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Original Research Article

Efficacy and safety of a ceramide-based moisturizer for xerosis and chronic kidney disease associated pruritus in maintenance hemodialysis: a randomized controlled trial

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ABSTRACT

Background: Xerosis and chronic kidney disease-associated pruritus (CKD-aP) impair sleep and quality of life in patients receiving maintenance hemodialysis. Evidence for ceramide-based moisturizers in this population is limited.
Methods: This prospective, single-center, parallel-group randomized controlled trial assigned 130 adults receiving maintenance hemodialysis to a ceramide-based moisturizer applied twice daily for 8 weeks (n=65) or standard skin-care advice alone (n=65). Co-primary outcomes were changes from baseline to week 8 in Overall Dry Skin (ODS) and pruritus Visual Analog Scale (VAS) scores. Secondary outcomes included Dermatology Life Quality Index (DLQI), sleep disturbance, adherence, satisfaction, and adverse events.
Results: All participants completed follow-up. ODS scores decreased from 3.2±0.8 to 1.4±0.6 in the ceramide group and from 3.2±0.8 to 2.4±0.7 in controls (group-by-time interaction, $p<0.001$). VAS scores decreased from 7.1±1.3 to 2.3±1.2 and from 7.0±1.4 to 5.1±1.5, respectively ($p<0.001$). DLQI scores decreased from 12.1±3.4 to 4.8±2.1 and from 11.8±3.2 to 8.9±2.9, respectively ($p<0.001$). Sleep disturbance and satisfaction also favored the ceramide group. No serious treatment-related adverse events occurred.
Conclusions: A ceramide-based moisturizer improved xerosis, CKD-aP, dermatology-related quality of life, and sleep disturbance compared with standard skin-care advice alone. Active-comparator trials are needed to determine whether the benefit is specific to ceramides or reflects moisturization generally.

Keywords: Ceramide, Chronic kidney disease-associated pruritus, Hemodialysis, Moisturizer, Randomized controlled trial, Xerosis

INTRODUCTION

Chronic kidney disease (CKD) is associated with a broad spectrum of cutaneous manifestations that can substantially affect patient comfort and quality of life. Among patients with kidney failure receiving maintenance hemodialysis (MHD), xerosis and chronic kidney disease-associated pruritus (CKD-aP), traditionally termed uremic pruritus, are among the most frequent and troublesome dermatological complications. CKD-aP is associated with sleep disturbance, psychological distress, impaired daily functioning, reduced health-related quality of life, and increased treatment burden. Although advances in dialysis care have reduced its prevalence and severity, clinically significant pruritus continues to affect a substantial proportion of patients undergoing hemodialysis.[1-6]

The pathogenesis of CKD-aP is complex and incompletely understood. Proposed mechanisms include systemic inflammation, immune dysregulation, accumulation of uremic toxins, abnormalities of calcium-phosphate metabolism, altered peripheral and central neural signaling, and dysregulation of the endogenous opioid system.[7-13] Xerosis and impaired epidermal barrier function may further intensify itching by increasing transepidermal water loss, reducing skin hydration, and facilitating cutaneous irritation. Impaired skin hydration and barrier function have been documented in patients undergoing hemodialysis and may contribute to the severity of CKD-aP.[14,15] The permeability barrier of the skin is primarily located within the stratum corneum and depends on the organization of intercellular lipids, particularly ceramides, cholesterol, and free fatty acids.[16-18] Ceramides play an important role in maintaining epidermal hydration and barrier integrity.

Topical formulations containing physiological lipids have been shown to facilitate barrier repair, improve skin hydration, and reduce transepidermal water loss in several xerotic and inflammatory dermatological conditions.[19-23] Several studies have evaluated topical emollients for xerosis and pruritus in patients receiving dialysis, using different formulations and study designs.[24-27] However, randomized evidence specifically evaluating ceramide-based moisturizers in the maintenance hemodialysis population remains limited. A topical intervention may be particularly useful in this population because it is noninvasive, easy to administer, and unlikely to produce the systemic adverse effects associated with pharmacological antipruritic therapies.

Chronic pruritus is classified according to the presence or absence of primary skin disease and its dermatological, systemic, neurological, psychiatric, or mixed origin.[28] Current guidelines recommend an individualized, stepwise, multimodal approach that includes treatment of the underlying disorder, general skin care, topical therapy, phototherapy, and systemic treatment when indicated.[29] Therefore, we conducted this prospective randomized controlled trial to evaluate the effectiveness and safety of a ceramide-based moisturizer compared with standard skin-care advice in patients undergoing maintenance hemodialysis who had clinically significant xerosis and CKD-aP. The co-primary outcomes were changes in the Overall Dry Skin (ODS) score and Visual Analog Scale (VAS) score for pruritus. Secondary outcomes included dermatology-related quality of life, sleep disturbance, treatment adherence, patient satisfaction, and adverse events.

METHODS

Study design and setting

This prospective, single-center, parallel-group randomized controlled trial was conducted in the Department of Nephrology, Shankus Hospital, Mehsana, Gujarat, India, from January through December 2025. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Approval was obtained from the Institutional Ethics Committee before study initiation, and written informed consent was obtained from all participants before enrollment. This randomized controlled trial was reported in accordance with the CONSORT 2025 statement.

Study population and eligibility

Adults receiving maintenance hemodialysis in the outpatient dialysis unit were screened during routine dialysis visits. Eligible participants were aged 18 years or older, had received maintenance hemodialysis for at least 3 months at a frequency of two or three sessions per week, had moderate-to-severe xerosis defined by an ODS score of at least 2, and had CKD-aP with a VAS score of at least 4. Patients were excluded if they had an active skin infection; eczema, psoriasis, ichthyosis, or another chronic dermatological disorder; known hypersensitivity to ceramide-containing products or any moisturizer ingredient; systemic corticosteroid or immunosuppressive treatment for dermatological disease; pregnancy or lactation; active malignancy; severe chronic liver disease; cognitive impairment preventing questionnaire completion; or participation in another interventional trial during the preceding 3 months.

Randomization, allocation concealment and masking

Participants were randomly assigned in a 1:1 ratio using a computer-generated sequence. Allocation was concealed in sequentially numbered, sealed, opaque envelopes that were opened only after enrollment. Because participants were aware of moisturizer use, participant blinding was not possible. Outcome assessment was performed by an investigator unaware of treatment allocation whenever feasible.

Interventions

Participants assigned to the intervention group received a commercially available ceramide-based moisturizer and were instructed to apply a thin layer over the body, excluding the face and scalp, twice daily for 8 weeks, preferably after bathing and before bedtime. Participants assigned to the control group received standard skin-care advice, including avoidance of hot water, use of mild soap, adherence to individualized fluid-management recommendations, and general skin-care education, without use of a ceramide-containing moisturizer. All participants continued their prescribed dialysis schedules, medications, phosphate binders, and routine nephrology care throughout the study.

Outcome measures

The co-primary outcomes were changes from baseline to week 8 in the ODS score and the VAS score for pruritus.

The ODS scale ranges from 0 (no xerosis) to 4 (severe xerosis), and the pruritus VAS ranges from 0 (no pruritus) to 10 (worst imaginable pruritus); higher scores indicate greater severity. Secondary outcomes included the DLQI, an instrument ranging from 0 to 30 in which higher scores indicate greater dermatology-related impairment; sleep disturbance assessed on an 11-point numeric rating scale from 0 (no disturbance) to 10 (worst possible disturbance); patient satisfaction; adherence to the assigned skin-care regimen; and treatment-related adverse skin reactions, including erythema, burning, contact dermatitis, and allergic reactions. Good adherence was defined as following more than 80% of the assigned regimen.

Data collection

Baseline demographic and clinical data included age, sex, dialysis vintage, diabetes mellitus, hypertension, hemoglobin, serum albumin, serum calcium, serum phosphorus, dialysis adequacy (Kt/V), and baseline ODS, VAS, and DLQI scores. Clinical assessments were performed at baseline, week 4, and week 8 by trained investigators using standardized instruments. The prespecified primary efficacy comparison was from baseline to week 8.

Sample size

The target sample size was 130 participants (65 per group). The calculation was based on 80% statistical power and a two-sided alpha level of 0.05 to detect the prespecified clinically meaningful between-group difference in the primary outcomes, with allowance for potential attrition.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics version 27.0 (IBM Corp., Armonk, NY, USA). All randomized participants were included in the intention-to-treat analysis. Continuous variables are presented as mean±standard deviation (SD) for approximately normally distributed data and as median with interquartile range for non-normally distributed data. Categorical variables are presented as frequencies and percentages. Distributional assumptions were evaluated before parametric testing. Baseline continuous variables were compared using the independent-samples Student t test or Mann-Whitney U test, as appropriate. Baseline categorical variables were compared using the Pearson chi-square test or Fisher's exact test when expected cell counts were less than 5. Because this was a randomized trial, baseline P values were considered descriptive.

For ODS, VAS, DLQI, and sleep-disturbance scores, the primary between-group comparison was the group-by-time interaction in a two-way repeated-measures analysis of variance using baseline and week 8 observations. Within-group changes were examined using the paired Student t test or Wilcoxon signed-rank test, as appropriate. Treatment adherence and satisfaction were compared using the Pearson chi-square test. Rare adverse events were compared using Fisher's exact test. All tests were two-sided, and $P<0.05$ was considered statistically significant. Exact P values are reported to two decimal places, except values below 0.001.

RESULTS

Participant flow and baseline characteristics

A total of 156 patients receiving maintenance hemodialysis were screened for eligibility. Twenty-six were excluded because they did not meet the eligibility criteria or declined participation. The remaining 130 participants were randomly assigned to the ceramide-based moisturizer group (n=65) or the standard skin-care group (n=65). All randomized participants completed the 8-week follow-up, and no participant discontinued the assigned regimen. Consequently, all 130 participants were included in the final analysis. Baseline demographic and clinical characteristics were similar between the groups (Table 1). No, statistically significant between-group differences were observed in the reported baseline variables.

Table 1: Baseline characteristics of the study participants.

Variables	Ceramide group (n=65)	Standard skin-care group (n=65)	P value
Age, years	54.8±12.6	55.4±11.9	0.78
Male sex, N (%)	39 (60.0)	41 (63.1)	0.72
Dialysis vintage, months	32.4±18.5	31.7±17.9	0.83
Diabetes mellitus, n (%)	34 (52.3)	36 (55.4)	0.72
Hypertension, n (%)	56 (86.2)	54 (83.1)	0.63
Hemoglobin, g/dL	9.8±1.2	9.7±1.3	0.65
Serum albumin, g/dL	3.7±0.4	3.6±0.5	0.21
Serum calcium, mg/dL	8.8±0.6	8.7±0.7	0.38
Serum phosphorus, mg/dL	5.1±1.1	5.2±1.2	0.62
Kt/V	1.35±0.18	1.33±0.20	0.55
ODS score	3.2±0.8	3.2±0.8	1.00

Continued.

Variables	Ceramide group (n=65)	Standard skin-care group (n=65)	P value
VAS pruritus score	7.1 ± 1.3	7.0 ± 1.4	0.67
DLQI score	12.1 ± 3.4	11.8 ± 3.2	0.61

Data are mean ± SD unless otherwise stated. P values were calculated using the independent-samples Student t test for continuous variables and the Pearson chi-square test for categorical variables. Baseline p values are descriptive.
Abbreviations: DLQI, Dermatology Life Quality Index; ODS, Overall Dry Skin; SD, standard deviation; VAS, Visual Analog Scale.

Primary and secondary outcomes

At week 8, the ceramide group demonstrated greater reductions in xerosis, pruritus severity, dermatology-related quality-of-life impairment, and sleep disturbance than the standard skin-care group (Table 2). The mean ODS score decreased by 1.8 points in the ceramide group and by 0.8 points in the control group. The mean VAS pruritus score decreased by 4.8 and 1.9 points, respectively. Significant group-by-time interactions were observed for both co-primary outcomes (p<0.001 for each). DLQI scores decreased by 7.3 points in the ceramide group and by 2.9 points in the control group. Sleep-disturbance scores decreased by 4.2 and 1.7 points, respectively. The group-by-time interactions for both secondary continuous outcomes were also statistically significant (p<0.001 for each).

Table 2: Changes in clinical outcomes from baseline to week 8.

Outcomes	Ceramide group Baseline → week 8	Mean change	Standard skin-care group Baseline → week 8	Mean change	P value
ODS score	3.2±0.8 → 1.4±0.6	-1.8	3.2±0.8 → 2.4±0.7	-0.8	<0.001
VAS pruritus score	7.1±1.3 → 2.3±1.2	-4.8	7.0±1.4 → 5.1±1.5	-1.9	<0.001
DLQI score	12.1±3.4 → 4.8±2.1	-7.3	11.8±3.2 → 8.9±2.9	-2.9	<0.001
Sleep-disturbance score	7.0±1.5 → 2.8±1.4	-4.2	6.9±1.6 → 5.2±1.5	-1.7	<0.001

Data are mean ± SD. Mean change was calculated as week 8 minus baseline; therefore, negative values indicate improvement. P values represent the group-by-time interaction from two-way repeated-measures analysis of variance using baseline and week 8 observations.
Abbreviations: DLQI, Dermatology Life Quality Index; ODS, Overall Dry Skin; SD, standard deviation; VAS, Visual Analog Scale.

Treatment adherence, satisfaction, and safety

Good adherence to the assigned regimen was observed in 59 participants (90.8%) in the ceramide group and 52 participants (80.0%) in the standard skin-care group (P=0.08). Patient satisfaction rated as excellent or good was more frequent in the ceramide group than in the control group (89.2% vs. 47.7%, P<0.001).

No serious treatment-related adverse events occurred. Mild skin irritation was reported in three participants (4.6%) in the ceramide group and two (3.1%) in the control group. Transient burning was reported in two participants (3.1%) and one participant (1.5%), respectively. Fisher's exact testing showed no significant between-group difference for either event. No allergic reaction requiring discontinuation occurred.

Table 3: Treatment adherence, satisfaction, and safety outcomes.

Outcomes	Ceramide group (n=65)	Standard skin-care group (n=65)	P value
Good adherence (>80%), N (%)	59 (90.8)	52 (80.0)	0.08
Patient satisfaction (excellent/good), N (%)	58 (89.2)	31 (47.7)	<0.001
Skin irritation, N (%)	3 (4.6)	2 (3.1)	1.00
Burning sensation, N (%)	2 (3.1)	1 (1.5)	1.00
Allergic reaction requiring discontinuation, N (%)	0	0	—

P values were calculated using the Pearson chi-square test for adherence and patient satisfaction and Fisher's exact test for rare adverse events. No, p value was calculated when both groups had zero events.

DISCUSSION

In this randomized controlled trial involving 130 patients receiving maintenance hemodialysis, twice-daily application of a ceramide-based moisturizer for 8 weeks resulted in significantly greater reductions in xerosis and pruritus severity than standard skin-care advice alone. Participants in the intervention group also demonstrated greater improvements in dermatology-related quality of life and sleep disturbance, together with high adherence and patient satisfaction. The intervention was well tolerated, and no serious treatment-related adverse events occurred.

CKD-aP remains an important and frequently underrecognized complication of kidney failure. Large observational studies have demonstrated that moderate-to-severe pruritus is associated with impaired sleep, depressive symptoms, poorer physical and mental quality of life, and increased mortality risk.[1-6] Although its pathogenesis is multifactorial, the present findings support the clinical relevance of addressing xerosis and epidermal barrier dysfunction as potentially modifiable contributors to the symptom burden experienced by patients receiving hemodialysis.

The improvement in ODS scores observed in the intervention group is biologically plausible. The stratum corneum barrier is maintained by an extracellular lipid matrix composed predominantly of ceramides, cholesterol, and free fatty acids.[16-18] Physiological lipid mixtures can facilitate barrier repair, improve water retention, and reduce transepidermal water loss.[19-23] Impaired hydration and altered skin-barrier function have also been reported in patients receiving hemodialysis and may contribute to CKD-aP.[14,15] Improvement in xerosis may therefore reduce cutaneous irritation, decrease exposure of superficial nerve endings to pruritogenic stimuli, and interrupt the itch-scratch cycle.

Previous studies have reported potential benefits of topical treatments in the dialysis population. Szepietowski et al observed improvements in uremic pruritus and xerosis following application of a cream containing structured physiological lipids and endocannabinoids; however, the study was preliminary and did not include a randomized control group.[24] Okada and Matsumoto reported improvement in mild uremic pruritus after application of an emollient with a high-water content.[25]

In the randomized EDIT trial, Boaz et al compared a Dead Sea mineral-enriched lotion with two placebo formulations and found improvement in all groups, without evidence that the mineral-enriched formulation was superior to the placebo lotions.[26] This finding suggests that regular moisturization itself may account for a substantial proportion of symptom improvement. Yoshida et al subsequently demonstrated that continuous application of a heparinoid-containing moisturizer improved skin hydration, xerosis, and pruritus in patients undergoing dialysis.[27]

The present study adds to this evidence by evaluating a ceramide-based moisturizer in a randomized parallel-group cohort. However, because the control group received standard skin-care advice rather than an active non-ceramide moisturizer, the study demonstrates the effectiveness of the ceramide-based moisturizer regimen compared with routine advice alone. It does not establish that ceramides are superior to other effective moisturizing ingredients.

The reduction in pruritus severity was accompanied by significant improvements in DLQI and sleep-disturbance scores. This finding is clinically important because the burden of CKD-aP extends beyond itch intensity alone. Persistent itching may interfere with sleep, emotional well-being, social interaction, and daily functioning.[1-6] The parallel improvements in xerosis, pruritus severity, sleep disturbance, and quality of life suggest that regular topical treatment may provide benefits across several patient-centered domains.

Topical moisturization has practical advantages over several systemic interventions used for CKD-aP. Gabapentin has demonstrated antipruritic efficacy in hemodialysis patients but requires appropriate dosing and may cause dizziness and somnolence.[30] Pregabalin may also reduce pruritus severity but is associated with similar neurological adverse effects and requires dose adjustment in kidney failure.[31] Difelikefalin has demonstrated efficacy in patients receiving hemodialysis with moderate-to-severe CKD-aP, although intravenous administration, availability, and cost may limit its use in some clinical settings.[32,33] Narrowband ultraviolet B phototherapy represents another therapeutic option for refractory symptoms, but randomized evidence has shown limited or inconsistent benefit compared with control phototherapy.[34]

The DLQI is a simple, validated measure of the effect of dermatological symptoms on daily activities, emotional well-being, interpersonal relationships, and treatment burden.[35] The improvement in DLQI observed in the intervention group indicates that the benefit of topical treatment extended beyond numerical reductions in skin dryness and itch intensity to patients' everyday functioning.

A systematic review has emphasized that the evidence supporting many treatments for CKD-aP remains limited by small samples, heterogeneous outcome measures, short follow-up periods, and variable methodological quality.[36] A contemporary review similarly recommends individualized treatment based on symptom severity, associated xerosis, treatment availability, comorbidities, and risk of adverse events.[37] The favorable safety and acceptability of topical moisturization make it a

reasonable initial or adjunctive treatment, particularly in patients with clinically apparent xerosis.

Treatment adherence was high, with more than 90% of participants in the intervention group achieving greater than 80% compliance. Patient satisfaction was also significantly higher in the ceramide group than in the standard skin-care group. These findings indicate that twice-daily moisturizer application was acceptable and could be incorporated into routine skin-care practices among patients receiving maintenance hemodialysis.

This study has several strengths. It used a randomized parallel-group design, a predefined treatment protocol, standardized assessment instruments, and both clinician-assessed and patient-reported outcomes. The evaluation of xerosis, pruritus severity, dermatology-related quality of life, sleep disturbance, adherence, patient satisfaction, and safety provided a comprehensive assessment of the intervention.

Several limitations should be acknowledged. First, this was a single-center study with a relatively short follow-up period of 8 weeks; therefore, the durability of the treatment effect remains uncertain. Second, participants could not be blinded to moisturizer use, which may have influenced self-reported outcomes such as pruritus, sleep disturbance, adherence, and satisfaction. Although outcome assessment was performed by an investigator unaware of allocation whenever feasible, complete assessor blinding may not always have been possible.

Third, objective measures of epidermal barrier function, such as transepidermal water loss, corneometry, or skin-lipid analysis, were not performed. Fourth, the control group received standard skin-care advice without an active non-ceramide moisturizer. Consequently, the observed benefit cannot be attributed specifically to the ceramide component because regular moisturization itself may have contributed to the treatment effect. Fifth, adherence was based on assessment of compliance rather than objective measurement of the quantity of moisturizer used. Finally, because the study included only patients receiving maintenance hemodialysis, the findings may not be generalizable to patients receiving peritoneal dialysis or those with earlier stages of CKD. Future multicenter trials should include longer follow-up, objective measurements of epidermal barrier function, and an active comparator containing a conventional non-ceramide emollient. Such studies would clarify whether ceramide-containing formulations provide additional benefit beyond moisturization alone and whether improvements are maintained over time.

CONCLUSION

In patients receiving maintenance hemodialysis with clinically significant xerosis and CKD-associated pruritus, twice-daily application of a ceramide-based moisturizer for 8 weeks resulted in greater improvement in skin dryness, pruritus severity, dermatology-related quality of life, and sleep disturbance than standard skin-care advice alone. The intervention was well tolerated and associated with high adherence and patient satisfaction. Ceramide-based moisturization may be considered a safe and practical adjunct to routine skin care in this population. However, randomized trials using an active non-ceramide moisturizer as the comparator are required to determine whether the observed benefits are specifically attributable to ceramides.

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