).

Treating the CKD initially include adjustment in the dietary intake of salt and use of loop diuretics and sometimes in combination with metolazone (thiazide- *related heterocyclics)* (6) may be needed to maintain euvolemia. In contrast, overzealous salt restriction or diuretic use can lead to ECFV depletion and precipitate a further decline in GFR (7).

Considering the above facts we hypothesized that administration of the *GudaArdrakarasayana* to confer renal Protection by increasing the GFR which may be inferred by the decrease in serum Urea and creati-

nine. The aim of this clinical trial was to evaluate the effect of the *Guda ArdrakaRasayanaon* blood Urea, Creatinine and Serum Uric Acid concentration in Patients of CKD.
The initial stages of the CKD like stage 1 and 2 are not associated with any symptoms arising from decrement in GFR. However there may be symptoms such as edema in patients with underlying renal disease like nephrotic syndrome, renal parenchymal disease, glomerulonephritis and polycystic kidney disease. The clinical symptoms such as edema and laboratory complications of CKD become more apparent with GFR decline and disease progress to the stage 3 & 4. This condition of the edema in the renal pathology can be paralleled with the pathology of the Shotha. Hence in present study *GudaArdrakaRasayana* is selected which is specifically indicated in the Shotha.

GudaArdrakaRasayana

Administration of Jaggery and ginger with specific pattern is explained in "Brihatrayi" which acts as *Rasayana* in *Shotha, Kasa, Shwasa, Pratishyaya, Alasaka, Gulma,Prameha,* and is also beneficial in *Kamala, Shosha, Manovikara* (8).
Jaggery and ginger in equal quantity starting with 12gms each increased daily up to 12gms daily in a single or divided dosage and increased up to 120 gms/day and this is maintained for a period of 30 days is the complete increased dosage of this rasayana. Conventionally medium dosage of the same i.e. 48gms/day in divided dose was administered in diagnosed case of CKD.

PATIENTS AND METHODS

Patients

Patients aged between 20 and 65 years who were diagnosed as having CKD clinically diagnosed by patient's history, physical examination, Renal Function Test in SDM College of AYurveda, Udupi between April 2012 and April 2015 were included in the study.

The inclusion criteria were persistent uremia (>50 mg/dL), Increased Serum Creatinine (>1.4 mg/dL), Uricemia (>7.0 mg/dL)

The exclusion criteria were: Uncontrolled Diabetes Mellitus, history ofmyocardial infarction, unstable angina, Congestive Heart Failure, Cerebro Vascular Accident, Bilateral Renal Artery Stenosis, Single Kidney, Collagen Vascular Disease, active liver disease; severe pulmonary disease; pregnancy or breast feeding, hypersensitivity or intolerance to Trial drug, Patients of End Stage Kidney Disease(ESKD).The study protocol was approved by the Head of the Deaprtment of Kayachikitsa, SDM College of Ayurveda. All patients gave informed consent.

Study design

This study was conducted as a prospective, Single Centre and open label trial with Pretest and Postest design. Patients diagnosed as CKD were allocated numbers were given; each patient was examined during the first visit, and every 15 days and a month thereafter.
The following variables were measured: Serum Urea, Serum Creatinine, and Serum Uric Acid before and after intervention *Gu-*

daArdrakaRasyana was administered in a dose of 48 gms/day in a divided dose in empty stomach with luke warm water as adjuvant for a period of 1 month with a follow up of 15 days

Data collection

All data were collected for analysis on before intervention, after the end intervention and follow-up. Patients' characteristics including sex, age, serum Urea, Serum Creatinine, Serum Uric Acid, were collected to determine the stage of the Kidney function, if there were any significant differences before and after the administration of the *GudaArdrakarasayana*. The collected data was evaluated as mentioned below.

Data analysis

All the collected Data were tabulated systematically, Student t test for samples was used to compare the baseline characteristics, for Assessment criteria i.e. Serum Urea, Serum Creatinine, Serum Uric Acid. . $p<0.05$ was considered significant. And statistically analyzed data were pictorially presented in double bar diagram.

OBSERVATIONS &RESULTS

The following table numerically indicated the incidence and distribution of the 10 patients in this study on different demographic parameters.

Distribution of the Patients:

Out of 10 Patients 50% were Males and 50% were females which indicates that CKD can affect both genders without discrimination. 3 (30%) patients belonged to the age group 41-50 years, 5(50%) patients fell under the range of 51-60 years , and 2 (20%)patients came under the range of the 61-65 years. This signifies that the prevalence of this CKD is much in the age group 51-60 yrs. which could be because gradual reduction in the functioning nephron in the system and also may be due to exposure to various toxins which will invariable effect the renal system.

8 (80%) patients were Hindu and 2(20%) patients were Cristian's. This may be because the major population of the area being Hindu. 3 (30%) patients were illiterate, 3(30%) patients completed their middle school and 4 patients (40%) had completed their degree. This signifies that the prevalence of this CKD has a less to do with the level of education. 3 (30%) patients were involved in mild physical work. 5 patients (50%) were involved in the moderate physical work and 2 patients (20%) belonged to the age group of heavy physical work. This signifies that the prevalence of this CKD is much in moderate physical work group and minimum incidence is identified in the heavy physical work group. This may be due to the hemodynamics that is directly related to the physical work. All the 10 (100%) patients had a habit of drinking coffee/tea, 4 (40%) of the patients had the habit of tobacco and 5(50%) had a habit of alcohol intake. This signifies that prevalence of this CKD is much in coffee/tea drinking persons and next majority is shared by alcohol and tobacco consumption. But it has to be considered that consumption of the coffee and tea once in a day has become a customary habit of this geographical area.

Patient Characteristics and General Variables.

Ten patients were enrolled in this study. The patients were clinically diagnosed as having CKD. All patients' completed the study. Table 1 presents the baseline characteristics of these groups with mean value along with standard deviation.

RESULTS

The following result was observed after administration of the *GudaArdrakaRasyana* which has been tabulated and diagrammatically represented

Changes in Serum Urea

After 1 months of treatment, Mean serum Urea concentration which was 53.8 mg/dL came down to 44.6 mg/dL with difference of 9.2 mg/dL. the change that occurred with the treatment is not great enough to exclude the possibility that the difference is due to chance with P = 0.279and t=1.151 after 1 months of treatment, serum Urea concentration was reduced than the baseline levels indicating Renal function change significance but could not overcome the effect from the chance.

Changes in Serum Creatinine

After the treatment with *GudaArdrakaRasayana*, Serum Creatinine decreased significantly from the baseline value 3.02 mg/dL to 2.53 mg/dL with difference of the 0.490 mg/dL . After 1 month, there was 16.23% average reduction in Serum Creatinine with p value 0.035 and t value 2.482. This signifies that there is increase in the creatinine clearance with increased glomerular filtration with trial drug.

Changes in Serum Uric acid

Serum Uric acid concentration had decreased from mean value 6.140 mg/dL to 5.710 mg/dL after 1 months of treatment from the GudaArdrakaRasayana. After 1 month, the trial drug had a 7% average reduction in Uricemia from the baseline. However the significance is not great enough to exclude the possibility that the difference is due to chance at P value being 0.318 and t value 1.057. This signifies that CKD being a progressive damage to the nephron and reduced filtration of the system a change was observed even though couldn't exclude the chance factor.

DISCUSSION

In our study, *GuadaArdrakaRasayana* significantly reduced Serum Urea, Creatinine and Serum Uric Acid concentration and maintained renal function in patients with CKD. To the best ofour knowledge, very minimum studies have been carried out to identify the renal function in CKD.

There will be increased Serum Concentration of the Urea, Creatinine & Uric Acid in impaired renal functioning in damaged kidney. The persistent increased level of the above said metabolic waste products is attributed to the CKD. Where, not only the persistent damage to the renal system but also progressive decline in its function is observed. This in turn points towards the major functioning of the kidney i.e. glomerular filtration apart from this there are other activities like production of the hormone, main-

taining acid base balance, & also fluid equilibrium.

Higher the rates of the Serum concentration of the Urea, Creatinine & Uric acid, greater the damage to the renal function and invariably lesser the glomerular filtration. Thus slowly progressing from the first stage of the CKD to End Stage Kidney Disease (ESKD) where only Kidney transplant and continuous dialysis are the treatment.

Other stages of the CKD can be managed by the oral medications to protect the functioning nephron there by reducing the damage to the kidney and increased or maintained glomerular filtration. Reduces the level of Uremia, Creatinine, Uricemiais emphasized to prevent the progression of the decline in renal function.

Current study was carried out with an intention of the rejuvenating the damaged kidney by administering the *Rsaayana* (Rejuvenator) mentioned in the classics. With this intention specific Rsayana i.e. *GudaArdrakaRasayana* was selected and administered in the dosage of 48 gms/ day in divided dose before food along with Luke warm water as adjuvant in patients suffering from CKD. This trial drug was administered for a period of 1 month followed by 15 days of follow up.

All the 10 patients who were selected from the OPD and IPD of department of Kayachikitsa, SDM College of Ayurveda & Hospital, Udupi were given with *GudaArdrakaRasayana* for a period of 1 month, before the administration of the trial drug and after the intervention The Level of the Serum Urea, Serum Creatinine and Serum Uric Acid were taken and tabulated. The collected data were then statistically analyzed using Paired t test and result were interpreted accordingly.

GudaArdrakaRasayana containing only two ingredients *Guda* (Jaggery) which is having purificatory properties over the urinary system as well as circulatory system which will be understood in bringing down the metabolic waste from the circulatory system by increasing the excretion from the Urinary system, further it also acts as rejuvenator.[9](9)Thus jaggery as an ingredient was found to be effective in CKD.

Ginger being the second key ingredient which is having gingerol and shagol as the active principles have many effect some of them are, in lower doses it said to have depressor activity on cardio vascular system and thereby lowering the blood pressure, which also needed in CKD (10). Apart from this gingerol being anti-oxidant showed its efficacy in reducing oxygen centered free radicals in renal failure (11).

Thus it can be understood that *GudaArdrakaRasayana* is effective in CKD, statistically by bringing down the Serum Concentration of Urea whose mean value before treatment 53.8 mg/dL dropped down to 44.6 mg/dL by giving 17.1% improvement by mean difference of 9.2 mg/dL.

Serum Creatinine concentration came down 16.23% from initial mean value 3.02 mg/dL to 2.53 mg/dL with difference of the 0.490 mg/dL after the administration of the trial drug for a period of 1 month.

Serum uric acid level from its baseline mean value 6.140 mg/dL to 5.710 mg/dL after 1 month of treatment from the *GudaArdrakaRasayana*. Thus by administering the *Gu-*

daArdrakaRasayana in dose of 48 gms/day in divided dose in empty stomach with luke warm water as adjuvant for a period of 1 month was found to be effective in cases of CKD by bringing down the Serum Urea , Serum Creatinine And Serum Uric Acid significantly.

There are some limitations in our study that should be considered. First, the results may be limited by the small number of patients. However, this is the first study to show the effect of *GudaArdrakaRasayna* on the reduction of Serum Urea, Creatinine & Uric Acid and increase in their excretion in patients with CKD. Second, the responses to *GudaArdrakaRasayana* may have inter individual variations caused by dietary or genetic factors. Dietary and genetic factors that affect the response to patients should be considered.

CONCLUSION

In summary *GudaArdrakaRasayana* treatment significantly reduced Serum Urea, Creatinine, Uric Acid Concentration and increasing the excretion, and preserved renal function by maintaining or improving the glomerular filtration in patients with CKD. The reno-protective effect of *GudaArdrakaRsayanamay* occurs by purificatory, rejuvenating, and Anti-oxidant action. Studies with a longer follow-up, larger sample size, and patients in various stages of CKD are required to confirm whether *GudaArdrakaRasayana* cause significant reduction in Serum Urea, Creatinine & Uric Acid & Increases the glomerular Filtration and induce long-term reno protection in patients with CKD.

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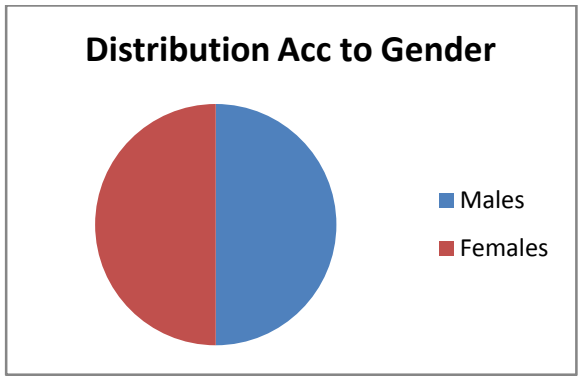
Available from: http://www.ncbi.nlm.nih.gov/pubmed/16971750.

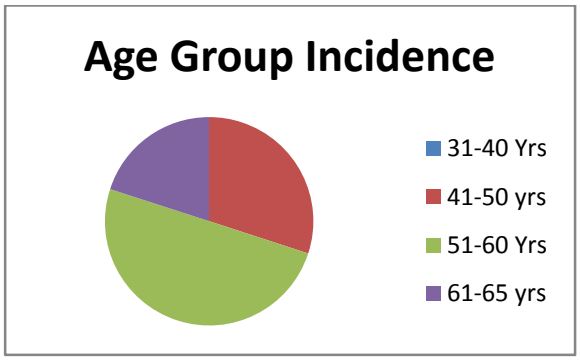
Table 1: Numerically indicated the incidence and distribution

Sl.No	Profile	Category	Subjects	
			No	%
1	Gender	Male	5	50
		Female	5	50
2	Age group	31-40	0	0
		41-50	3	30
		51-60	5	50
		61-65	2	20
3	Religion	Hindu	8	80
		Muslim	0	0
		Cristian	2	20
		others	0	0
4	Education	Illiterate	3	30
		Primary School	0	0
		Middle School	3	30
		College	4	40
5	Work	Mild Physical activity	3	30
		Moderate Physical Work	5	50
		Heavy Physical work	2	20
		No Physical work	0	0
6	Habits	Tobacco	4	40
		Alcohol	5	50
		Coffee/Tea	10	100

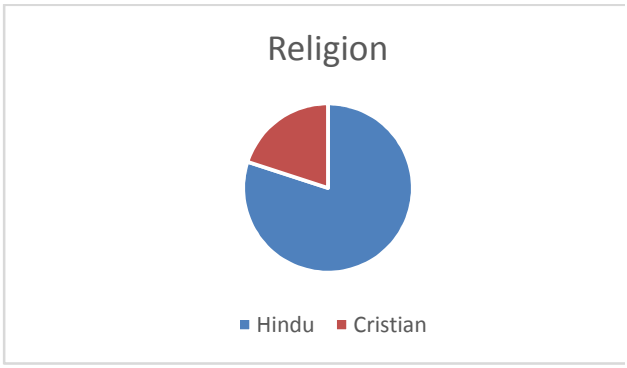
Distribution of the Patients according to the Gender:



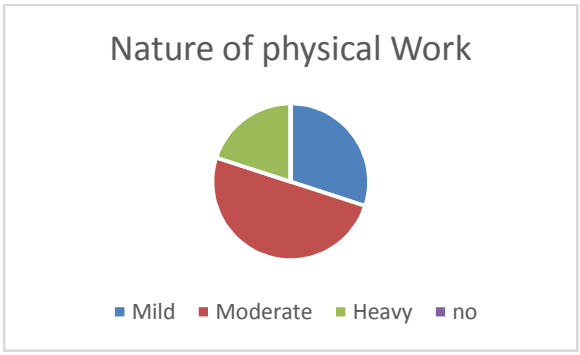
Distribution of the Patients according to the Age:



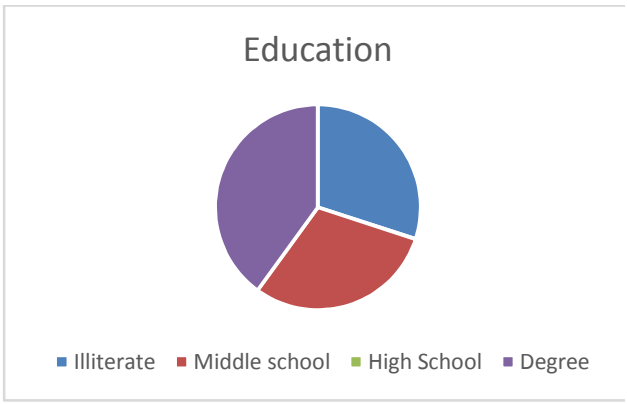
Distribution of the Patients according to the Religion:



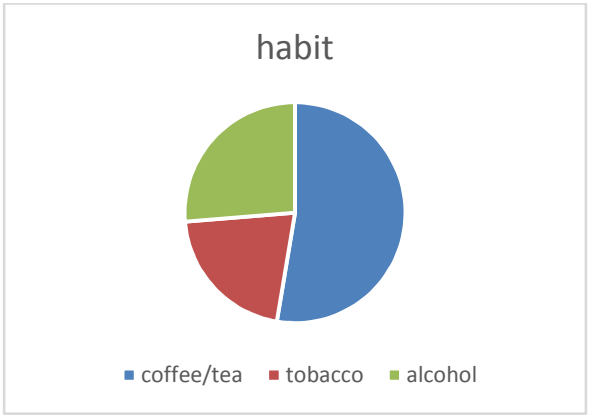
Distribution of the Patients according to Nature of work:



Distribution of the Patients according to the Education:



Distribution of the Patients according to the Habit:



Sl.No	baseline characteristics	Variables
1	Sex (M/F)	5/5
2	Age (Years)	53.5±6.5
3	Serum Urea (mg/dL)	53.8±21.3
4	Serum Creatinine (mg/dL)	3.02±1.88
5	Serum Uric Acid (mg/dL)	6.14±2.02

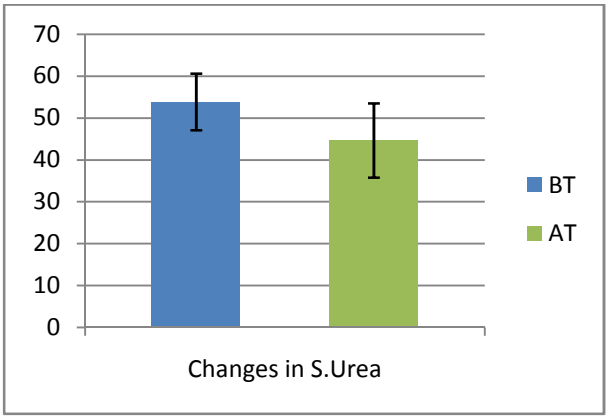
RESULTS

Effect of *GudaArdrakaRasayana* on Renal function Parameters

Parameters	BT	AT	difference	%	Paired 't'		
					SD	P	t
Serum Urea	53.8	44.6	9.2	17.10	±21.3	0.279	1.151
Serum Creati-	3.02	2.53	0.490	16.23	±1.88	0.035	2.482

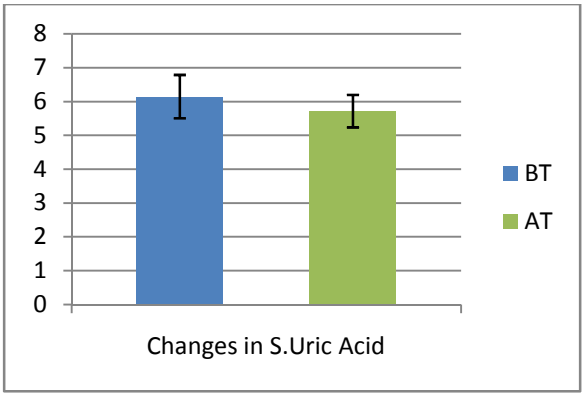
nine							
Serum Uric Acid	6.140	5.710	0.43	7.0	±2.02	0.318	1.057

Changes in Serum Urea



Changes in Serum Uric acid

Changes in Serum Creatinine



Source of Support: Nil
Conflict Of Interest: None Declared

How to cite this URL: K.Nishanth Pai Et Al: Evaluation Of Gudaardrakarasayana On The Renal Function Test In Chronic Kidney Disease. International Ayurvedic Medical Journal {online} 2017 {cited April, 2017} Available from: http://www.iamj.in/posts/images/upload/1391_1400.pdf