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Evaluation of the Effect of Ayurvedic Herbo-minaral Formulation: *Chandraprabha vati* on *Albuminuria*

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Abstract: *Ayurveda* is a science of life, based on its basic principles, time tested and experienced through centuries. It is an evidence of experimental research in *Ayurveda* and proves that *Ayurveda* has its own scientific methodology of research and this could be effectively tested with ailments like albuminuria. Albuminuria is a one of the early symptoms of chronic kidney diseases (CKD) and CKD is a very common disorder in present era. For albuminuria, *Chandraprabha vati* is a commonly used *Ayurvedic* drug and its efficacy on albuminuria is not scientifically validated yet. Therefore this clinical study was aimed at to re- establish the efficacy of *Ayurvedic* formulation *Chandraprabha vati* on albuminuria, which can be compared to some of the types of disease of *Prameha* (urine abnormality) in *Ayurveda*, along with the assessment of the effects on the basis of scientific, disease specific biochemical parameter. Hundred patients with albuminuria were selected randomly and divided into two groups, group1was treated with *Chandraprabha vati* (1000 mg twice daily) and the other was considered as placebo. The results review that the *Candraprabha vati* has significantly reduced the signs and symptoms of albuminuria, mainly albuminin urine and although turbidity, organisms, pus cells, red cells, colour and frequency of urine and as well as the some pre-monitory symptoms of disease of *Prameha*. In the light of the results obtained this study proved the fact that *Chandraprabha vati* has been immensely effective and safe *Ayurvedic* drug and particularly been the vital factor in reducing the level of albuminin urine significantly in conclusion.

Keywords: Albuminuria, *Candraprabha vati,* Chronic Kidney Diseases, *Prameha*

1. Introduction

Ayurveda is a science of life, based on its basic principles, time tested and experienced through centuries. It is an evidence of experimental research in *Ayurveda* and proves that *Ayurveda* has its own scientific methodology of research. In present era, there is a need of proofs and evidence based study which resulted from careful investigations, experiments and observations. There is also need to support of accurate convincing reasoning which can persuade the people about its validity. It is also necessary to prove that the ancient concepts in the light of modern theories and experiments. *Chandraprabha vati* (CV) [1] is a very common *Ayurvedic* formulation, prescribed for Kidney diseases. Chronic kidney disease (CKD) has become a major public health problem worldwide. The high cost involved in the management of end stage renal failure has led to a substantial burden on global health-care resources. [2] The mortality and morbidity due to CKD is increasing in Sri Lanka and this burden is even more pronounced in the North Central Province (NCP) of the country where the under lying causes of CKD remain unrecognized. [3] CKD is defined as kidney damage evidenced by structural or functional abnormalities of the kidney with or without decreased GFR over a three months period. Staging of CKD into grades1-5 according to the severity is based on the National Kidney Disease Outcomes Quality Initiative (KDOQI) criteria [4]. The disease mainly affects males from poor socio-economic backgrounds who are involved in paddy farming [3]. Chronic kidney diseaseis100 times more prevalent than end-stage renal disease and its incidence is increasing at an even faster rate. Early treatment of chronic kidney disease and its

complications may delay or prevent the development of end-stage renal disease.[5] In early stages of Kidney diseases can be recognized with mild albuminuria was present (<1g/24 hours).[6] Therefore this clinical study was aimed at to establish the efficacy of *Ayurvedic* formulation CV on albuminuria, which can be compared to some of the types of disease *Prameha* [7] (urine abnormalities) in Ayurveda, and is very common in present era, along with the assessment of the effects on the basis of scientific, disease specific biochemical parameter.

2. Material and Methods

2.1. Preparation of Chandraprabha vati

Rhizomes of Acorus calamus, Zingiber officinale and Curcuma longa, tubers of Cyperus rotandus, whole plant of Berberis aristatam, Andrographis paniculata and Tinospora cordifolia, heartwood of Cedrus deodara, roots of Ipomea turpethum, Aconite heterophyllium, Plumbago zeylanica, Baliosperum montanum fruits and dried spikes of Piper lomgum, fruits of Coriandrum sativum, Terminalia belarica, Terminalia chebula, Emblica officinale, Emblica ribe, Scindasus officinalis, Piper nigrum, Piper cheba, Elettaria cardomomum outer cover of Cinnamomum zeylanicum and sugar were purchased from registered Ayurvedic drug sales outlets in Colombo Sri Lanka and washed and shade dried for 3 days. Leaves of Cinnamomum tamala and 5salts (Rock salt, Black salt, Ammonium chloride, Sodium chloride and Potassium carbonate), metal ashes (Ferrum and Copper), Shilajatu (Aspelt mineral pitch) and Guggulu (purified resinous gum of Balsamodendron mukul H) were purchased from the Indian Medical practitioners co-operative pharmacy and stores, LT, Chennai, India. All these ingredients were identified and authenticated by Head of the Department of Materia Medica, Institute of Indigenous Medicine, University of Colombo, Sri Lanka and Using appropriate each of these ingredients of CV was made according to details description given in the Ayurvedic pharmacopeia [8] at the pharmacy of above said Institution.

2.2. Selection of Patients

This study was conducted after obtaining the ethical clearance from Ethical clearance committee from Institute of Indigenous Medicine, University of Colombo, Rajagiriya. Selection of patients has been done from March 2012 to November 2014, from the *Kaya Cikitsa* clinic at Ayurvedic Teaching Hospital, Borella, Sri Lanka. Hundred (age between 35 to 75, both sex) patients were registered for the clinical study. Out of these, fifty patients were registered for the CV (test drug) treated group and fifty patients for placebo group. Detailed clinical examinations were done for all the cases. Mostly, these patients had the symptoms of passing large quantity of urine, frequency of urination, turbidity of urine and change of colour of urine. All these patients were examined thoroughly and their signs and symptoms, routine examinations, nature of urine and laboratory investigations were done and all symptoms were noted as per standard proforma. For the laboratory investigation, patients morning voided urine was subjected to analyze.

Exclusion Criteria

1. Patients with type 1 Diabetes Mellitus and Type 2 Diabetes Mellitus patients who were insulin dependent.
2. Diabetic patients with severe complications like cardiovascular diseases, Nephropathy, Retinopathy, Diabetic foot etc. and Diabetes due to endocrinopathy e.g. Cushing's syndrome, Hyperthyroidism, Acromegaly etc.
3. Patients along with genetic syndromes associated with Diabetes mellitus. E.g. Stunner syndrome, Down syndrome etc.
4. Patients with Chronic renal failure, Heart diseases, urinary tract infections, high blood pressure, or with a high fever during an infection.

2.3. Study Plan

After selecting the albuminuria patients, they were randomly divided into two groups. The first group of the patients was administered CV and the second group was administered placebo for four weeks. Symptoms were weekly noted as per performa and assessments of the symptoms were made in terms of their absence, presence and severity grade.

2.4. Drug Schedule

2.4.1. Group 1

Candraprabha vati-2gm/day (4 tablets per day in 2 divided doses–1 tab = 500mg) with lukewarm water after the meals for 4 weeks [9].

2.4.2. Group 2

Placebo {the internal placebo is prepared with husk of the red rise and wheat flour with mixing water until it makes a paste. Then with this paste makes 500mg weight *vati* (tablet) and shade dried of two days} and the dose was 2gm/day (4 tablets per day in 2 divided doses) with lukewarm water for 4 weeks.

2.5. Statistical Methods Used in Present Study

Statistical analysis of collected data was done. It was analyzed in terms of means±SEM. Mann-Whitney U-test and Paired 't' test was carried out at level of 0.05,0.01,0.001of P values.

3. Results

3.1. Response of Therapy in Term of Frequency of Urine

Table 1. *Response of Therapy in term of Frequency of Urine (per day) (mean±SEM).*

Group (n=50)	BeforeTreatment	AfterTreatment	Inhibition%
Treatment	1.54±0.15	0.980±0.14*	36.36%
Control	1.4±1.24	1.34±0.16	04.28%

As shown in Table 1; after the treatment period, treated group of CV patients frequency of passing urine was decreased by 36.36% where as the control group inhibition was 4.28%.

3.2. Response of Therapy in Term of Quantity of Urine

Table 2. *Response of Therapy in term of Quantity of Urine (ml-per day) (mean±SEM).*

Group (n=50)	Before Treatment	After Treatment	Increased %
Treatment	1376.6±65.1	1549±59.4*	12.57%
Control	1387.4±64.6	1401.4±62.4	1.01%

The quantity of urine is increased in some extent of treatment group by 25.43% and the control group quantity of urine increased by 1.01% (Table 2).

3.3. Response of Therapy in Term of Drinking Water (per day)

Table 3. *Response of Therapy in term of Drinking Water (per day) (mean±SEM).*

Group (n=50)	Before Treatment	After Treatment	Inhibition %
Treatment	2029±78.2	2028±67.1	0.05%
Control	1942±74.8	1946±71.0	-0.21%

As shown by the Table 3; amount of drinking water per day decrease in the treated group by 0.05% and increased in control group by 0.21%.

3.4. Response of Therapy in Term of Colour of Urine

Table 4. *Response of Therapy in term of Colour of Urine (mean±SEM).*

Group (n=50)	Pre Treatment	Treatment				Inhibition %
		Endof1st Week	End of 2nd Week	End of 3rd Week	End of 4th Week	
Treatment	1.32±0.07	1.22±0.08	1.18±0.07	1.14±0.07	0.98±0.07	25.75%
Control	1.32±0.07	1.22±0.08	1.20±0.07	1.14±0.08	1.36±0.07	-3.03%

It was observed that the colour of urine changed from yellow to pale yellow in treated groups' urine after the treatment and the inhibition was 25.75% but the control groups colour of urine increased by 3.03%. This data is shown in Table 4.

3.5. Response of Therapy in Term of Turbidity of Urine

Table 5. *Response of Therapy in term of Appearance (Turbidity) of Urine (mean±SEM).*

Group (n=50)	Pre Treatment	Treatment				Inhibition %
		End of 1st Week	End of 2nd Week	End of 3rd Week	End of 4th Week	
Treatment	1.46±0.15	1.34±0.15	1.36±0.14	1.18±0.13	0.78±0.12	46.58%
Control	1.46±0.15	1.38±0.14	1.44±0.14	1.40±0.13	1.58±0.12	-8.21%

As shown in table 5, CV markedly decreased the turbidity of urine after the treatment by 46.58% and control group by 8.21%. End of the 1st, 2nd and 3rd weeks of treatment the treated group inhibition was 8.21%, 6.84% and 19.18% respectively. Although end of the treatment period in control group turbidity of urine increased by 8.21%.

3.6. Response of Therapy in Term of Presence of Albuminin Urine

Table 6. *Response of Therapy in term of Presence of Albuminin Urine (mean±SEM).*

Group (n=50)	Pre Treatment	Treatment				Inhibition %
		End of 1st Week	End of 2nd Week	End of 3rd Week	End of 4th Week	
Treatment	1.52±0.08	1.46±0.08	1.38±0.10	1.02±0.01	0.48±0.10	68.42%
Control	1.44±0.09	1.44±0.09	1.44±0.09	1.34±0.09	1.40±0.12	2.78%

As shown in Table 6, the inhibition of albuminin urine was significantly decrease in CV treated group by 68.42%. And the end of the 1st, 2nd and 3rd weeks of treatment inhibition was 3.94%, 9.21% and 32.89% respectively.The decrease of albumin in urine noticeably shown after the 3rd week of treatment but the onset of inhibition of albumin in urine was detected after first week of treatment with CV. The control group inhibition was 2.78% at the end of the treatment period.

3.7. Response of Therapy in Term of Specific Gravity of Urine

Table 7. *Response of Therapy in term of Specific Gravity of Urine (mean±SEM).*

Group (n=50)	Pre Treatment	Treatment				Inhibition %
		End of 1st Week	End of 2nd Week	End of 3rd Week	End of 4th Week	
Treatment	1.0201±0.00	1.02±0.00	1.02±0.00	1.0191±0.00	1.0197±0.00	0.04%
Control	1.0198±0.00	1.023±0.00	1.0207±0.00	1.0197±0.00	1.0226±0.00	-20.21%

As shown in table 7, Specific gravity was decreased by 0.04% in the treated groups urine and it was increased in control groups urine by 20.21% at the end of the treatment period.

3.8. Respone of Therapy in Term of Organisms in Urine

Table 8. *Response of Therapy in term of Organisms in Urine (mean±SEM).*

Group (n=50)	Pre Treatment	Treatment				Inhibition %
		End of 1st Week	End of 2nd Week	End of 3rd Week	End of 4th Week	
Treatment	0.86±0.11	0.86±0.12	0.76±0.01	0.66±0.84	0.30±0.07	65.12%
Control	0.88±0.12	0.88±0.11	0.85±0.10	0.82±0.10	0.78±0.12	11.36%

As shown in Table 8, present of the organisms in the urine are markedly reduced after the treatment of CV by 65.12%. End of the 1st week no reduction was noted and end of the 2nd and 3rd weeks of treatment with CV the reduction was noted as 11.62% and 23.25% respectively. The control group reduction of organism in urine was11.36% at the end of the treatment period.

3.9. Response of Therapy in Term of Pus Cells in Urine

Table 9. *Response of Therapy in term of Pus Cells in Urine (mean±SEM).*

Group (n=50)	Pre Treatment	Treatment				Inhibition %
		End of 1st Week	End of 2nd Week	End of 3rd Week	End of 4th Week	
Treatment	3.02±0.19	3.00±0.19	2.86±0.18	2.56±0.16	2.10±0.15	30.46%
Control	2.88±0.19	2.86±0.19	2.78±0.18	2.65±0.17	2.88±0.16	0.0%

As shown in Table9, at the end of the treatment pus cells present in the urine was reduced in the treatment group by 30.46% hence the end of the 1st, 2nd and 3rd weeks of treatment of CV, the reduction was 0.66%, 5.29% and 15.23% respectively. There was no reduction seen in the control group after the treatment period.

3.10. Response of Therapy in Term of Red Cells in Urine

Table 10. *Response of Therapy in term of Red Cells in Urine (mean±SEM).*

Group (n=50)	Pre Treatment	Treatment				Inhibition %
		End of 1st Week	End of 2nd Week	End of 3rd Week	End of 4th Week	
Treatment	1.2±0.13	1.16±0.13	1.14±0.13	1.06±0.11	0.74±0.11	38.33%
Control	1.12±0.12	1.10±0.12	1.06±0.12	1.02±0.10	1.08±0.12	3.57%

As shown in Table 10, the red cells present in the treatment groups urine was reduced by 38.33% and after the 1st, 2nd and 3rd weeks of treatment the inhibition was noted as 3.33%, 5% and 11.66% respectively. The control group inhibition after the treatment period was 3.57%.

3.11. Response of Therapy in Term of Urine Albumin / Creatinine Ratio (ACR)

Table 11. *Response of Therapy in term of Urine Albumin/ Creatinine Ratio (ACR) (mean±SEM).*

Group (n=50)	Pre Treatment	Post Treatment	Inhibition %
Treatment	50.35±9.20	29.82±7.68	40.77%
Control	57.8±10.7	54.68±9.14	5.39%

As shown by the table11, the response of therapy in term of urine albumin /creatinine ratio is markedly decreased in treatment group by 40.77% and the control group albumin/creatinine ratio was decreased by 5.39%.

4. Discussion

When evaluate the efficacy of CV, frequency of urine was markedly relieved but quantity of urine is increased. According to pharmacodynamic actions of CV mentioned Mutra janana (urine producing) property [10]. This producing urine eliminates as urine and this will cause diuretic activity. Experimental study was carried out using wistar rats also showed a statistically significant diuretic activity in vivo [11]. This experimental study also proved *Ayurveda* theory. Apart from urine producing property, properties of *Dipana* (appetizer) [10] and *Pachana* (digestant) [10] is also have the CV. This digestant action can cause *Ama pachana* undigested particles) in *Dhatvagni* (tissue) level and digestion the *Mala* (unwanted substances) in *Dhatu* (tissues) and turn to *Kleda* (waterly substances) and this produce *Kleda* means liquid like water can pass like urine.

Though the quantity of urine was increased but drinking water is not changed. This also suggests that it increased the quantity of urine is not due to intake of water.

The colour change observed in this study due to *Rakta prasadana* (blood purify) and *Mutra Virajaniya* (brings back the colour of urine to normal) properties of CV and *Vishagna* [10] (detoxicant) effect also could support the action. In *Rakta Prasadana* (blood purify) property may purify the

blood and eliminate the *Mala Dhatu* (unwanted substances in tissue level) and it will help to change the colour of urine. Due to *Mutra Janana* (producing urine) [10] property excess the quantity of urine and it may support to reduce the colour of urine too.

As observed in this study significantly reduced the *Avila* (turbidity) of urine after 4 weeks of treatment. The properties of *Dipana* (appetizer), *Rakta Prasadana* (blood purify), *Pacana* (digestant), *Ama Dosa hara* (alleviates unwanted substances), *Lekhaniya* (reducing), *Medogna* (alleviates fat) will help to decrease the Avila Mutrata (turbidity) in urine. *Dipana* (appetizer), *Pacana* (digestant), *Ama Dosahara* (alleviates unwanted substances) actions will help to assimilate the impurities in *Dhatu* (tissue) and also help to pacify *Mutra Dosha* (unwanted substances) which occurs in *Prameha* (urine abnormalities). In addition to that *Medogna* (alleviates fat) property supports to reduce the impurities with destroying morbid fat. Therefore the impurities eliminate with the urine and after the treatment period clear urine eliminates. *Rakta Prasadana* (blood purify) property will help to purify the blood and this purify blood came to the kidneys and hence decreased the *Avila Mutrata* (turbidity of urine).

In addition, in diuretic study using rats [11] was also noted that the purity of urine markedly noted the treated group's urine and this also proved the reduction in *Avila* (turbidity) in urine.

In this study, it was observed that the significant inhibition of albumin present in the urine after one month of treatment with CV. This *Mutra Dosha* correlate with *Prameha* and the properties of *Dipana, Pacana, Rakta Prasadana, Pramehagna, Ama Doshahara, Lekhana* and *Medogna* properties of CV are helpful to reduce the albumin in urine.

In mechanism of albuminuria is mentioned inflammation altering permeability of layers and focal loss of epithelium and endothelium mainly. In anti inflammatory study using CV statistical significant effect was observed in acute and chronic inflammatory models using rats [12]. This may be an important factor of reduction the albumin present in urine and also anti-oxidant effect [13] will help to prevent cell damage, further it will help to prevent focal loss of epithelium and endothelium.

By measuring an albumin to creatinine ratio (ACR) was helpful to detect in approximating a 24hour albumin excretion rate and reduction of this ratio also proved that CV can control the albuminuria.

In Ayurveda, CV has *Rasayana* (rejuvenator), *Balya* (strengthen), *Vrushya* (aphrodisiac) [10] properties which revenue that the property of stabilizing tissues and prevent cell damage. The anti-oxidant properties also stabilize tissues and lead to prevent cell damage and this experimental study substantiate the anti-oxidant property of CV and this could be safely considered as proved by this study that CV contains *Rasayana* (rejuvenator), *Balya* (strengthen), *Vrushya* (aphrodisiac) properties there by healing and stabilize the cells that cause to transpire albuminuria.

Anti-inflammatory activity detected in term of reduced induced paw oedema and reduction of paw oedema [12] considered as *Shothahara* (alleviates oedema) [10] property. *Ayurveda* states that drugs which all eviate oedema should have *Shothahara* property. The CV has *Shothahara* property and it will help the reduction of inflammation. The result of this anti-inflammatory study further confirms this *Ayurveda* theory. And also detected diuretic activity of CV also help to reduce oedema by eliminating water in our body.

Reduction of organisms and pus cell in urine can be seen in this study. This can be caused by *Krimigna* (anthelmintic), property of CV. *Krimigna* (anthelmintic is described under *Krimi nidana* [7] and *Krimi* is classified *Drushya* (visible) and *Addrushya* (invisible). Organisms can include *Adrushya Krimi* and this property can cause the reduction of organisms in urine. Pus cells in urine will also cause by organisms. Formation of pus cells is caused due to white blood cells and it happens with attack by organisms to white cell and after that the white cell become pus cells. Hence this *Krimign*a property is also help to reduce pus cells in urine.

The toxicity study [11] was also proved the *Vishagna* (detoxicant) property of CV by evaluating overt signs of toxicity, hepatotoxicity, nephrotoxicity and neurotoxicity and also proved that CV is a safe drug to prescribe for the patients.

5. Conclusion

Chandraprabha vati showed significant reduction in signs and symptoms of albuminuria, mainly albumin in urine and although turbidity, organisms, pus cells, red cells, colour and frequency of urine and well as the some pre-monitory symptoms of *Prameha*. Subsequently, anti-oxidant, diuretic and anti-inflammatory effects of the same have been significantly intensified the reduction of albuminuria. In the light of the results obtained this study proved the fact that *Chandraprabha vati* has been immensely effective and safe Ayurvedic drug and particularly been the vital factor in reducing the level of albumin in urine significantly in conclusion.

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