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CLINICAL STUDY TO EVALUATE THE NEPHROPROTECTIVE EFFECT OF ELADI CHURNA IN DIABETIC KIDNEY DISEASE.

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ABSTRACT

Diabetic Kidney Disease is now a worldwide health crisis. It is a spectrum of different pathophysiologic processes associated with abnormal kidney function and a progressive decline in glomerular filtration rate. Globally it is the 12th cause of death and 17th cause of disability. Clinically this condition can be correlated to *Madumeha* and *Mutrakshaya*. The present study focuses on the efficacy of the Poly herbo-mineral compound, *Eladi Churna* in the nephroprotective effect in DKD. Consent from all the selected patients was taken before the study. Ethical clearance was accredited by the Government Ayurvedic college and Hospital, Guwahati Assam and CTRI registration was done for the trial. The patients were given the trial drug 1gm twice daily after food with *Tandulodak* 25 ml and *Swadangstradi kwath* 25 ml as *Anupana* for 3 months. A marked improvement was found in eGFR, Serum Creatinine, Blood Urea and Urine Albumin levels. Satisfactory results were noted in chief complaints like urine output, oedema, nausea, vomiting and muscle cramps and Serum Uric acid level. No change was observed in Serum Sodium and Serum Potassium levels at the end of the course.

Key words: Diabetic kidney disease, poly herbo-mineral, *Anupana, Tandulyodak, Swadangstradi kwath*

INTRODUCTION

According to the IDF Diabetes Atlas (2021), 10.5% of adults (20-79 years aged) have diabetes, with nearly half of them being completely unaware that they have it. Diabetes-related complications of kidney function account for a substantial but underappreciated portion of the global burden of kidney disorders.

Although current treatments have helped manage the disease, there is still an elevated risk of disease onset and progression [1]. The effects of DKD on society and the economy are staggering. Diabetes already affects more than 371 million people worldwide, and by 2030, that number is expected to rise to 552 million, with 101 million of those individuals living in India [2].Diabetes has increased in prevalence, making DKD one of the most frequent causes of end-stage renal disease (ESRD)[3].

Significantly underdiagnosis of diabetes results in a lucky break for DKD prophylaxis. Furthermore, DKD advances as a result of insufficient or incorrect care for known diabetics [4]. Clinically, increased urine albumin excretion is the best indicator of DKD. The condition is arbitrarily categorised as microalbuminuria, an early stage with an acceptable increase in urine albumin that is thought to be associated with stable kidney function but has a higher propensity to advance if not treated in a timely manner. The other is the subsequent stage, macroalbuminuria, a higher increase in urine albumin associated with kidney disease progression, with a clear progressive decline in glomerular filtration rate, deteriorating hypertension, and a significant risk of developing kidney failure.[5] Nevertheless, diabetes care has been refined with extensive adoption of methodical preventive medicine with timely usage of angiotensin converting enzyme inhibitors, angiotensin receptor blockers and statins in view of DKD[6].

According to Ayurveda *Prameha*, one of the difficult disease conditions that is comparable to diabetes is mentioned under the term "*Ashthaumahagad*"(Eight disease which are incurable in nature)[7], which refers to entities with significant adverse impacts on health affecting all three Doshas and the majority of the body's Dhatus [8]. Based on *Astanga Hridayakara, Mutra rogas* (Urinary disorders) can have either *Mutra apravruttajanya*(reduced output of urine) *or Mutra atipravrittijanya vikaras* (over excretion or frequent micturition) as their pathology. All 20 types of *Prameha* fall under *Mutra atipravrittijanya vikars* as a result of *the Pratyatma lakshana*(Cardinal features) *of Prameha,*referred to as "PRABHUTA AVILA MUTRATA." When describing it, Acharya Charak stated in *Nidan Sthan* chapter 4[9] that the disease worsens and inevitably takes on an incurable form when the pathogenesis in *Prameha* progresses to *Mutravah Strotas*,(Urinary system) which includes the *Vankshan* (Inguinal region or Groin)and *Basti*. (Urinary bladder)Disease progresses and eventually takes on an irreversible form, which we can correlate with its stage by complications that are typical of DKD. One of the *Trimarma,* or "three vital organs," is the *Basti*. [10] As a result, proper palliative care should be delivered using Ayurveda since it has fewer side effects and the ability to revive viable nephrons. In light of all of this, an effort was made to prepare a poly herbo-mineral compound and assess its nephroprotective effects. In *Chakradutt* Chapter 32 and Chapter 33, the trial drug "ELADI CHURNA" with TANDULODAKA and SWADANGSHTRADI KWATH *Anupan*(adjuvant) is elicited. in Ch 32 of *Chakradutt* and Ch 35,37 of *Bhaisajya Ratnawali*.[11] [12][13] It is being used judiciously in medicating *Prameha and Kaphaj Mutrakriccha*.(Difficulty in passing urine) There are hardly any evidence based studies on effect of *Eladi churna* with *Tandulodaka* and *Swadangshtradi kwath* in DKD hence to explore its utility and for scientific validation present study had been undertaken to explore efficacy, safety and tolerability of *Eladi churna* in Diabetic Nephropathy.

AIMS AND OBJECTIVES:

1. To evaluate the nephroprotective effect of the poly herbo-mineral compound in DKD
2. And, to find out the adverse effect of poly herbo-mineral compound (if any)

MATERIAL AND METHODS:

Reference of Trial Drug:

The selection of the drug is made keeping in mind the *Samprapti* of *Prameha* and its *Upadrava* i.e Diabetic Nephropathy here.

Reference: *Chakradutta, Mutrakriccha Chikitsa*, Chapter 32, Sloka no 24

Bhaisajya Ratnavali , Mutrakriccha Chikitsa, Chapter 35, Sloka 33

Bhaisajya Ratnavali, Prameha Chikitsa , Chapter 37, Sloka 44

And *Anupana Swadangstradi Kwath* is mentioned in : *Chakradutta, Mutrakriccha Chikitsa*, Chapter 32, Shloka 13

Table 1: Contents of the *Eladi Churna*, poly herbo-mineral compound prepared:

SL. NO.	Drugs	Botanical Names	Parts used
1	*Ela*	*Elettaria cardamomum*	Seeds
2	*Pashanbheda*	*Bergenia ligulata*	Root
3	*Shilajit*	*Asphaltum punja-bianum*	Whole
4	*Pippali*	*Piper longum*	Dried fruit

Dose of *Eladi churna*: 1g twice daily after food
Dose of *Tandulyodak*: 25ml
Dose of *Swadangstradi kwath*: 25ml
Duration of the study: 3 months
Follow up interval: 1 month.

CRITERIA FOR SELECTION OF THE PATIENT [14]

1. **Abnormalities of kidney structure and/or function noticed for >=3 months.**
2. Medical history & Clinical features:

- Present history of Diabetes mellitus, hypertension
- Family history of diabetes mellitus, systemic hypertension
- Obstetric history like Gestational Diabetes or delivery of Macro Baby
- Chief complaints like low urine output, turbid urine, oedema, loss of appetite, nausea, vomiting, abdomen bloating, fatigue, muscle cramps
- Dietic history like details of intake of calorie, protein, fat, sodium, potassium.

Phase 1
Prior to Starting Trial

- After approval of synopsis and clearance from ethical committee drug was prepared in State Ayurvedic Pharmacy, GACH. The IEC/2021/249
- A sample was send in Drug Testing Laboratory-Physical evaluation of drug was done and no heavy metals or toxicity was observed, similarly Pharmacognostic evaluation and chemical evaluation was done and authorized certificate of the Trial drug test analysis is obtained :DTL/(AY)/PGR/019/23-24.
- Before enrolling patient for the study, clinical trial registration was done for this study and the CTRI trial number was: CTRI/2023/06/054530.
- It is a single arm random open clinical study with sample size 60.
- Registration of 68 cases was done in the OPD/IPD of the department of *Kayachikitsa*, GACH, 8 of them are drop out so excluded for the study**.**
- The detailed research Performa was prepared incorporating all the clinical features of *DIABETIC KIDNEY DISEASE* and assessment criteria from synopsis mentioned for statistical analysis of the study.
- Before administration of trial drug in patient, signature in consent form was taken.
- All patients taken after considering inclusion and exclusion criteria.

INCLUSION CRITERIA:

1. Patients coming under the diagnostic criteria.
2. Adult patients between 18 years and 70 years of age irrespective of sex
3. Patients with and without dialysis

EXCLUSION CRITERIA:

1. Patients less than 18 years and more than 70 years of age
2. Patients suffering from major diseases-

- Coronary artery diseases(CAD)
- Malignancy
- Chronic liver disease
- Ascites
- Tuberculosis
- Sexually transmitted disease

3. Pregnancy and lactating mother

Phase 2

Clinical Study Design

- Patients were selected for trial according to Inclusion and exclusion criteria.
- Total numbers of 60 patients were registered for the Open labelled Interventional Clinical Trial from the OPD of *Kayachikitsa*, Govt. Ayurvedic College and Hospital, Ghy-14 The *Eladi churna* along with *Tandulyodak* and *Swadangstradi kwath* as *Anupana* was given. The fine powder of all the ingredients of the poly herbo-mineral compound(*Eladi churna)* was mixed in equal proportions in *churna* form and packed weighing

100gm each.

3. Investigations:

a) eGFR (CKD-EPI 2021 equation) [eGFR calculator app by National Kidney Foundation]
b) Serum creatinine
c) Blood urea
d) Serum uric acid
e) Haemoglobin
f) Serum sodium
g) Serum potassium
h) Fasting blood sugar
i) Post prandial blood sugar
j) Urine albumin
k) HbA1C

ASSESSMENT CRITERIA

1. Subjective Criteria

a) Urine output
b) Pedal oedema
c) Nausea
d) Vomiting
e) Loss of appetite
f) Fatigue
g) Abdomen bloating
h) Breathlessness
i) Muscle cramps
j) Retro orbital oedema

Grade scoring scale:

Subjective criteria	Severity	Grade
1. Urine output	Normal	0
	Oliguria present	1
	Anuria	2
2. Oedema (Retroorbital oedema and Pedal Oedema)	Normal	0
	Mild	1
	Moderate	2
	Severe	3
3. Nausea	No nausea	0
	Mild nausea	1
	Moderate nausea	2
	Severe nausea	3
4. Vomiting	No vomiting	0
	Mild	1
	Moderate	2
	Severe	3
5. Abdomen bloating	No bloating	0
	Mild	1
	Moderate	2
	Severe	3
6. Fatigue	No fatigue	0
	Patient likes to stand in comparison to walk	1
	Patient likes to sit in comparison to stand	2
	Patient likes to lie down in comparison to sit	3
	Patient likes to sleep in comparison to lying down	4
7. Loss of appetite	no loss of appetite	0
	Mild	1
	Moderate	2
	Severe	3
8. Breathlessness	No breathlessness	0
	Present during walking	1
	Present during sitting position	2
	Present during lying position	3
9. Muscle cramps	No muscle cramps	0
	Mild	1
	Moderate	2
	Severe	3

2. Objective Criteria

a) eGFR (CKD-EPI 2021 equation) [eGFR calculator app by National Kidney Foundation]
b) Serum creatinine
c) Blood urea
d) Serum uric acid
e) Haemoglobin
f) Serum sodium
g) Serum potassium
h) Urine albumin
i) FBS
j) PPBS
k) HBA1C

DATA ANALYSIS: The data obtained were organized and then analysed using the arithmetic mean, standard deviation and paired t-test.

OBSERVATION AND RESULTS:

Table 2: Effect of Treatment on Chief complaints and associated symptoms of 60 DKD patients

SL. NO	Subjective	Mean value			S.D			t-value	p-value
		BT	AT	BT-AT	BT	AT	BT-AT		
1	Urine output	0.68	0.25	0.43	0.54	0.47	0.07	4.8098	0.0001
2	Pedal oedema	1.83	0.62	1.21	0.56	0.61	0.05	11.419	0.0001
3	Nausea	1.23	0.47	0.76	0.70	0.57	0.13	6.4042	0.0001
4	Vomiting	0.58	0.18	0.40	0.59	0.39	0.20	3.6459	0.0005
5	Abdomen Bloating	0.57	0.23	0.34	0.70	0.46	0.24	4.7636	0.0001
6	Fatigue	2.18	0.60	1.58	0.77	0.49	0.28	15.575	0.0001
7	Loss of Appetite	1.65	0.23	1.42	0.63	0.43	0.20	14.766	0.0001
8	Breathlessness	0.07	0.02	0.05	0.25	0.13	0.12	1.7622	0.0832
9	Muscle cramps	0.32	0.22	0.10	0.47	0.52	0.05	1.1366	0.2633
10	Retro orbital oede-ma	0.48	0.38	0.10	0.62	0.49	0.13	1.0000	0.3214

Table 3: Effect of Treatment on Pathological investigations on 60 DKD patients

SL. NO	Objective	Mean value			S.D			t-value	p-value
		BT	AT	BT-AT	BT	AT	BT-AT		
1	e GFR	15.48	34.27	18.79	6.23	17.31	11.08	9.7441	0.0001
2	Serum Creatinine	3.6500	2.0772	1.5728	1.1560	0.9750	0.181	13.0514	0.0001
3	Blood Urea	76.22	35.95	40.27	13.04	7.41	5.63	20.6397	0.0001
4	Serum Uric acid	8.168	4.732	3.436	0.795	1.122	0.327	19.0360	0.0001
5	Haemoglobin	9.367	11.182	1.815	1.649	1.091	0.558	7.8622	0.0001
6	Serum Sodium	140.37	140.22	0.15	4.31	3.50	0.81	0.2164	0.8295
7	Serum Potassium	4.583	4.703	0.12	0.544	0.558	0.014	2.2251	0.0299
8	Urine Albumin	817.33	481.75	335.58	654.08	487.25	166.83	9.0972	0.0001
9	FBS	221.03	194.18	26.85	29.92	33.33	3.41	9.1501	0.0001
10	PPBS	238.77	178.35	60.42	26.92	20.36	6.56	12.6810	0.0001
11	HBA1C	7.143	5.878	1.265	0.801	0.836	0.035	10.4964	0.0001

Here's a summary of the results from the Repeated Measures ANOVA for various clinical parameters at four different time periods namely Before Treatment, First follow up, Second Follow Up, Third Follow Up in an interval of 1 month each.

Urine Albumin:

- F-ratio value: 45.00412
- p-value: < 0.00001
- Significant at $p < 0.05$
- Interpretation: Statistically significant differences in Urine Albumin levels among treatment groups at different time periods. Strong evidence against the null hypothesis, suggesting variations between groups.

Sr Creatinine:

- F-ratio value: 101.05144
- p-value: < 0.00001
- Significant at $p < 0.05$
- Interpretation: Statistically significant differences in Sr Creatinine levels among treatment groups over time. Strong evidence against the null hypothesis, indicating significant variations between treatment groups.

Blood Urea:

- F-ratio value: 212.00834
- p-value: < 0.00001
- Significant at $p < 0.05$
- Interpretation: Statistically significant differences in Blood Urea levels among treatment groups across different time periods. Strong evidence against the null hypothesis, highlighting significant variations between treatment groups.

Sr Uric Acid:

- F-ratio value: 197.35159
- p-value: < 0.00001
- Significant at $p < 0.05$
- Interpretation: Statistically significant differences in Sr Uric Acid levels among treatment groups at various time points. Strong evidence against the null hypothesis, signifying significant variations between treatment groups.

In summary, all four repeated measures ANOVA analyses demonstrated highly significant results, with low p-values and high F-ratio values. These findings indicate that there are substantial differences in the respective clinical parameters (Urine Albumin, Sr Creatinine, Blood Urea, and Sr Uric Acid) among treatment groups at different time periods. These results provide robust evidence for the effectiveness of the treatments and highlight variations between the groups over time.

DISCUSSION

Vedanga and Upanishad from the Vedic era make reference to *Mutra*(Urine) *Vrikka*(Kidney)and *Mutraghata rogas*(disease of urinary system)This suggests that the illness has existed since prehistoric times. The Samhitas do not adequately explain DKD as a single disease, but rather on the basis of its clinical presentations and consequences in several chapters of the various Samhita. The pathogenesis of the illness is described in different ways in the ayurvedic classics, including as *Rasa Pradosaj vicar* (Disease caused by contaminated Rasa tissue), *Pandu*,(Anaemia) *Kaphaj sotha(*inflammatory consitions caused due to Kapha Dosha), *Mutrakriccha, Mutraghata* (a syndrome of onstructive urinary pathology due to deranged vata dosha) *Prameha*, and its *Upadrava*(complication)

Vrikka is formed during the embryological stage from the sara of Rakta and Meda. *Sharangadhar* asserts that the purpose of *Vrikka* is to provide the *Jatharasta meda* with nutrition. The *Tridosha* supports the mudra's healthy operation at all stages, from production through excretion through *Basti*. *Vrikka* and *Mutra's* physiology depends heavily on Agni. Adequate *Jatharagni* (digestive fire)and *Dhatwagni* (the fire which is located inside the tissue)aid in the normal elimination of the mala as well as the circulation of *Ahar rasa* (essence of food after the first level of digestion)to other areas of the body. The Ahara's mala is called Mutra. It is said that *Pakwashay(place, space, abode for digested food or large intestine)* is the *Utpatti sthan (originating place)of Mutra.* The *Prasad amsha* is distributed throughout the body by *Dhamanis* (tubular channel taking origin from the heart) because the *Ahara rasaa* is split into *Kitta*(waste products of dhatu*) and Prasad*(nutritional

juice beneficial to the body) *Purisha, Mutra, and Vayu* separate from the *Kitta amsha*, nevertheless. The *Purisha* is the *Shtulabhaga* (macro portion), and the *Mutra* is the *Sukshmabhaga*(minute portion*)*

The *Visarga sansthan* (discharge abode)also referred to as *Vrikka*, functions with *Twaka'*s(skin) assistance. *Sweda* and *Mutra* share the same features in that they both remove *Mala*, or unwanted substances, from the body. *Yakrita*, which synthesises *Ranjaka pitta*(type of *Pitta* which colours *Rasa dhatu*), performs the *Mutra's Ranjan karma* (providing colour*)*and assigns a colour according on the patient's state of health. According to Charaka, a person with *Shuddha rakta* (pure blood)properly excretes their *Mala*(excretory waste) like *Mutra (*urine)and *Purisha*(stool*)*. One of the *Mula sthan* (originating point)is *Vrikka* of *Medovaha srotas*. The pathogenesis of DKD is caused by the hetus of DKD, such as *Apatarpan*(therapy to decrease excessively increased body components like fats), *Santarpan(*nourishing therapy*), Ajeernavastha(*state of incomplete digestion), *and Nidanarthakara(a disease that stimulates another disease)*. The vitiation of the *Samana vayu* and *Apan vayu* during the pathogenesis also affects the *Vyan vayu*. In summary, the entire physiology of the human body becomes out of balance, which leads to a number of difficulties.

Probable Mode of Action of the Trial drug

The probable mode of action of the drug can be discussed from the results obtained. The trial drug contains *Ela, Pashanbheda, Shilajita and Pippali*. The properties are:

	ELA	PASHANBHEDA	SHILAJITA	PIPPALI
RASA	*Katu, Madhura*	*Kasay, Tikta*	*Madhura, tikta*	*Katu*
GUNA	*Laghu, Ruksha*	*Laghu , Snigdha*	*Sheeta*	*Laghu, Snigdha, Tikshna*
VIRYA	*Sheeta*	*Sheeta*	*Sheeta*	*Anushnasheeta*
VIPAK	*Katu*	*Katu*	*Katu*	*Madhura*
KARMA	*Kapha-vatahara, Anuloman, Mutrajanan, Balya, Hridya, Deepan, Rochan,*	*Tridoshahara Mutravirechan*	*Tridoshahara, chedana, vrishya, balya, lekhana, rasayana*	*Kapha-vatahara Vrishya, Dipana, Rasayana*

Ela has *Anuloman*(the drug which makes the digestion of mala breaks its firmness and after that brings towards the adhobhaga) property and *Mutrajanan(*that initiates urine production*)*, therefore, it acts as *Bastisodhana*(purification of urinary bladder*)*. *Pashanbheda* act as *Mutravirechana*(eliminates mutra by its action). Due to *Laghu* (light), *Ruksha(*dry) and *Tikshna guna* (sharp) the aggravated *Kapha* gets alleviated and the *Avarana of vata* (obstruction of vata) mainly *Udan* and *Apan vayu* gets removed. Due to the *Sheeta virya(*cold in potency*) of Ela, Pashanbheda, Shilajit*, the aggravated *Kapha* and *Pitta* gets subsided and therefore the *Dhatwagni* gets ignited. Whereas due to *Katu vipaka*, it also has mild action on *Jatharagni* [15]. Because of the *Rasayana* property of *Shilajit* and *Pippali*, it acts as *Srotasodhan*, rejuvenates the deranged *Srota* and clears the *Abaddha meda(obstructed fatty tissue). Eladi Churna* has less action on *Jatharagni* but more on *Dhatwagni*. Therefore, it has mild action on nausea, vomiting, abdomen bloating and loss of appetite and highly significant action on eGFR, Se- rum Creatinine and Urine Albumin. *Anuloman, mutra- janan* and *Mutravirechaniya* properties present in the trial drug help in correcting the low urine output and pedal oedema. According to various researchers, Ela (*Elettaria cardamomum*) has a Renal protective effect [17]; *Pashanbheda* (*Bergenia ligulata*) has Free radical scavenging activity, Anti-diabetic and Diuretic activity[18]; *Shilajit* (*Asphaltum punja-bianum*) has anti- oxidation and immuno-modulatory effect[19]; *Pippali* (*Piper longum*) possess Vasodilator effect, Blood pressure-lowering effect and Immuno-modulatory effect[20]. *Tandulyodak* has a soothing effect due to its *sheeta virya*[16]

Gokshur rasa is *Madhura*(sweet) *Tikta*(bitter); *Guna: Guru*(heavy), *Snigdha*(unctuousness*); Virya: Sheeta; Vipaka: Madhura; Doshaghnata: Tridoshahara(*keeps equilibrium of all the dosha*); Karma:*

Vrishya(spermatogenic and aphrodiasic property), *Brimhana*(nourishing*), Mutrala(*induces urine) leads to its anti-diabetic, diuretic, antioxidant, anti-inflammatory actions.[21]

Sunthi's Veerya is Ushana(hot); *Vipak is Madhur(*sweet*); Guna is Laghu*(light*) and Snigdha and Rasa is Katu* attributes to its anti-inflammatory and antioxidant property.[22]

Unfavourable impact/side effects

The substance *"Eladi churna"* was the subject of a 3-month clinical research with 60 patients, during which time no adverse side effects or advancements were seen in any of the patients. However, if the *Tandulyodak* dose is less than 25 ml or given as "*Eladi churna*" alone, the burning sensation is experienced in the chest and epigastric region.

CONCLUSION

This study is working on focusing on the Ayurvedic management of Nephropathy holistically. In a nutshell, the following points and facts regarding the study and can be stated that the poly herbo-mineral compound i.e ELADI CHURNA here showed a very impressive response. Most of the cases responded to the treatment. A satisfactory reduction in the signs and symptoms has been noticed from the treatment. A marked improvement has been observed in laboratorial investigations. Therefore, an inference can be drawn that the poly herbo-mineral compound "ELADI CHURNA'' with *Tandulyodak* and *Swadangstradi kwath* as *Anupana* has anabolic, anti-inflammatory, anti-oxidative effects and helps in reducing albuminuria. Thus, all the three compounds together are said to have promised nephroprotective effect in the management of Diabetic Kidney Disease. The dose of the trial drug may be enhanced to get a better result. A large number of patients or sample size should be taken, and treatment should be made for a longer duration of time with proper implementation of Diet and Lifestyle.

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