



“CLINICAL STUDY OF EFFICACY OF SHILAJATU WITH DURALABHA SWARAS AS AN ADJUVANT THERAPY IN MUTRAKSHAYA WITH SPECIAL REFERENCE TO CHRONIC RENAL FAILURE”

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ABSTRACT

CRF is an emerging to be an important chronic disease globally. The kidney disease is a leading cause of morbidity & mortality now a day. Kidney disease is the leading cause of death in industrialised nations. It is an irreversible deterioration in renal function. This initially manifest as a bio-chemical abnormality. The management include dialysis and renal transplantation which is not easily affordable. There is an urgent need to explore, highlight new interventions and modify modifiable risk factors as a basis for treatment strategies to prevent the development and progression of CRF. The present study was carried out on 30 patients of CRF for 45 days at the OPD and IPD of Kayachikitsa of Seth Tarachand Ramnath Ayurvedic Hospital, Pune. They were given *shilajatu* with *Duralabha swaras* twice a day for 45 days. Results were assessed statistically on 15 parameters using Wilcoxon and (paired) 't' test.

KEYWORDS

shilajatu, duralabha swaras, basti, vrukka, Triphala kwatha.

Introduction:-

CRF is an emerging to be an important chronic disease globally. CKD is defined by a state of kidney damage or decreased kidney function for 3 or more months. Decreased kidney function is defined by GFR of less than 60ml/min per 1.73m². Based on guidelines of the National Kidney Foundation (KDOQI) (Kidney dialysis outcomes quality initiative) in which stages of CKD are defined according to the estimated GFR.

The kidney disease is a leading cause of morbidity & mortality now a day. Kidney disease is the leading cause of death in industrialised nations. Factors that influence development & progression of CKD include hypertension, hyperglycaemia, dyslipidemia, obesity, age, smoking, history of cardio-vascular disease & exposure to nephrotoxic agents. Non-traditional risk factors such as oxidative stress. Renal disease is associated with a graded increase in oxidative stress markers even in early CKD. This could be consequence of an increase in reactive oxygen species as well as decrease in antioxidant defence. CRF is growing public health concern worldwide.

No matter whatever the cause once the creatinine level goes beyond the normal limit it becomes very difficult to bring it back in the range. It has been recently estimated that in India, the incidence rate of ESRD to be 229 per million population. 5 & more than 1,00,000 new patients enter renal replacement progression annually

The current therapy in Kidney pathology is having minimal scope for specific curative treatment. Dialysis & Renal transplantation are applicable only in selected class of sufferer. So the management of kidney diseases is a challenge for medical profession.

In Ayurveda, the term “*Basti*” refers to urinary organ from kidney to bladder. *Apanvayu* is the controlling principle for proper functioning of Basti. In vitiation of *apanvayu* the act of micturition is affected. Ayurvedic text & Samhitas also describe various categories of *Mutra roga* like *Mutraghata*, *Mutrakshaya* etc. For this wide range of herbo-mineral drugs used as therapeutic measures. In this background of increasing cases of CKD & the economical difficulties of its treatment we planned to investigate the clinical efficacy of *Shilajatu* with *Duralabha Swaras* as an adjuvant therapy in *Mutrakshaya* with special reference to Chronic Renal Failure.

AIM and OBJECTIVES

AIM:

“CLINICAL STUDY OF EFFICACY OF SHILAJATU WITH DURALABHA SWARAS AS AN ADJUVANT THERAPY IN MUTRAKSHAYA WITH SPECIAL REFERENCE TO CHRONIC RENAL

FAILURE.”

OBJECTIVES:

- To analyze the concept of *mutrakshaya* correlating with chronic renal failure
- To evaluate the efficacy of “*shilajatu* with *Duralabha swaras* in *mutrakshaya*” as mentioned in ayurvedic classic by clinical study.

Materials and method:

Detailed study plan:

- Presence of chronic kidney disease was established based on the presence of kidney damage and the level of kidney function through glomerular filtration rate (GFR), irrespective of the cause of renal failure, according to the K/DOQI guidelines.
- Presence of oligouria (*mootrakshaya*) was established based on the calculation of urine output.
- Diagnosed patients of chronic kidney disease having *mootrakshaya* were registered from the OPD of Kayachikitsa department of hospital.
- All the patients were selected according to the inclusion and exclusion criteria in the OPD and IPD of the Seth Tarachand trust hospital, Rastapeth, Pune.

Shilajatu was collected from authentic unit and *shodhan* was done with *Triphala kwatha* and given in 3gm dose with *Duralabha swaras* 20 ml in two divided doses for 45 days.

Table (1) Drug and details of its administration

Drug	Shuddha Shilajatu
Dosage	3 gm (In 2 divided doses)
Anupana	Duralabha swaras (40ml)
Sevan Kala	Morning (7 am) – Evening (6pm)
Duration of Trial	45 days
Route of Administration	Oral
Follow up	7 th , 15 th , 30 th , 45 th day

Inclusion Criteria: -

Patients having textual symptoms of *Mutrakshaya*, Chronic Renal Failure; will be taken as a subject to study.

- Sex: Male or Female
- Age 20 - 60 years
- Diagnosed patients of chronic renal failure.
- The patient is able and willing to give informed consent.

Exclusion Criteria:-

- Age below 20 years and above 60 years
- Other: HIV- associated nephropathy and transplant allograft failure
- Psychological ill patient
- Patient undergone renal transplantation.
- Acute Renal Failure and rapid progressive glomerulonephritis
- Patient having any kind of malignancy.

Assessment Criteria:-

Breathlessness, Facial Oedema, Bilateral pedal oedema, Urine Output, Urine Qualitative Analysis (Appearance, Colour, odour, Turbidity), Hypertension.

Investigations:

BUL
Serum Creatinine
Serum Electrolyte
Hb %
Urine routine

Results and Observations:-

All the patients were clinically assessed before and after treatment. The following result were observed

In this study sex and religion didn't show significant factor. Age wise distribution showed old patients were more prone to CRF; in this study among 30 patients 60% were from the age group 51-60 years of age.

Diet also shows significant criteria in this study, 83.33% were on mixed diet and 16.67% were pure vegetarian.

Occupation wise distribution shows 53.33% patients were having moderate physical work, 26.67% with mild & 20% with severe physical work.

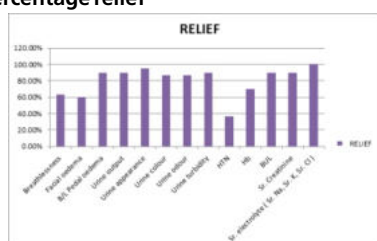
Addiction seems to be an important criteria of causing CRF; in this study 43.33% were alcoholic, 33.33% patients having habit of drinking excess tea, 26.67% patients using mishri, 20% were smoker, 13.3% patient were tobacco chewer, 10% drinking excess coffee and only 3% with none of any addiction.

The main causative factor for CRF in this study was Hypertension; 56.67% were found in this group, 33.33% were having Diabetes mellitus, 26.67% were having nephritis, 3.33% were having anaemia and pulmonary tuberculosis and 20% were without any concurrent disease.

In this study the qualitative criteria showed significant result as breathlessness showed 63.33% relief, generalise weakness, facial oedema showed 60% relief and B/L pedal oedema had 90% relief. Relief in urine appearance was 95%, urine colour and odour was 86.67% and urine turbidity was 89.5%.

Quantitative parameters also showed significant results as relief in urine output was 90%, in hypertension was 36.67%. Hb% increases in 70% patients as well in BUL and Sr.creatinine was reduced in 90% patients. Serum Electrolytes(Sr.Na, Sr.K, Sr.Cl) level was maintained in 99.99% of patients.

Reduction in all these signs and symptoms were statistically significant; showed in (Table2)

Table (2) percentage relief**Discussion:-**

CRF is a degenerative form of renal disease. According to Ayurveda CRF is a disease of Mootravaha strotas. Though all the three doshas as well as dushyas are involved in the disease, vata is responsible for degeneration of the structure of kidney. According to Bhaishajya ratnavali vrukka roga is not completely curable disease so; major target is to improve the quality of living. For these rasayan chikitsa is explained; which is used to prevent & repair the tissue damage or degeneration.

Shilajatu is a Rasayan dravya. It has very important role in mootravaha strotas. Shilajatu and Duralabha swaras both acts as diuretics and antioxidant. New research shows shilajatu contain 85 minerals in ionic form and it contains fluvic acid, humic acid, hippuric acid, and benzopyrones. The active principle in shilajatu as fluvic acid regenerates & prolongs the degeneration of essential nutrients in the cells. Fulvic acid restores electrical balance to damage cells, neutralizes toxins & eliminates food poisoning in a short duration. Shilajatu provides iron to the body that are necessary for making the red blood cells (RBC's). It also acts as a stimulant for immune system. It is a strong kidney tonic.

Duralabha also acts as a diuretic, it contains flavonoid as explained earlier which acts as antioxidant. It contains triterpens which acts on kidney.

On the basis of above and as explained by chakradatta in mootraghat shilajatu (3gms) is used with duralabha swaras (40ml) in two divided doses for 45 days in 30 patients.

In the above study, out of 30 patients CRF is seen mostly in old patient, about 60% patients are old age between 51-60 yrs. CRF is mostly seen in male as compared to female in these study as 60% male and 40% female.

Occupation doesn't show any significant change in cause of CKD as 53.33% are moderately physical working, 26.27% patients are doing mild physical work while only 20% patients were pursuing severe physical work.

Religion doesn't show any significant relation with CKD.

In these study 43% patients were addicted to alcohol, 10 were addicted to tea and 3 patients with coffee. 4 patients were having habit of chewing tobacco and 8 having habit of taking mishri and 6 used to smoke. One patient having no addiction; this might be an inherited case. In rest we can conclude the addiction as one of the cause of CRF.

Smoking increases the risk of micro-albuminuria; shortens the interval between onset of diabetes and the start of albuminuria or proteinuria; and pathologically promotes the progression of diabetic nephropathy to ESRD. Tobacco chewers may be associated with albuminuria and abnormal renal function in non diabetic and non hypertensive people in future.

Diet wise distributions as 5 are vegetarian and 25 are having mixed diet. High protein diet is strictly avoided in CKD patients so major changes to be done for patients on mix diet.

Many diseases may produce renal damage & lead to CRF. In this study among 30 patients 10 were diabetic, 17 were hypertensive, 8 were having nephritis, 1 was anaemic and pulmonary Koch's patient and 6 were without any previous illness.

In this study it is observed that DM and HTN are the main cause of renal failure and their incidences are rising worldwide.

Results of the clinical study, obtained are discussed under different parameters of assessment accordingly:

In this study the tested drug shows good result in those qualitative criteria and hence, improves quality of life. Those parameters are breathlessness, facial oedema, B/L pedal oedema, urine

appearance, its colour odour and turbidity. This might be due to the strong anti oxidant and diuretics activities i.e. the rasayan karma as per Ayurveda. It also seen to be energetic health tonic, decreases the generalise weakness of the patients.

Quantitative parameters also show significant results. The assessment parameters are urine output, hypertension, and haemoglobin

(Hb %), blood urea level, serum creatinine level, serum electrolytes (Sr.Na, Sr.K, Sr.Cl).

Urine output - As both study drugs have diuretic action the study showed significant improvement in urine output. Totally 90% relief showed in this study on 30 patients.

Hypertension – In this study there was not too significant relief but mild improvement was seen; 36.67% relief was seen.

Hb% - Anaemia is one of the major complications in CRF. erythropoiesis. In this study the drug is helpful in maintaining the Hb%. It might be due to the iron containing property of shilajtu. Among 30 patients 70% patients showed an increase in Hb%.

BUL- Blood urea level shows significant improvement in this study. Among 30 patients 90% patients show significant decrease in BUL level.

Serum creatinine – It is determined both by kidney function and muscle mass. In this study the level of sr.creatinine was not decrease significantly but has mild decrease in the level.

Serum Electrolyte – Sodium, potassium, and chloride is considered in this study. In this study 99.99% of improvement is seen in all three electrolytes level.

Overall the study shows significant action of the tested drug in mootrakshaya and CRF. As it was an adjuvant therapy the patients were on their medicine other than the tested drug but the relief seen after the use of tested drug was significant. As the drugs were used in shuddha form there we didn't have any adverse effects.

Conclusion:-

- Shilajatu with Duralabha swaras showed promising results in parameters pertaining to the quality of life.
- On blood and bio-chemical parameters, Shilajatu with Duralabha swaras showed marginally better results without any adverse effect
- Further long duration studies are needed to observe exact drug action.

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