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Exploring the efficacy of *Ayurvedic* interventions in managing Chronic Kidney Disease: A Pilot Study

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ABSTRACT

Introduction: Chronic Renal Failure (CKD) refers to a continual, irreversible reduction in nephron count. Identifying risk factors for CKD, even in those with normal GFR, is crucial factors include hypertension, diabetes, autoimmune issues, older age, African ancestry, family history of renal disease, previous acute renal failure, and indications like proteinuria or structural urinary tract irregularities. Materials and Methods: Study was conducted at the O.P.D. of Dept. of Kayachikitsa, State Ayurveda College & Hospital Lucknow, A total 34 patients were screened out of which 30 Patients meeting inclusion criteria were registered. The patient was given Gokshuradi Guggulu, Mutraghata Har Yoga (MGH Yoga) & Trina Panchmula Kwatha. Results: Out of 26 participants, 57.7% reported relief, 15.4% noted moderate improvement, and 7.7% reported mild improvement. Additionally, 19.2% stated no change, and none reported worsened health. These percentages indicate the intervention's potential effectiveness, with the majority experiencing relief. Discussion: Ayurvedic formulations, such as Trinpanchmool Kwath, Gokshuradi Guggulu, And MGH Yoga, exhibit promise in CKD management by addressing oxidative stress, diuretic action, and nephroprotective qualities.

Key words: Ayurveda, CKD, Gokshuradi Guggulu, MGH Yoga & Trina Panchmula Kwatha

INTRODUCTION

The Samhita period (2000-1000 B.C) is supposed to be the golden period when Ayurveda flourished as a scientific and systemic system of physiology, etiopathogenesis, classification and management of disease of the urinary system are available. Ancient Acharya detailed about the 13 types of Mutraghata (Obstructive and suppressive uropathies), 8 types of Mutrakrichha (dysuria), and 20 types of Prameha (metabolic disease) but no one has a complete

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resemblance to CKD. Only Mutrasada Mutrakshaya have some similarities in the features of oliguria and anuria which are the characteristics of the advanced stage of CKD and ESRD. Chronic kidney disease (CKD), refers to an irreversible deterioration in renal function in which the body's ability to sustain metabolic fluid and electrolyte balance fails, which usually develops over a period of years. Initially, it manifests only as a biochemical abnormality but, eventually, loss of the excretory, metabolic, and endocrine functions of the kidney leads to the clinical symptoms and signs of renal failure, resulting in uremia or Azotemia. It is considered a long-term form of kidney disease and is differentiated from acute kidney disease in that the reduction in kidney function must be present for over 3 months.[1]

The modern management of CKD is not satisfactory and the ultimate goal is renal transplant. It seeks attention from nephrologists and researchers to find out suitable remedial measure from other alternative resources. Ayurvedic medicine may provide new therapeutic options for patients with CKD and may

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mitigate symptoms and improve health-related Quality of life (QOL), which conventional therapies such as drugs and dialysis may not achieve. However, the short-term as well as possible long-term complications attributed to their use are presently unknown.

REVIEW OF THE LITERATURE

Modern Review: Chronic Renal Failure refers to a continual, irreversible reduction in nephron count. Identifying risk factors for CKD, even in those with normal GFR, is crucial - factors include hypertension, diabetes, autoimmune issues, older age, African ancestry, family history of renal disease, previous acute renal failure, and indications like proteinuria or structural urinary tract irregularities.

According to KDOQI, CKD encompasses kidney abnormalities or damage markers, with or without decreased GFR, persisting for ≥ 3 months, with a GFR < 60 ml/min/1.73 m2. NKF's classification divides CKD into 5 stages based on GFR: from physiological decompensation (stage I) with GFR > 90 ml/min to End-Stage Renal Failure (ESRD - stage V) with GFR < 15 ml/min.^[2]

Stages 1 and 2 CKD typically show no GFR-related symptoms, but underlying renal issues like oedema or hypertension may manifest. In stages 3 and 4, complications become more apparent - manifesting across multiple organ systems - including anaemia, malnutrition, mineral and hormone imbalances, and disturbances in electrolyte and fluid balance. By stage 5 CKD, toxin buildup severely impacts daily life, causing marked disturbances in well-being, nutrition, and overall health, culminating in the uremic syndrome.^[3]

Ayurvedic Review: Acharya Charaka wisely noted that naming diseases isn't always the key. What truly matters is understanding symptoms and effectively treating them.

CRF is an entity of varied etiology; it is also termed as a syndrome and is considered as *Sannipataj Vyadhi*. CRF may be termed as a *Vyadhi Sankar* consisting of various conditions e.g. *Prameha* (Diabetes Mellitus), *Shotha* (oedema), *Pandu* (Anaemia), *Udavart*, *Vata Vyadhi*, *Mutraghata*, *Mutra Jathar*, *Mutrakshay*, *Mutra Kriccha* etc.^[4]

Hetu (cause) behind vitiated Raktavaha, Medovaha, Mutravaha, and Svedavaha Srotas are responsible for the etiology of Vrikka Vikar (Nephropathy). In CRF there is Asthi Vaha Srotas Dusti present in Sookshma form. It is corroborated by the modern concept of Hypocalcaemia occurring in CRF due to a deficiency of hormone calcitriol-D3. Anemia is a prominent characteristic of Chronic Kidney Disease (CKD), and the principles of Pandurog Chikitsa and Shotha Chikitsa can be effectively applied in the management of both anemia and swelling associated with CKD.

Hetu (Causes) as per Ayurveda

- Bija Doşa
- Vega Dharana (esp. Apana Related)
- Marmabhighata
- Viṣamasana
- Diseases Of Mutravaha Srotas e.g. Mutrakṛcchra, Mutraghata, Asmari, Arbuda, Granthi, Prameha especially Madhumeha
- Bala Bhramsa
- Ama
- Jirna Jvara
- Daiva

Samprapti Ghatak

- Dosas: May vary according to basic etiopathogenesis. However, a *Tridosaja* condition often dominance of *Kapha* later *Vata* involvement takes place.
- Duşyas: Mutra, Rasa, Udaka, Sveda, Rakta, Sira are the basic Duşyas. Later all Dhatus and Upadhatus may get involved. Clinical conditions related to Snayu, Mamsa, Asthi, and Sukra are often observed
- Srotas: Mutravaha, Medovaha, Udakavaha, Svedavaha, Rasavaha, Raktavaha as disease advances becomes multi-srotas (multi-system).
- Srotoduşţi in Mutravaha Srotas Kharatava, Kathinya, Gaurava, Rauksya

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- Agni & Ama: Generally, Agni is Manda at every level mostly Malasamcayatmaka Ama is present
- Udbhavasthana: Pakvasayottha
- Rogamarga (Route): initially Madhyama Marga but later all three Marga, which increases its incurability.

DRUG REVIEW

Trina Panchamoola Kwatha, renowned for its Vata-Pitta pacifying, diuretic, kidney-stimulating, and hemopoietic properties, holds promise in chronic kidney disease treatment. Its ingredients, outlined in Mutra Virechniya Dashemani, are traditionally used for asthma, anemia, and diuretic purposes. In vitro studies indicate its potential in scavenging free radicals, suggesting a role in conditions involving oxidative stress.^[5] Gokshuraadi Guggulu, known for its diuretic action, not only reduces fluid overload in renal impairment but also strengthens the renal and cardiac systems. [6] With its focus on Mutravaha Srotas, it addresses conditions like Mutrakrichhra, Mutraghata, Ashmari, and Prameha. Possessing Tridoshahara, Madhura, Tikta, and Katu Rasa Pradhan properties, it is effective against pain during micturition, UTIs, edema, BPH, and chronic renal failure.^[7] Its broadspectrum anti-inflammatory and nephroprotective qualities, along with lymphatic detoxification, make it a potent herbal remedy for kidney health.[8] Mutraghata Har Yog^[9] contains Punarnava and Makoi work synergistically to protect the kidneys from damage induced by diabetes, particularly safeguarding the nephrons. Kaasni contributes to electrolytic homeostasis by enhancing Na+ K+ ATPase activity, rectifying serum electrolyte imbalances, maintaining Glomerular Filtration Rate (GFR). [10] Shigru is rich in antioxidant, anti-inflamatory and diuretic phytoconstituents, potentially prevent renal damage and reducing the frequency of renal dialysis significantly.[11] Shigru, along with Saariva, aids in preserving cellular integrity and kidney architecture, preventing renal injuries, and improving hemopoiesis.[12] Varun's nephroprotective properties stem from the antioxidant and free radical scavenging attributes of its lupeol alkaloid. Guduchi exhibits

antioxidant, hypoglycemic, and hypolipidemic effects, addressing dyslipidemia and cardiac disorders, common complications in Chronic Kidney Disease (CKD). [13] *Pravaal Pisthi*, a source of calcium carbonate, helps prevent bone demineralization and acidosis, addressing late-stage complications of CKD. [14]

AIM AND OBJECTIVES

- To Evaluate the Effect of Ayurveda Regimen In The Cases of Chronic Kidney Disease.
- 2. To Evaluate the Effect of Indigenous Formulations In The Management Of CKD.
- 3. To Assess the Effectiveness of The Drugs On Selected Subjective And Objective Parameters.
- 4. To Assess the Side Effect of Trial Drugs If Any

MATERIALS AND METHODS

Selection of the patients: Study was conducted at the O.P.D. of Dept. of Kayachikitsa, State Ayurveda College & Hospital Lucknow. A total 34 patients were screened out of which 30 Patients meeting inclusion criteria were registered.

Method of Treatment/Intervention: The patient was given Gokshuradi Guggulu, Mutraghat Har Yoga (MGH Yoga) along with Trina Panchmula Kwatha as Anupana.

- Dose of Gokshuradi Guggulu: 2 Tab each 250mg, (Twice daily) after the meal
- Dose of MGH Yoga: 2 Tab 500mg (Twice Daily) after a meal
- Dose of Trina Panchmula Kwatha: 40ml (Twice daily) as Anupana

Type of Study: Pilot Study

Period of Study: 90 Days

Sample Size: 30 patients

Duration: 90 days

Follow Up During Treatment: D15, D30, D45, D60,

D75, D90

Follow-Up After-Treatment: 7 days (without drug) after treatment is completed.

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Ethics Committee Clearance and Consent: As this was clinical research, Institutional Ethics Committee (IEC) approval was taken. Its approval number is SAC/IEC/2021/28 dated 17/09/2021.

CTRI: This research study was registered in the Clinical Trials Registry - India. The CTRI registration number of the present study, CTRI/2022/09/045326 registered on 08/09/2022 prior to the initiation of research work.

Inclusion Criteria

- Age- 35-65 years
- History of reduction of kidney function must be present over 3 months.
- Serum Creatinine level above 1.4 mg/dl and below 4.6 mg/dl
- Serum Urea level above 40mg/dl and below101mg/dl
- Patient having Hb level >8gm/dl
- GFR 30- 90ml/min/1.73m2
- BUN [Blood urea Nitrogen] above 18.6mg/dl and below 46.8mg/dl

Symptoms

A. Essential Criteria

Objective Criteria

- 1. Blood Urea
- 2. Serum Creatinine
- 3. GFR (Glomerular filtration rate)
- 4. Blood Urea Nitrogen

B. Non-Essential Criteria

Subjective Non-Essential

- 1. Mutravarodha (obstructed Micturition
- 2. Mutrakruchra (difficulty micturition)
- 3. Mutradaha (burning micturition)
- 4. Anorexia
- 5. Vomiting
- 6. Pruritis

7. Oedema

- 8. Nocturia
- 9. Thirst
- 10. Dozing & Sleeplessness
- 11. Dyspnoea

Objective Non-Essential

- 1. Anaemia
- 2. Lipid Profile
- 3. Mutralpata (Oliguria)

Exclusion Criteria

- 1. Age below 35 and above 65 years.
- Blood Urea more than 100mg/dl and below 41mg/dl
- Serum creatinine level above 4.5 mg/dl and below 1.5mg/dl
- BUN [Blood urea Nitrogen] above 46.7mg/dl and below 18.7mg/dl
- 5. GFR < 30ml/min/1.73m2 and > 90ml/min/1.73m2
- 6. Patients under frequent dialysis
- 7. Uncontrolled Diabetes mellitus
- 8. Malignant Hypertension
- 9. Grade III Prostate
- 10. Prostate Carcinoma
- 11. Tubercular Nephritis
- 12. Hypovolemia
- 13. Liver Failure
- 14. Heart Failure
- 15. Acute Myocardial Infarction
- 16. Sever Valvular Disease
- 17. Tense Ascites
- 18. Sepsis
- 19. Hemorrhage
- 20. Pancreatitis

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- 21. Renal artery/ vein obstruction
- 22. Microangiopathies like DIC, TTP
- 23. Systemic Diseases like lupus, lymphoma, Leukemia, sarcoidosis
- 24. Congenital Disease of kidney: Polycystic kidney disease
- 25. Transplant allograft failure

Objective Parameters

Essential Criteria

1. Blood Urea

Grade	mg/dl
0	≤ 40mg/dl
1	41-60mg/dl
2	61-80mg/dl
3	>81 mg/dl

2. Serum Creatinine

Grade	mg/dl
0	Below 1.5
1	1.5-3.0
2	3.1-4.5
3	Above 4.5

3. GFR (Glomerular filtration rate)

Grading	Features	GFR ml/min/1.73m ²
0	Kidney damage with normal or 个 GFR	≥ 90
1	Kidney damage with mild ↓ GFR	60 – 89
2	Moderate ↓ GFR	30 – 59
3	Severe ↓ GFR	< 30

4. Blood Urea Nitrogen (BUN) mg/dl

Grade	BUN (mg/dl)	Severity	
0	<18.7 Normal		
1	18.8-28.0	Mild	
2	28.1-46.7	Moderate	
3	>46.7	Severe	

Non-Essential Criteria

1. Mutralpata (Oliguria)

Grade	ml/24hr
0	> 400ml/24hr
1	400-250ml/24hr
2	249-100ml/24hr
3	100ml/24hr

2. Anaemia (Hb %)

Grade	Gm/dl
0	≥ 12.1 (Normal)
1	10.1-12.0
2	8.1-10.0
3	≤8.0

3. Lipid profile

Grade	Severity	Serum Cholesterol (mg/dl)	LDL (mg/dl)	HDL (mg/dl)	Triglyceride (mg/dl)
0	Ideal	< 200	<100	>60	<150
1	Borderlin e	201-239	101- 159	40-59♀ 50-59 ♂	151-199
2	High/low	240-499	160- 189	39-20♀ 49-30 ♂	200-499

3 Very ≥500 ≥190 ≤ 20 ♀ ≥500 High/ Very low ≤ 30 ♂

Subjective Parameters

Non-Essential Symptoms

1. Mutravarodha (Obstructed Micturition)

Grade	Features	
0	No obstruction during the act of micturition	
1	Rare obstruction during micturition or at start of micturition	
2	Obstruction at the start and/ or during the whole act of micturition most of the time.	
3	Complete obstruction of voluntary act of micturition but dribbling or incontinence may present	

2. Mutrakrichrata (Difficulty in micturition)

Grade	Features
0	No Difficulty
1	Difficulty present at the beginning of act
2	Difficulty present at the beginning of act and partially during the rest of act
3	Difficulty present throughout the act

2. Mutradaha (Burning micturition)

Grade	Features
0	No Burning
1	Mild- rare burning in morning / at start of act
2	Tolerable burning at starting, during micturition
3	Not tolerable at starting, during micturition and sustained after micturition.

3. Anorexia

Grade	Features
0	Absent
1	Reduced Appetite
2	Very reduced Appetite
3	Almost complete loss of appetite

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4. Vomiting

Grade	Features	
0	Absent	
1	1 Episode in 24 hrs	
2	2-5 episodes in 24 hrs	
3	>5 episodes in 24hrs	

5. Dozing or Sleepiness (EPWORTH Sleepiness Scale)

Grade	Score	Features
0	0 -10	Normal Range in healthy adults
1	11-14	Mild Sleepiness
2	15-17	Moderate Sleepiness
3	18 or higher	Severe sleepiness

6. Nocturia

Grade	Features
0	No Voids / night
1	Mild (1-2 Voids/ night)
2	Moderate (3-4 voids/ night)
3	Severe (> 4 voids/ night)

7. Thirst

Grade	Features
0	Feeling of thirst (7-9 times/ 24hrs) and relieved by drinking water
1	Feeling of moderate thirst (>9-11 times/24hrs) and relieved by drinking water
2	Feeling of excess thirst (>11-13 times/24hrs) not relieved by drinking water
3	Feeling of severe thirst (>13 times) not relieved by drinking water

8. Pruritis

Grade	Features
0	No Pruritis (Absent)

1	Mild (Pruritis is episodic and localized without disturbance in routine work)
2	Moderate (Pruritis is generalised and continuous without any sleep disturbance)
3	Severe (Pruritis is generalised and continuous disturbing sleep)

9. Oedema

Grade	Features
0	No Oedema
1	Oedema over eyelids
2	Oedema over eyelids + face + ankle
3	Generalised oedema

10. Breathlessness (NYHA New York Heart Association)

Grade	Features
0	No symptoms and no limitation in ordinary activity e.g., shortness of breath when walking climbing stairs etc.
1	Mild symptoms (mild shortness of breath and or angina and slight limitation during ordinary activities)
2	Marked limitation in activity due to symptoms even during less than ordinary activity e.g., walking short distances (20-100meters) comparable only at rest
3	Severe limitation (experience symptoms even while at rest mostly bed bound patients)

Investigations

- Renal Function Test [Blood urea, Sr. Creatinine, GFR, BUN] / Fortnightly
- Following test will be done monthly
 - CBC
 - HB%
 - Erythrocyte's sedimentation rate (ESR)

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- Liver Function Test [Sr. Bilirubin, SGOT, SGPT, Alkaline Phosphatase (ALP)]
- Serum Uric Acid
- Lipid profile [Total cholesterol, Total glycerides, LDL, HDL]
- Urine routine and microscopic /M
- Following 3 Test will be done before and after treatment.
 - Blood Sugar (Fasting & Postprandial) in nondiabetic patients
 - HBA1C in both diabetic and non-diabetic patients
 - USG Whole abdomen/ KUB region
- o FBS, PPBS twice a week in a Diabetic patient.
- Serum Na+, K+, Cl-, Phosphorus as per requirement of patients condition
- X-ray chest PA View (if required)
- Echocardiography (if required)
- Doppler Ultrasonography (if required)
- Renal Biopsy (if required)
- Prostate-specific Antigen (PSA) (if required)
- PTH (if required)
- Culture sensitivity (if required)

Assessment of objective criteria

Criteria for assessment of Creatinine - To calculate the % relief in creatinine, the formula used was

% relief in Creatinine = (B.T. - A.T.)/ (B.T.-1.5) x 100

Criteria for assessment of blood urea - To calculate the % relief in blood urea, the formula used was

% relief in blood urea= (B.T. - A.T.)/ (B.T. - 40) x 100

Total effect of therapy

The total effect of therapy of this trial will be grouped as follows

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1. Relieved

- Patients having 76-100 % relief in terms of symptoms
- ≥ 50% improvement in the initial value of essential objective criteria.

2. Improved

Patients have improvement between 51-75% in clinical symptoms.

Mild Improvement

- a) Improvement between 51-63.5% in clinical symptoms.
- b) Upto 24.9% improvement in the initial value of essential objective criteria.

Moderate Improvement

- a) Improvement between 63.5-75% in clinical symptom
- b) ≥25% and <49.9% improvement in the initial value of essential objective criteria

3. Unchanged

- a) Patients having improvement of less than 50% in terms of clinical symptoms.
- b) Pathological findings (Blood Urea, Serum Creatinine, GFR, and BUN) remain the same as before the trial.

4. Worsened

- a) Patients have no improvement in terms of clinical symptoms.
- Pathological findings get disturbed (Blood urea and Creatinine level, BUN may get increased & GFR goes down).

OBSERVATION

In the present study, a total of 30 patients were registered out of which 26 completed the trial and 4 patients left the trial.

Among 30 participants, demographic analysis revealed a predominant age bracket of 55-65 years, with males constituting 63.3%. Hypertension was prevalent in 73.33%, and 46.7% Diabetic. About 26.7% were having obstructed micturition, 23.3% experienced difficulty in micturition, and 36.7% had burning micturition. Anorexia was prevalent, with 86.7% while vomiting was reported by 10.0% of subjects. 10.0% reported dozing or sleepiness, 23.3% experienced nocturia, and increased thirst was noted in only 3.3% of cases. Pruritis was reported by 36.7%, oedema by 93.3%, and breathlessness by 66.7%. Interestingly, no subjects reported oliguria, resulting in a 0.0% percentage. Anemia based on hemoglobin levels was prevalent, with 76.7% reporting it.

Observation on essential and non-essential criteria:

Essential Objective Criteria	% Change	Mean Change	P- Value
Blood Urea	37.22	7.56	0.015
Serum Creatinine	44.44	0.38	<0.001
eGFR (Estimated Glomerular filtration rate)	25.00	-11.10	0.003
Blood Urea Nitrogen (BUN) mg/dl	29.31	4.21	0.007

Non-Essential Subjective Parameters	% Change	P-Value
Obstructed Micturition	88.46	0.020
Difficulty in micturition	61.54	0.059
Burning micturition	100.00	0.002
Anorexia	75.71	<0.001
Vomiting	100.00	0.083
Dozing or Sleepiness	100.00	0.083
Nocturia	65.38	0.020
Thirst	100.00	0.317
Pruritis	100.00	0.005
Oedema	63.80	<0.001
Breathlessness	73.78	<0.001

Non-Essential Objective Criteria

Anemia Hb% (Grade)

Lipid Profile (Grade)

Oliguria

P-Value	
0.008	
0.414	

NA

% Change

35.90

6.25

NA

Non Essential Objective Criteria	Mean Change	P-Value
Uric Acid (mg/dl)	-0.02	0.932
Hb (gm/dl)	-0.15	0.694
TLC Cells/mm3	215.04	0.706
Neutrophils %	-2.24	0.288
Lymphocytes %	-0.90	0.597
Monocytes %	0.58	0.650
Eosinophil %	0.51	0.488
Basophil %	-0.04	0.446
Total RBC Count	0.05	0.613
Total platelet count (x103)	-1.92	0.796
FBS mg/dl	9.21	0.323
PPBS mg/dl	18.12	0.279
HBA1C	0.32	0.070
Sodium mmol/L	-0.77	0.550
Potassium mmol/L	0.15	0.351
Total cholesterol mg/dl	4.05	0.562
HDL mg/dl	-2.41	0.324
LDL mg/dl	2.68	0.509
Triglycerides mg/dl	7.23	0.241
Serum Bilirubin mg/dl	-0.04	0.486
SGOT IU/ml	3.59	0.060
SGPT IU/ml	0.51	0.733

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ALP IU/I	10.48	0.450

RESULT

Out of 26 participants, 57.7% reported relief, 15.4% noted moderate improvement, and 7.7% reported mild improvement. Additionally, 19.2% stated no change, and none reported worsened health. These percentages indicate the intervention's potential effectiveness, with the majority experiencing relief.

Final Status	No. (N=26)	%
Relieved	15	57.7%
Moderate Improvement	4	15.4%
Mild Improvement	2	7.7%
Unchanged	5	19.2%
Worsened	0	0.0%

DISCUSSION

Chronic Kidney Disease (CKD) poses a global public health crisis, impacting quality of life and economies. Ancient Ayurvedic texts indirectly reference CKD through conditions like Mutrasada and Mutrakshaya, offering insights into its recognition and progression. Ayurveda interprets CKD as Mutravaha Srotas disorders, focusing on personalized treatments based on Dosha, Dhatu, and Mala imbalances. Ayurvedic such Trinpanchmool Kwath, formulations, as Gokshuradi Guggulu, and Mutraghata Har Yoga, exhibit promise in CKD management by addressing oxidative stress, diuretic action, and nephroprotective qualities.

CONCLUSION

This pilot study aimed to evaluate the impact of an Ayurvedic regimen on Chronic Kidney Disease (CKD), providing valuable insights for future research. Key conclusions include the recognition of CKD as a complex disorder with varied etiology, highlighting the prevalence and demographics of CKD globally and in India. The study a safe and effective Ayurvedic regimens, with the combination of *Trinpanchmool*

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Kwath, Gokshuradi Guggulu, and Mutraghat Har (MGH) Yoga and emerging as promising for CKD management.

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