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Parallel Group Open Label Study of Clinicopathological Variables in Stage III Diabetic Kidney Disease Patients Receiving Standard Care Alone or with Ayurvedic Treatment

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ABSTRACT

Background: Diabetic nephropathy (DN) is the chronic loss of kidney function occurring in those suffering from Diabetes Mellitus (DM). It is one of the leading causes of end-stage renal disease (ESRD), particularly among patients who suffer from Type II Diabetes Mellitus (T2DM). Proteinuria and estimated glomerular filtration rate (eGFR) (based on creatinine value) are two basic pillars for the diagnosis of kidney disease. A randomized, parallel-group open-label clinical study was carried out to assess if the progression to ESRD can be stopped or delayed at an early stage using Ayurvedic treatment regime (ATR) in subjects with stage III diabetic nephropathy.

Methods: Total 30 subjects were screened for DN, and those fitting the inclusion criteria and providing informed consent were included and randomized into 2 groups: Group A (Experimental, n = 15) receiving ATR *Madhutailika basti* along with standard of care (Allopathy KDIGO guidelines) and Group B (Control, n = 15) only standard allopathic treatment. The analysis was done based on results obtained from signs and symptoms and lab investigations. Clinical and pathological variables between patients receiving ATR and those not receiving ATR were assessed.

Results: It was observed that patients in the ATR group showed improved e-GFR preservation and a reduction in the albumin-creatinine ratio (ACR).

Conclusion: The addition of ATR to the standard of care (Allopathy) exhibits renoprotective effects by significantly preserving eGFR and reducing proteinuria values within 180 days, thereby preventing further progression of Stage III DN. Subjects in the ATR group also showed significant improvement in Quality-of-Life parameters.

Key-words: Ayurvedic Treatment Regimen, Chronic Kidney Disease, Diabetes, Diabetic Nephropathy, Standard of Care

INTRODUCTION

The global prevalence of diabetes has reached epidemic proportions affecting over 8% of the world population (approximately 350 million people) and is expected to rise to over 550 million people by 2035. Talking about this, more than 40% of people with diabetes has chronic kidney disease (CKD) [1].

Individuals with diabetes suffer chronic loss of kidney function called diabetic nephropathy (DN) defined by increased urinary albumin excretion, decreased glomerular filtration rate (GFR), or both, and affects approximately 20% to 40% of patients with diabetes [2,3].

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Nearly 40% of T2DM patients and 30% of Type 1 causes of CKD and ESRD globally[2]. The Stage III of Diabetic Kidney Disease (DKD) is presented with clinically identifiable evidence of glomerular impairment and microalbuminuria (albumin 30-300 mg/day). It typically develops 5 to 10 years after the onset of the condition [4]. Proteinuria and GFR are the greatest predictors of disease severity [5]. Table 1 shows the relationship between eGFR impairment and CKD stage [6].

Table 1: Stages of CKD as per eGFR criteria

Stages	eGFR (mL/min/1.73m^2)	Renal Function
G1	>90	Normal or high
G2	60-89	Mild reduction
G3a	45-59	Mild to Moderate reduction
G3b	30-44	Moderate to Severe reduction
G4	15-29	Severe reduction
G5	<15	Kidney failure

Protein loss in the urine (Proteinuria) due to damage to the glomeruli may become massive and cause a low serum albumin with resulting generalized body swelling (edema) and thus result in nephrotic syndrome [7]. Likewise, with an increase in serum creatinine value, the eGFR may progressively fall from a normal of over 90 ml/min/1.73m^2 to less than 15, at which point the patient is said to have ESRD, which usually progresses over the years [8]. To determine the likelihood of progression to ESRD, a "heat map" (a color-coded classification table) was developed in January 2013 by the Kidney Disease Improving Global Outcomes (KDIGO) Work Group. This new approach for prognosis of CKD was built on the recognition that albuminuria is an important marker of kidney function as well as of the risk of progression to ESRD. It uses both albuminuria categories and eGFR to identify four levels of risk, which are represented by colors, i.e., green, yellow, orange, and red, where green is safe, and the risk increases with yellow, orange, and red (Fig. 1) [9].

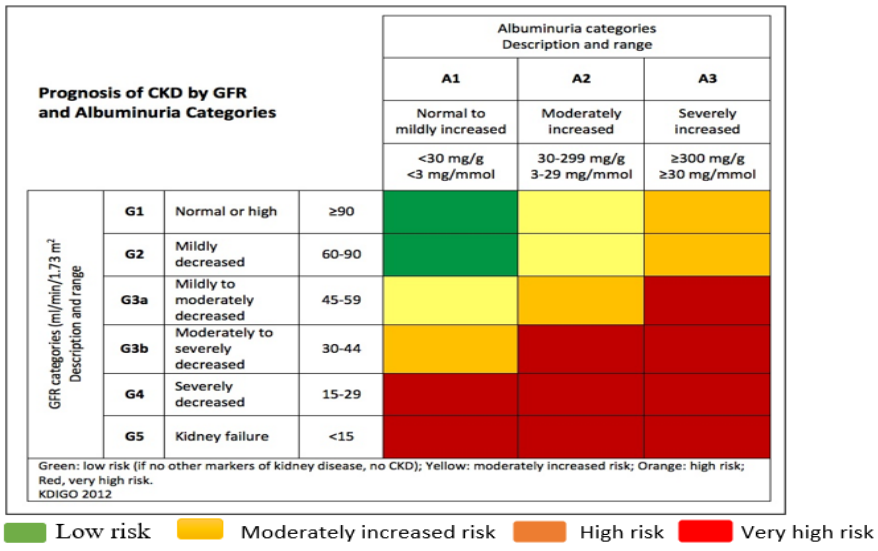

Fig. 1: Stages of CKD as per eGFR and albuminuria criteria

Despite the standard of care treatment for DKD as per KDIGO, many patients still progress to ESRD, who eventually need dialysis if they progress to stage IV or V [10]. Growing numbers of patients are becoming open to seeking alternative medical system interventions, especially Ayurveda, for their issues, with a hope to delay the progression to ESRD or reverse the pathogenesis of the disease [11]. Ayurveda, the ancient Indian system of medicine, offers a new perspective on lifestyle-related and non-communicable diseases. It has described its own

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system of diagnosing and treating diseases based on its understanding of the structure and functioning of the human body. The primary goal of Ayurveda is to maintain the good health of healthy people and treating illness is its secondary goal.

In Ayurveda, Diabetes Mellitus, known as *Madhumeha,* is described as a systemic disease known to affect the patient for a prolonged period and has the potential to cause damage and complications to vital organs of the body. Ayurvedic texts have also mentioned that prolonged diabetes leads to micro-inflammation, microvascular complications, and destruction of the tissues. The severity of the disease and its complications increases over the period [12]. This is particularly visible in vital organs. In Ayurveda, vital organs are named as *Marma* and those like *Shiro* (~Brain), *Hridaya* (~Heart), and *Basti (~ bladders*), etc., are referred to as *Maha Marma* (~most important vital organs). The study also demonstrated that Tantrayukti interpreted two terms, *Vrukka* (Kidney) and *Basti Marma* (Kidney, Ureter and bladder) (one of three *Maha Marmas*). In addition, this study also concluded how the various factors, such as *Kleda* (~body fluids), *Kalaa* (~Internal membranes), *Marma* (~vital organs), *Oja* (~vitality), *Prana* (~life force), *Jathar Agni, Bhutagni, Dhatvagni*, etc., contribute to the pathogenesis of chronic kidney disease [13].

DN is interpreted in Ayurveda as a body condition arising due to *Basti Marmabhighata* (~damage to kidneys) due to internal factors, in this case, vitiation of all the three *doshas* due to long standing DM, the presentation, i.e., the signs and symptoms that occur in each patient, may vary as per the stage of the disease and many other factors. In most patients, DN is diagnosed as *Nija Basti Marmabhighata* leading to *Udara.* According to Ayurveda, its stages can be categorized as *purvarupa, rupa* and *updadrava* [14].

This study is made to develop a treatment regimen based on Ayurvedic diagnosis of CKD, applying Ayurveda's principles of diagnosis and treatment described in Ayurvedic classical texts, based on a recently published study. According to current standards of care for DKD, some patients still progress despite following all KDIGO protocols and guidelines. Hence, it was thought that further treatment to prevent progression of DKD can be done by the utilization of ATR developed based on principles of Ayurvedic Diagnosis and treatment of DKD.

MATERIALS AND METHODS

Subjects were screened as per the eligibility criteria and were recruited in study. Written informed consent was obtained from each subject for a study of 6 months. The study continued for 6 months with regular follow-up of subjects every 15 days.

Study Design- This study was an open-label, prospective study conducted at Ayurved Seva sangh's Ayurved Mahavidyalaya, Nasik under AYURGYAN (erstwhile EMR) Scheme by the Ministry of Ayush, Government of India. Enrolled participants from the Kaychikitsa OPD. An informed consent was obtained in English AND in local languages.

Inclusion Criteria- Subjects between the age group 18 to 60 years, of either sex, with a prior diagnosis of stage III DN, with GFR Stage 3a or b (30 – 59 mL/min/1.73 m^2), and albuminuria categories A1 to A3 as per KDIGO 2012 guidelines, and who were willing to provide informed consent, were enrolled for the study.

Exclusion Criteria- Exclusion criteria included patients who are on dialysis or with ESRD but also have severe related co-morbidities such as heart failure (HF) or any co-existing malignancy, such as acute renal Failure (ARF). Also, subjects with Non-Diabetic Renal Disease (NDRD) and other illnesses were excluded from the study as per Investigator discretion.

Sample size and Study Intervention- The sample size taken was 30 subjects i.e. 15 subjects in each group: Group A and Group B, both received standard of care (Allopathy) as per KDIGO guidelines. In Group A, ATR along with standard care were given for a period of 180 days. Madhutailika basti was given for the last 45 days of trial. Group B received only standard allopathic treatment. Monthly assessment included blood sugar level, blood pressure, liver function tests, lipid profile, kidney function tests, and urine examination. Study drugs were analyzed as per API Standards at an AYUSH-approved NABL Laboratory and were found to be within acceptable limits, complying quality control and safety parameters of the Ayurveda Pharmacopoeia of India.

Primary outcome measure- The primary outcome measures included mean changes in eGFR, serum

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creatinine levels, and proteinuria (Urine albumin-to-creatinine ratio) post-treatment.

Secondary outcome measures- The secondary outcome measures included mean change improvement in the quality of life in study population based on KDQOL (kidney disease related Quality of Life) Instrument SF-36. and assessment of the effect on cardiac status of study population by way of monitoring ECG, stress test and 2D-ECHO cardiograph.

The clinical parameters were assessed at follow-up visits, scheduled on days 15, 30, 45, 60, 75, 90,105 120, 150, 180 of the study, whereas laboratory investigations were done on baseline, Day 30, Day 60, Day 90, Day 120, Day 150 & Day 180.

Assessment Criteria:

Objective Criteria- Monthly assessment once in 6 months of the following variables was done throughout the study: weight assessment, hemoglobin, urea, creatinine, eGFR, calcium, phosphorous, uric acid, HbA1C, FBSL (Fasting Blood sugar level), PPBSL (post-prandial blood sugar level), PTH (Parathyroid Hormone) once in 6 months. Other criteria included blood pressure, symptomatic assessment, cardiac assessment by 2D-Echo.

Safety assessment- There was no incidence of adverse events/adverse drug reactions reported during the study period and no changes were noted in liver function test and kidney function test at the end of the treatment.

Treatment and Duration- The duration of the treatment is 180 days. The standard of care included the following (Group A: ATR):

- Sugar control Target BSL 120 - 150 mg/dl and HbA1c 6.5 with Oral Hypoglycemic Drugs (Gliclazide 80mg/ Tab, Metformin 500 mg / Tab, Glimepiride 2 mg/ T. Pioglitazone 15 mg/ Teneligliptin -Metformin/ and /or insulin, etc. (Targets reference - ADA American diabetes Association).
- Control of Blood Pressure target BP 120/80 mmHg if proteinuria and target Blood Pressure 130/80 mmHg if no proteinuria. (Tab Telmisartan-amlodipine/ Benedipine 4 mg. etc)
- Lipid control included cholesterol less than 200 mg/dl, triglycerides less than 150 mg/dl and LDL cholesterol less than 100 mg/dl.
- BMI within acceptable limits i.e. less than 25.
- Target to be achieved as per suitable drugs according to patients needs decided by Nephrologist.
- Diet – dietary advice for calculated GFR and Diabetes Mellitus.
- Avoidance of Smoking and other addictions was advised.

Rationale of Ayurvedic Treatment Regimen (ATR)- ATR is developed for the Ayurvedic Diagnosis of DN as *Nija Basti Marmabhighata janya Udara.* The damage to the Kidneys (*Basti Marma Abhighata)* leading to *Udara* due to longstanding Diabetes Mellitus is the main event in the pathogenesis of DN [13]. The signs and symptoms found at various stages of DN are like *Udara purva rupa* (~pre-disposing symptoms of Ascites). Here kidneys are described as *Basti Marma* and *Abhighata* is Sanskrit word for damage.

The interpretation of CKD pathogenesis according to Ayurvedic principles was also taken into consideration. The ATR is as follows and for more info, like dose, duration, refer to (Supplementary material Table 2).

Tab Panchakola [15] – For eliminating *Ama formation* (~a toxic metabolite) in the body due to *Mala Sanchaya* (~ *mala* is wastes*, Sanchay* is accumulation) [16]. The *Panchakola* tablet, valued for its potent Deepana (enhancing metabolic fire) and Pachana (enhancing digestion), is aimed at correcting the metabolism and reducing the *ama* (~metabolic toxins) [17]. It was given during the initial 28-day period out of 180 days.

Tab Abhayadi Modaka– For *Nitya virechana* – Enhancing elimination of Ama is further facilitated by the action of compound *Abhayadi Modaka*. This compound has a purgative effect which acts on *Pakwashaya* (~distal part of large intestine), which plays an important role in the formation of Urine according to Ayurveda[18,19]. The laxative action is a part of the recommended line of treatment for the *Udara,* which is an important aspect of the diagnosis of Diabetic Nephropathy, as *Nija Basti Marmabhighata Janya Udara.* This laxative action is probably useful for improving the clearance of toxins by improving the filtration process of the kidneys.

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It is in line with the concept of Ayurveda that the process of urine generation starts in the *Pakwashaya* [19]**,** and hence *Pakwashaya* is the same place where the pathogenesis of the disease starts.

Punarnavadyarishta [20] It is aimed at treating the pathogenesis of *Udara.* It is probably the most important compound particularly useful for those having symptoms of dyspnea, edema, anemia, breathlessness, etc [20]. The probable mode of action of this compound is to take care of *srotorodha* (~obstruction due to various causes, probably sclerosis in such cases), which is an important aspect of the pathogenesis of CKD. It may have some role in improving the filtration process of the kidneys.

Vidangadi Yoga- This ayurvedic medicine is claimed to have an effect against type 2 diabetes mellitus as per the randomized controlled clinical study [21]**.** It is also aimed at treating the pathogenesis of *Udara.*

Tab Vrukka Poshan Yoga- is a compound designed to correct the *Marmabhighata* (~damage to the vital organ, the kidneys), which is the main event in the pathogenesis of DN. This compound is used to rejuvenate and cure the damage caused to *Basti* Marma, hoping to revive the nephrons.

Madhutailika Basti [22] – This is a specific type of basti (~ enema therapy) administered rectally. It is described as a *yapana (~ rejuvenative)* type of therapy designed to rejuvenate the nephrons. It is given in the last forty-five days of 180 days study period.

Ethical Consideration- The study was conducted in accordance with GCP guidelines for ASU drugs, ICMR ethical guidelines (2006), derived from WMA-Declaration of Helsinki (Appendix A). IEC approval was obtained on the date – 20thSept 2018. Participant safety, rights, and well-being were prioritized throughout the study. Study drugs were prepared following GMP and GSP standards for Ayurvedic products in India. Written and audio-visual informed consent was obtained from all participants before enrollment. The trial was prospectively registered with the Clinical Trials Registry of India (CTRI/2018/09/015796).

RESULTS

Changes were measured at different parameters and noted the initial value at Day 0 and the final recorded at 180 days and found that both treatments are equally effective in reducing serum creatinine and increasing eGFR. More detailed table is mentioned in Table 3 and 4; Fig. 2 and 3 in Supplementary materials.

As shown in Table 5 for ACR and e-GFR, the proportion of improved patients in Group A is significantly higher than that of Group B. Based on the observed proportions, it can be said that Group A (ATR) is better than Group B (Control).

Table 5: Post-treatment classification of ACR and eGFR in Group A and Group B

Parameter	Group	Improved	Constant	Worsened
ACR	Group A (ATR)	3	12	0
	Group B (Control)	0	13	2
eGFR	Group A (ATR)	14	1	0
	Group B (Control)	6	8	1

The reversal of stages was assessed in both groups based on Heat Map used for classification of CKD Based on eGFR and Albuminuria Categories (Table 6 Supplementary material):

In Group A:

For eGFR : 14 subjects there was reversal from Stage III to Stage II (*G3 to G2*) whereas in 1 subject, the stage remained constant & no progression was seen *(G3 to G3)*.

For proteinuria: 3 subjects, there was a reversal of stage from *A2 to A1.*

Stage remained constant in 12 subjects, including 8 subjects (*A1 to A1*), 3 Subjects (*A2 to A2*) and 1 Subject (*A3 to A3*).

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In Group B:

For eGFR: 6 subjects improved from Stage III to Stage II (G3 to G2). Meanwhile, 8 subjects stayed at the same stage (G3 to G3) without any progression. Whereas one subject became worsened during treatment.

For proteinuria: 13 subjects kept the same stage. This included 7 subjects (A1 to A1), 4 subjects (A2 to A2), and 2 subjects (A3 to A3). However, 2 subjects did show progression, with the stage changing from A1 to A2.

Signs and symptom-based assessment was done before and after treatment. Analysis of acquired data showed the following results in both groups. Assessment was done with the help of gradations and changes in gradations were noted before and after treatment, as shown in Table 6.

Table 6: Table shows Data as per division of signs and Symptoms

	Group A (ATR Group)			Group B (Non-ATR Group)		
Signs & Symptoms	**A**	**B**	**Percentage relief**	**A**	**B**	**Percentage relief**
Daurbalya	15	0	100%	11	7	36.64
Adhmaan	11	3	72.73	4	4	0%
Shwaskashtata	7	1	85%	1	1	0%
Kandu	7	2	71.43%	5	3	40%
Agnimandya	6	1	84.34%	3	5	0%
Malavrodh	6	0	100%	3	3	0%
Annanabhilasha	3	0	100%	2	3	0%
Hrulas	3	0	100%	1	1	0%
Hastashoth	3	0	100%	0	0	-
Padashof	2	0	100%	1	1	0
Akshishoth	2	0	100%	3	2	33.34
Sarvangashoth	2	0	100%	0	0	-

***A**- Number of Subjects having symptoms before treatment; **B**- Number of Subjects having symptoms after treatment*

DISCUSSION

The present study demonstrates that adding an ATR to standard-of-care therapy (KDIGO guidelines) in patients with Stage III DKD resulted in significant preservation of eGFR, reduction in ACR, and improvements in quality-of-life parameters within 180 days of treatment. These findings suggest that an integrative approach combining conventional nephroprotective strategies with evidence-based complementary ayurvedic medicines may offer incremental benefits in slowing the progression of DN.

The integration of Ayurvedic therapy with conventional management observed in this study aligns with a growing body of literature demonstrating the potential of alternative and integrative approaches in the management of chronic kidney disease. Research has assessed several botanical interventions as adjuncts to standard care, with multiple studies showing positive effects on renal function markers and inflammatory parameters.

In the Ayurvedic medicine literature, a clinical study evaluating Eladi Churna, another Ayurvedic polyherbal formulation, reported marked improvements in eGFR, serum creatinine, blood urea, and urine albumin among patients with DKD [23]. Similarly, a multicenter randomized trial protocol for Tangshen Fang (a Traditional Chinese Medicine formulation) in conjunction with guideline-directed therapy was designed with eGFR change at 24 weeks as the primary endpoint, reflecting growing interest in rigorously evaluating integrated traditional and Western medicine approaches [24].

Stage III DKD represents a critical phase in the disease trajectory, where both a decline in eGFR and a rise in albuminuria are strong predictors for the progression to ESRD and cardiovascular morbidity. Research has consistently emphasized that stabilization or modest improvement in these parameters at this stage can meaningfully delay disease progression and improve long-term outcomes [9,25]. In this context, the observed

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preservation of eGFR and reduction in proteinuria in the ATR group are clinically relevant and align with established prognostic indicators in DKD.

In the present study, both treatment groups showed statistically significant improvement in serum creatinine and eGFR; however, the magnitude of improvement and the proportion of patients demonstrating reversal of CKD stage on the KDIGO heat map were greater in the ATR group. Notably, 14 of 15 patients in the ATR group showed reversal from Stage III to Stage II according to eGFR categorization, with no progression during the study period. In contrast, fewer reversals and instances of worsening albuminuria were observed in the control group. Natural history studies of DKD suggest that patients at Stage III commonly experience gradual but persistent renal function decline despite optimized guideline-directed therapy [10,26]. Against this background, the stabilization and partial reversal of the stage observed in the ATR group suggest a potential incremental benefit of adjunctive integrative therapy.

Proteinuria is a well-established surrogate marker of renal damage and an independent predictor of DKD progression. Reduction in albuminuria has been consistently associated with improved renal outcomes [9]. In the present study, a higher proportion of patients in the ATR group demonstrated improvement or stabilization of ACR compared with the control group, supporting the potential antiproteinuric role of ATR. While the study was not designed to evaluate mechanistic pathways, the observed improvement in albuminuria is clinically meaningful and aligns with the primary therapeutic goals of DKD management.

The significant improvements in KDQOL parameters observed in the ATR group represent an important patient-centred outcome. Quality of life is increasingly recognized as a critical dimension of chronic kidney disease care, as symptom burden, functional limitations, and treatment-related side effects substantially impact patients' daily lives and treatment adherence [24].

Safety is a critical consideration in DKD patients, who are frequently exposed to polypharmacy and are vulnerable to adverse drug reactions. In the present study, ATR was well tolerated, with no reported adverse events and no deterioration in liver or kidney function tests during the treatment period. these findings are consistent with earlier reports emphasizing the relative safety of well-standardized ayurvedic formulations when used under clinical supervision [11].

LIMITATION

This study is limited by the sample size. Further studies with a larger sample size across multiple centres can be undertaken to validate the approach in patients with Stage III DKD.

CONCLUSIONS

In conclusion, the addition of an Ayurvedic Treatment Regimen to standard-of-care therapy was associated with preservation of eGFR, reduction in proteinuria, improvement in quality of life, and favorable safety outcomes in patients with Stage III Diabetic Kidney Disease over 180 days. These findings are consistent with existing literature on DKD progression and integrative therapeutic approaches and suggest that combining Ayurvedic interventions with conventional nephrology care may offer additional benefits in slowing disease progression. Further well-designed studies are required to confirm these observations and establish their long-term clinical significance. The findings of this pilot study warrant further investigation through larger, multicenter randomized controlled trials with longer follow-up periods. Future studies should include standardized formulations, objective mechanistic markers, and clinically meaningful hard renal endpoints to better define the role of ATR as an adjunctive therapy in DKD management.

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