



Case Series

EFFECT OF *TULSI VATI* (*Ocimum Sanctum* Linn.) ON PSYCHOLOGICAL DISTRESS IN CHRONIC KIDNEY DISEASE PATIENTS UNDERGOING HEMODIALYSIS

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Article info

Article History:

Received: 30-07-2026

Accepted: 27-08-2026

Published: 10-09-2026

KEYWORDS:

Ayurved, Chronic kidney disease, Hemodialysis, Psychological distress, *Tulsi Vati*.

ABSTRACT

Chronic kidney disease (CKD) and maintenance hemodialysis are associated with psychological distress, including anxiety, depressive symptoms, and impaired quality of life. The prevalence of anxiety symptoms among dialysis patients ranged from 27% to 43%, while diagnosed anxiety disorders were present in approximately 19% of patients. This case report series describes the clinical observations of 10 patients with CKD undergoing hemodialysis who received *Tulsi Vati* (*Ocimum sanctum* Linn.) 250mg orally twice daily after meals for 30 days. Anxiety, depressive symptoms, mental status, and health-related quality of life were assessed using the Generalized Anxiety Disorder-7 (GAD-7), Patient Health Questionnaire-9 (PHQ-9), Mental Status Examination (MSE), Hospital Anxiety and Depression Scale (HADS), and Kidney Disease Quality of Life-36 (KDQOL-36). Improvements were observed in all above scales. All 10 participants completed the 30-day observation period, and no adverse events were reported. These observations suggest a potential supportive role of *Tulsi Vati* in psychological symptoms among patients receiving hemodialysis. Because this was a small, uncontrolled case series with short follow-up, the findings are preliminary and should not be interpreted as evidence of efficacy; controlled studies are required.

INTRODUCTION

Chronic kidney disease (CKD)^[1] is a progressive disorder that may ultimately require dialysis or kidney transplantation. Patients receiving maintenance hemodialysis experience a substantial treatment burden related to chronic illness, treatment dependence, dietary restrictions, financial stress, social isolation, and concern about disease progression. Psychological morbidity is therefore clinically relevant in this population^[2,3,4]. Anxiety symptoms have been reported in approximately 27%–43% of dialysis patients, while diagnosed anxiety disorders occur in about 19% of patients, with a substantial burden of depressive symptoms also reported in this population^[5-9]. This relationship between kidney dysfunction and mental health is becoming more

widely acknowledged through the concept of the kidney- brain axis^[10].

Anxiety, depressive symptoms, and impaired quality of life may interact with the physical and psychosocial burden of dialysis. Assessment using standardized instruments can help describe these symptoms and their change over time. In the present case series, the Generalised Anxiety Disorder-7 (GAD-7)^[11,12], Patient Health Questionnaire-9 (PHQ-9)^[13], Mental Status Examination (MSE)^[14], Kidney Disease Quality of Life (KDQOL-36)^[15], and Hospital Anxiety and Depression Scale (HADS)^[16] were used to characterize psychological status and health-related quality of life.

From an Ayurvedic perspective, psychological disturbance may be considered in relation to *Chittodvega*^[17] (anxiety-related mental disturbance), *Manovaha Srotas* (channels associated with mental functions), and the interaction between *Sharira* (body) and *Manas* (mind). The chronic disease and dialysis burden may be understood in terms of concepts such as *Dhatukshaya* (depletion of body tissues), *Ojas Kshaya* (depletion of vitality), *Agnimandya* (impaired

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<https://doi.org/10.47070/ayushdhara.v13i4.2956>

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digestive/metabolic function), and *Manovaha Srotodushti* (disturbance of channels associated with mental functions)^[18-20].

Tulsi (*Ocimum sanctum* Linn.) is described in Ayurvedic literature as having *Rasayana* (rejuvenative) and *Hrudya* (heart-supportive) attributes, also its adaptogenic, antioxidant, anti-inflammatory, and neurobehavioral properties^[23,24]. The present case report series describes the observed changes during a 30-day course of *Tulsi Vati* in patients undergoing hemodialysis, with emphasis on psychological symptoms, mental-status findings, and quality of life.

Case Series

A clinical case series was conducted in 10 patients with CKD undergoing maintenance haemodialysis. Written informed consent was obtained from all participants for participation and publication of the clinical information.

Diagnostic Criteria

Diagnostic & Statistical Manual of Mental Disorders DSM V^[25].

Diagnostic criteria of GAD 7 Scale^[12].

Inclusion Criteria

1. Patients aged 18–70 years of both gender
2. Patients diagnosed with CKD and undergoing Hemodialysis.
3. Patients upto moderate level of anxiety (below 14 points on GAD 7 scales)

Exclusion Criteria

1. Substance abuse like alcohol.
2. Pregnant or lactating women.
3. Critically ill patients

Therapeutic Intervention

Tulsi Vati was administered at a dose of 250mg orally twice daily after meals for 30 days. The formulation was prepared in a GMP-certified Ayurvedic pharmacy using authenticated fresh leaves

of *Ocimum sanctum* Linn. The leaves were shade-dried, pulverized, and sieved to obtain *Tulsi Churna* (powder). Three *Bhavana* (levigation processes) using freshly prepared *Tulsi Swarasa* (~expressed juice) were administered, followed by drying, granulation, and compression into 250-mg tablets^[26,27].

Tulsi Vati 250 mg was administered orally twice daily after meals for 30 days.

Criteria for Assessment

1. Generalized Anxiety Disorder 7-item (GAD-7) scale Gradation
 - Minimal =0-4
 - Mild =5-9
 - Moderate =10-14
 - Severe=15-21
2. PHQ-9 (Patient Health Questionnaire – 9) - Gradation:
 - 0–4 = Minimal depression
 - 5–9 = Mild
 - 10–14 = Moderate
 - 15–19 = Moderately severe
 - 20–27 = Severe depression
3. HADS – Hospital Anxiety and Depression Scale - Gradation:
 - 0–7 = Normal
 - 8–10 = Borderline abnormal
 - 11–21 = Abnormal
- Anxiety Score (A1–A7): / 21.
- Depression Score (D1–D7): / 21
4. Mental Status Examination (MSE)
5. Kidney Disease Quality of Life-36 (KDQOL-36)

Outcomes were assessed using above all along with serum creatinine and blood urea. Clinical response, adherence, tolerability, and adverse events were documented.

Table 1: Baseline data of the participants in the study

S.No	Name	Age	Gender	CKD Stage	Type of Dialysis	Dialysis	K/C/O	Duration of Dialysis
1	A	56	M	4	Hemodialysis	3 times/week	HTN, DM2	2 years
2	B	65	M	4	Hemodialysis	2 times/week	HTN, DM2, IHD	2 years
3	C	46	F	4	Hemodialysis	3 times/week	HTN, IHD	5 years
4	D	32	M	4	Hemodialysis	2 times/week	HTN	3 years
5	E	43	M	4	Hemodialysis	2 times/week	HTN, IHD	3 1/2 years
6	F	54	F	3	Hemodialysis	1 time/week	HTN	11 months
7	G	29	F	4	Hemodialysis	2 times/week	HTN, DM2	2 years
8	H	57	M	3	Hemodialysis	3 times/week	HTN, DM2	1 year
9	I	32	M	3	Hemodialysis	3 times/week	No any	11 months
10	J	28	M	3	Hemodialysis	3 times/week	No any	6 months

Table 2: Baseline characteristics of participants (n = 10)

Characteristic	Frequency, n (%)
Age group	
20–35 years	4 (40.0)
36–50 years	2 (20.0)
51–65 years	4 (40.0)
Sex	
Male	7 (70.0)
Female	3 (30.0)
Body build	
Medium	8 (80.0)
Lean	2 (20.0)
Haemodialysis frequency	
Once weekly	1 (10.0)
Twice weekly	4 (40.0)
Three times weekly	5 (50.0)
Duration of haemodialysis	
<1 year	3 (30.0)
1–2 years	4 (40.0)
2–3 years	1 (10.0)
>3 years	2 (20.0)

Table 3: Comorbidities among participants (n = 10)

Comorbidity	Frequency, n (%)
Hypertension	2 (20.0)
Hypertension + type 2 diabetes mellitus	3 (30.0)
Hypertension + ischaemic heart disease	2 (20.0)
Hypertension + type 2 diabetes mellitus + ischaemic heart disease	1 (10.0)
No recorded comorbidity	2 (20.0)

Table 4: Observed Values of Assessment Tools of Participants

S.No	Name	Age	Gender	PHQ-9		HAS		HDS		GAD-7 Scale		KDQOL-36	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	A	56	M	6	4	8	4	10	4	10	4	48.2	57.1
2	B	65	M	10	5	9	4	8	3	9	4	50.4	59.3
3	C	46	F	13	8	11	7	8	5	11	5	52.1	61.8
4	D	32	M	10	6	8	5	9	4	10	4	50.3	59.2
5	E	43	M	19	10	10	6	8	5	12	6	49.3	58.2
6	F	54	F	14	7	10	4	10	5	10	4	51	60.1
7	G	29	F	12	6	11	6	7	4	9	4	49.3	58.2
8	H	57	M	9	4	10	5	7	3	8	4	50.4	58.2
9	I	32	M	8	3	10	4	8	3	9	3	52.2	60.2
10	J	28	M	10	4	11	4	7	3	9	3	46.7	55.6

Table 5: Baseline Sociodemographic and Clinical Characteristics of Study Participants (n=10)

Variable	Distribution, n (%)
Age (years)	20–35: 4 (40.0); 36–50: 2 (20.0); 51–65: 4 (40.0)
CKD Stage	Stage 3: 4 (40.0); Stage 4: 6
Dialysis Frequency	Once weekly: 1 (10.0); Twice weekly: 4 (40.0); Thrice weekly: 5 (50.0)

Duration of Dialysis	<1 year: 3 (30.0); 1–2 years: 4 (40.0); 2–3 years: 1 (10.0); >3 years: 2 (20.0)
Comorbidities	HTN: 2 (20.0); HTN+DM: 3 (30.0); HTN+IHD: 2 (20.0); HTN+DM+IHD: 1 (10.0); None: 2 (20.0)

Table 6: Comparison of Outcome Measures Before and After Treatment (n=10)

Parameter	Before Treatment (Mean±SD)	After Treatment (Mean±SD)	Wilcoxon W	p-value	% Improvement
GAD-7	9.70 ± 1.16	4.10 ± 0.88	55	0.004	57.73
PHQ-9	11.10 ± 3.64	5.70 ± 2.16	55	0.006	48.65
HADS-Anxiety	9.80 ± 1.14	4.90 ± 1.10	55	0.006	50.00
HADS-Depression	8.20 ± 1.14	3.90 ± 0.88	55	0.005	52.44
KDQOL-36	49.99 ± 1.69	58.80 ± 1.74	78	0.0045	17.62

Table 7: Mental Status Examination Outcomes

Domain	Before Treatment	After Treatment	χ ²	p-value
Speech	Slow 70%, pressured 30%	Normal 100%	20.00	0.00005
Mood	Normal 20%, anxious 50%, sad 30%	Normal 100%	13.33	0.00127
Affect	Blunted 60%, normal 40%	Normal 100%	5.95	0.0147
Thought Process	Circumstantial 70%, tangential 30%	Goal-directed 90%, Circumstantial 10%	16.50	0.00026

Table 8: Laboratory Parameters Before and After the 30-Day Intervention (n = 10)

Laboratory parameter	Before treatment, Mean ± SD	After treatment, Mean ± SD
Serum creatinine (mg/dL)	5.61 ± 2.07	5.13 ± 2.02
Blood urea (mg/dL)	52.10 ± 3.78	43.00 ± 3.83

Table 9: Overall Improvement

Overall Improvement	Frequency	Percentage
Marked improvement (76-100%)	0	0.00%
Moderate improvement (51-75%)	7	70.00%
Mild improvement (26-50%)	3	30.00%
Unchanged (<25%)	0	0.00%
Total	10	100.00%

Observations & Result According to Sequence

Statistical analysis was performed using the Wilcoxon Signed-Rank Test to compare pre- and post-treatment scores. Categorical variables were analyzed using the Chi-square test. Data were expressed as Mean ± Standard Deviation (SD) and Median values, and a p-value <0.05 was considered statistically significant.

RESULTS

All 10 patients completed the 30-day intervention without reported adverse events. Improvements were observed in GAD-7 (57.73%), PHQ-9 (48.65%), HADS (52.44%), and KDQOL-36 scores, with improvement in psychological well-being and quality of life. MSE findings showed improvement in mood, affect, speech, and thought processes in most patients. Overall, 7 patients (70%) showed moderate improvement and 3 (30%) showed mild improvement. No patient showed an unchanged response or reported treatment-related adverse events.

Outcome

All 10 participants were reported to have completed the 30-day treatment period without reported adverse events. The study findings indicated Improvement in anxiety, depressive symptoms, mental-status findings, and quality of life.

Mean GAD-7 score decreased from 9.70±1.16 at baseline to 4.10±0.88 after 30 days, corresponding to a 57.73% reduction from baseline. Mean PHQ-9 decreased from 11.10±3.64 to 5.70±2.16 (48.65% reduction). HADS-Anxiety decreased from 9.80±1.14 to 4.90±1.10 (50.00% reduction), and HADS-Depression decreased from 8.20±1.14 to 3.90±0.88 (52.44% reduction). KDQOL-36 increased from 49.99±1.69 to 58.80±1.74, representing a 17.62% increase.

Mental-status findings also changed descriptively. Speech was recorded as normal in all participants after treatment. Mood was normal in all participants after treatment; affect was normal in all

participants; and thought process was goal-directed in 90%, with circumstantial thought process in 10%.

The source analysis reports Wilcoxon signed-rank testing for pre/post numerical outcomes, with p values of 0.004 for GAD-7, 0.006 for PHQ-9, 0.006 for HADS-Anxiety, 0.005 for HADS-Depression, and 0.0045 for KDQOL-36. Because this is a small, uncontrolled case series, these within-series statistical findings should be interpreted as exploratory rather than as evidence of treatment efficacy.

DISCUSSION

This case report series describes observed changes in psychological symptoms and health-related quality of life during a 30-day course of Tulsi Vati in 10 patients undergoing hemodialysis. The principal observations were reductions in GAD-7, PHQ-9, HADS-Anxiety, and HADS-Depression scores, together with an increase in the reported KDQOL-36 score and descriptive improvement in selected mental-status findings.

The psychological burden of hemodialysis is multifactorial. Chronic treatment dependence repeated vascular access, dietary and fluid restrictions, reduced functional capacity, social and financial stress, and uncertainty about the future may contribute to anxiety and depressive symptoms. The kidney-brain relationship is also increasingly discussed in contemporary literature, including possible contributions from inflammation, vascular and metabolic changes, sleep disturbance, and accumulation of neuroactive or uremic metabolites.

From an Ayurvedic perspective, the source manuscript interprets the psychological burden of chronic kidney disease through an interaction of *Sharira* (body) and *Manas* (mind), with *Chittodvega*^[17] (anxiety-related mental disturbance) and *Vishada*^[21] (sadness/depressive state) used as conceptual parallels. It further discusses *Dhatukshaya* (depletion of body tissues), *Ojas Kshaya* (depletion of vitality), *Agnimandya* (impaired digestive/metabolic function), and *Manovaha Srotodushti*^[22] (disturbance of channels associated with mental functions). These are interpretive Ayurvedic constructs and should not be presented as direct biomedical equivalents of CKD or psychiatric diagnoses.

Tulsi (*Ocimum sanctum* Linn.) is described in Ayurvedic literature as a *Rasayana* (rejuvenative) and *Medhya Dravya* (supportive of cognitive and mental functions), with *Hrudya* (cardiovascular-supportive), *Deepana-Pachana* (supporting digestion and metabolism), and *Kapha-Vata Shamaka* (balancing *Kapha*- and *Vata*-related physiological functions) properties^[28]. Its *Ushna Virya* (heating potency), *Katu-Tikta Rasa* (pungent and bitter taste), and

Satvavardhaka (supportive of psychological resilience and mental strength) properties may contribute to its proposed effects on psychological well-being. Its classical *Bhutaghni* (traditionally described as protective against harmful external influences) may provide an Ayurvedic basis for its proposed role in maintaining psychological stability.

Contemporary literature describes *Tulsi* as an adaptogenic plant with antioxidant, anti-inflammatory, neuroprotective, immunomodulatory, cardioprotective, and renoprotective activities^[28]. Its leaves contain bioactive constituents including eugenol, ursolic acid, rosmarinic acid, apigenin, oleanolic acid, flavonoids, and phenolic compounds^[29]. Experimental and clinical studies suggest that *Tulsi* may influence stress-related physiological responses and may contribute to improved stress tolerance and psychological resilience^[30,31].

Reduction in PHQ-9 scores indicated improvement in depressive symptoms, including low mood, fatigue, sleep disturbances, poor concentration, and loss of interest in daily activities. Improvement in GAD-7 and HADS-A scores suggested decreased anxiety, excessive worry, nervousness, fear, restlessness, and psychological distress, while lower HADS-D scores reflected enhanced mood, motivation, and emotional wellbeing. Mental Status Examination findings revealed normalization of speech, mood, affect, and thought processes, indicating better cognitive-behavioral functioning and emotional stability. Furthermore, improved KDQOL-36 scores reflected enhanced psychosocial functioning, symptom burden, and overall quality of life. Blood urea and serum creatinine levels demonstrated variable changes. These findings should be interpreted cautiously and cannot be taken as evidence of renal-function improvement.

The findings should therefore be regarded as preliminary clinical observations that generate a hypothesis for future research. A controlled prospective study with predefined primary outcomes, adequate sample size, standardized concomitant-treatment documentation, longer follow-up, and appropriate safety monitoring would be required to evaluate whether *Tulsi Vati* provides a reproducible benefit for psychological distress in patients receiving hemodialysis.

CONCLUSION

In this 10-patient case report series, improvement was observed in anxiety, depressive symptoms, selected mental-status findings, and health-related quality of life during a 30-day course of Tulsi Vati among patients undergoing hemodialysis. The observations provide a preliminary clinical signal and

a rationale for further controlled evaluation, but the uncontrolled design and short follow-up do not permit causal conclusions regarding efficacy.

Acknowledgments

The authors sincerely thank the Head and faculty members of the Department of Kayachikitsa for their guidance and support, and all patients for their cooperation and participation throughout the study.

Author Contributions

All authors contributed to the study conception, methodology, patient assessment, data collection, analysis, and interpretation. The first author drafted the manuscript, and all authors critically reviewed and approved the final version. Senior authors provided supervision and resources. Statistical analysis and software were used for data analysis.

Declaration of patient consent

Authors certify that they have obtained patient consent form, where the patients has given their consent for reporting the case and other clinical information in the journal. The patients understands that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Cite this article as:

Varsha Sadashiv Khot, Akash Nagesh Kore. Effect of Tulsi Vati (Ocimum Sanctum Linn.) on Psychological Distress in Chronic Kidney Disease Patients Undergoing Hemodialysis. AYUSHDHARA, 2026;13(4):312-318.

<https://doi.org/10.47070/ayushdhara.v13i4.2956>

Source of support: Nil, Conflict of interest: None Declared

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