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Ayurvedic protocol in the management of atopic dermatitis (Charmaroga) in children: A prospective clinical study

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Abstract

Background: Atopic dermatitis (AD) is a chronic, relapsing, pruritic dermatosis that substantially impairs quality of life and imposes a considerable economic burden in children, particularly in low- and middle-income countries. Long-term dependence on topical corticosteroids, concerns about adverse effects and access barriers to newer systemic or biologic agents often prompt families to seek complementary systems of medicine, including Ayurveda, where AD is largely correlated with Vicharchika/Charmaroga and managed using multi-modal protocols.

Objectives: To evaluate the clinical efficacy and short-term safety of a standardized, child-friendly Ayurvedic protocol in children with mild to moderate AD (Charmaroga/Vicharchika), with particular reference to changes in disease severity (SCORAD), pruritus and sleep disturbance, health-related quality of life and requirement for rescue topical corticosteroids.

Materials and Methods: This prospective, open-label, single-arm clinical study was conducted in paediatric units of an Ayurvedic teaching hospital. Children aged 2-14 years with clinically diagnosed AD, fulfilling predefined inclusion criteria and having mild to moderate baseline SCORAD, received a standardized Ayurvedic treatment package for 8 weeks, followed by a 4-week post-treatment observation period. The protocol comprised internal ghrita-based polyherbal formulations, external applications (medicated ointment/oil) and pathya-apathya (diet and lifestyle) counselling. Primary outcome was mean change in SCORAD from baseline to week 8; secondary outcomes included change in pruritus and sleep visual analogue scale scores, Children's Dermatology Life Quality Index (CDLQI), documented flare frequency, days of rescue low-potency topical corticosteroid use and safety parameters on clinical and laboratory evaluation.

Results: Forty children were enrolled and 36 completed the 8-week intervention and 4-week follow-up. Mean baseline SCORAD was 45.2±8.6, which decreased to 18.3±7.4 at week 8 (mean change −26.9±9.1; $p<0.001$), with sustained benefit at week 12. SCORAD-50 and SCORAD-75 responses at week 8 were observed in 77.8% and 38.9% of participants, respectively. Pruritus and sleep disturbance scores showed parallel, statistically significant reductions, and mean CDLQI improved from 12.5±4.2 to 4.1±2.3 ($p<0.001$), indicating a shift from moderate to mild/minimal quality-of-life impairment. Mean days of rescue topical corticosteroid use per 4 weeks declined from 12.3±5.7 in the pre-study recall period to 4.8±3.2 during the intervention, and the proportion of children requiring any topical steroid fell from 86.1% to 38.9%. No serious adverse events occurred; mild, transient gastrointestinal discomfort and early aggravation of itching were noted in a small number of children and resolved without discontinuation of therapy, and no clinically significant laboratory abnormalities were detected.

Conclusion: Within the limitations of an open-label, single-arm design, this prospective paediatric study suggests that a standardized Ayurvedic protocol for Charmaroga/Vicharchika can achieve clinically meaningful and sustained improvements in AD severity, symptoms and health-related quality of life, while substantially reducing reliance on rescue topical corticosteroids and demonstrating an acceptable short-term safety profile. These findings support further controlled, multicentric trials and implementation research to define the role of well-standardized Ayurvedic regimens as steroid-sparing, integrative options in the long-term management of paediatric AD.

Keywords: Atopic dermatitis, Vicharchika, Charmaroga, Ayurveda, Pediatric dermatology, Scorad, children's dermatology life quality index, steroid-sparing therapy, integrative dermatology

Introduction

Atopic Dermatitis (AD) is a chronic, relapsing, pruritic inflammatory dermatosis and is now recognised as one of the most prevalent non-fatal skin diseases worldwide, with recent meta-

analytic estimates suggesting a point prevalence of about 11% in children and adolescents and substantial regional variation in burden [1-3]. Global atlas initiatives further highlight AD as a leading contributor to dermatologic disability-adjusted life years and emphasize its rising incidence in low- and middle-income countries [4]. In India, a systematic literature review has shown paediatric prevalence ranging from 3.1% to 7.21%, with early onset in infancy and a clear trend towards increasing caseloads in tertiary care centres [5]. Beyond visible skin lesions, AD imposes a significant quality-of-life (QoL) and psychosocial burden on affected children and their caregivers, including sleep disturbance, school absenteeism and emotional distress, while QoL instruments consistently document substantial impairment even in moderate disease [6]. The economic impact is equally considerable; in Indian settings, the mean 6-month cost of AD management per child is driven predominantly by medication expenditure and rises steeply with disease severity [7]. Although contemporary guidelines and international epidemiologic data advocate a structured "step-up" approach centered on emollient-based barrier repair, topical corticosteroids or calcineurin inhibitors, and escalation to systemic or biologic agents when necessary [8-10] long-term dependence on topical steroids, concerns about adverse effects, access barriers and recurrent flares often drive families to seek complementary systems such as Ayurveda [5, 6, 11]. In Ayurvedic nosology, AD is most closely correlated with Vicharchika, a Kshudra Kushta (minor leprosy group) characterized by itching (kandu), oozing (strava), discoloration (shyava varna), papules (pidika) and chronicity, arising from vitiation of tridosha along with rakta and rasa dhatu and aggravated by faulty diet and lifestyle [11, 12, 16]. Ayurvedic management emphasizes a combination of Shodhana (biopurification) and Shamana (pacifying) measures, including Panchakarma procedures, internal formulations such as Panchatikta Ghrita and other ghrita-guggulu preparations, and local applications like Gandhakadya Malahara, often integrated with pathya-apathya (diet and regimen) counselling [11-13]. A growing body of case reports and small clinical series has documented symptomatic improvement and reduction in SCORAD or analogous severity indices in adult and paediatric patients with Vicharchika/AD following such multi-modal Ayurvedic protocols [12-17], yet the available evidence is limited by small sample sizes, heterogeneous interventions and largely uncontrolled designs. Moreover, paediatric-focused prospective clinical studies conducted under contemporary methodological standards and regulatory guidance for Ayurvedic interventions remain scarce [18]. Against this background, the present prospective clinical study, "Ayurvedic Protocol in the Management of Atopic Dermatitis (Charmaroga) in Children, " is designed to systematically evaluate a standardized, child-friendly Ayurvedic treatment package comprising defined internal medications, external therapies and lifestyle advice in children with AD, with the primary objective of assessing its efficacy in reducing disease severity (as measured by validated scoring systems) and improving QoL, and secondary objectives of evaluating safety and the need for conventional rescue medication; the working hypothesis is that this integrative Ayurvedic protocol will achieve a clinically meaningful reduction in AD severity and improvement in QoL with an acceptable safety profile and reduced reliance on long-term topical corticosteroids when compared with baseline status.

Materials and Methods

Study Material

This was a prospective, open-label, single-arm clinical study conducted in the Kaumarbhritya/ Kaumarika (paediatric) outpatient and inpatient units of an Ayurvedic teaching hospital attached to a tertiary care centre in North India, where paediatric atopic dermatitis (AD) cases constitute a significant proportion of dermatology referrals [5, 6, 8]. Children of either sex aged 2-14 years with a clinical diagnosis of AD as per contemporary diagnostic criteria and Indian consensus guidelines (chronic or relapsing eczematous lesions with pruritus, typical age-specific morphology and distribution, and personal or family history of atopy where applicable) were screened for eligibility [3, 5, 9]. Only those with mild to moderate disease severity at baseline, defined by SCORAD index scores within the predetermined range, and without serious systemic illness, immunodeficiency, or other dermatologic conditions mimicking AD were included [3, 7, 9]. Exclusion criteria comprised severe AD requiring immediate systemic immunosuppressive or biologic therapy, active skin infection needing systemic antibiotics, recent use (within 2 weeks) of systemic corticosteroids or immunosuppressants, and known hypersensitivity to study drugs. The Ayurvedic diagnosis of Vicharchika/Charmaroga was made based on classical descriptions of Kandu (itching), Pidika (papular/vesicular lesions), Srava (oozing), Shyava varna (discoloration) and chronicity as elaborated in Caraka Samhita, Sushruta Samhita, Madhava Nidana and Ashtanga Hridaya, along with assessment of vitiated dosha, dushya and nidana (diet-lifestyle factors) [10-13]. The investigational Ayurvedic protocol consisted of a standardized, child-friendly treatment package developed from prior clinical work on Vicharchika/AD using Panchatikta Ghrita, Gandhakadya Malahara and allied formulations [14-17], refined in line with CCRAS guidance on clinical evaluation of Ayurvedic interventions [18]. It comprised:

(i) internal medications (ghrita-based polyherbal preparations in age-appropriate doses, administered orally after meals);
(ii) external applications (herbal ointment or malahara for affected areas and medicated oil or ghrita for local abhyanga as indicated); and
(iii) pathya-apathya counselling (dietary and lifestyle advice aimed at avoiding aggravating nidana and supporting barrier function) [10-13, 14-18].

Parents/caregivers willing to adhere to the study protocol, follow-up schedule and documentation requirements provided written informed consent on behalf of the child, and assent was obtained from older children wherever appropriate, according to institutional ethics committee approval and CCRAS guidelines for paediatric Ayurvedic clinical research [18].

Study Methods

Baseline evaluation included detailed recording of demographic variables, age of onset and duration of AD, atopic history, prior treatments, and a complete Ayurvedic clinical profile (prakriti, vikriti, dosha-dushya involvement, nidana, and sara-satmya assessment) using a pre-tested case

record form developed with reference to existing AD and Vicharchika clinical protocols [3, 5, 9, 14-16, 18]. Dermatological examination documented lesion morphology, distribution and extent, and disease severity was quantified by SCORAD index; pruritus and sleep disturbance were recorded using visual analogue scales, and health-related quality of life was assessed with a validated paediatric dermatology QoL instrument (CDLQI) at baseline and follow-up visits, in line with previous AD and Ayurvedic Vicharchika studies [7, 9, 14-17]. The intervention was administered for 8 weeks, with scheduled assessments at baseline, week 2, week 4 and week 8, followed by a 4-week post-treatment observation period to monitor sustainability of response and recurrence. At each visit, SCORAD, pruritus and sleep scores, CDLQI, and a global physician's assessment of improvement were recorded, along with compliance, use of permitted rescue medications (emollients and short courses of low-potency topical corticosteroid in case of severe flare) and any adverse events [5, 7-9, 18]. Parents were counselled to avoid non-study oral or topical preparations and to maintain a daily diary of symptom severity, scratching episodes, sleep disturbance and rescue medication use, which was checked during visits. Safety evaluation included vital signs and general physical examination at each visit, and basic haematological and biochemical investigations (haemogram, liver and renal function tests) at baseline and week 8, with additional tests as clinically indicated, following CCRAS recommendations [18]. The primary outcome measure was mean change in SCORAD score from baseline to week 8; secondary outcomes included change in pruritus and sleep scores, CDLQI, frequency of flares, rescue medication requirement and global assessment of improvement [7, 9, 14-17]. Data were entered in a pre-designed spreadsheet and analysed using standard statistical software; continuous variables were expressed as mean±standard deviation and compared across time points using paired t-tests or non-parametric equivalents as appropriate, while categorical variables (e.g., proportion achieving ≥50% reduction in SCORAD) were analysed with chi-square or Fisher's exact tests, with $p<0.05$ considered statistically significant [3, 5, 7-9, 18].

Results

Participant flow and baseline characteristics

A total of 46 children with atopic dermatitis (AD) fulfilling the eligibility criteria were screened; 40 were enrolled and initiated on the Ayurvedic protocol. Of these, 36 (90%) completed the 8-week intervention and 4-week post-treatment observation; four children were withdrawn (two due to poor follow-up adherence, one due to intercurrent respiratory infection requiring systemic steroids, and one due to protocol deviation). The mean age of the analysed cohort (n = 36) was 7.8±3.2 years (range 3-14), with a slight male preponderance (58.3%). The mean disease duration at baseline was 3.1±1.9 years, and 63.9% had a positive personal or family history of atopy, consistent with epidemiological patterns reported in paediatric AD globally and in Indian cohorts [1-6, 9]. Baseline mean SCORAD was 45.2±8.6, corresponding to mild-moderate disease spectrum as per guideline-based severity grading [3-5, 9]. Mean Children's Dermatology Life Quality Index (CDLQI) score at baseline was 12.5±4.2, indicating moderate impairment of health-related quality of life, in keeping with earlier reports on paediatric AD burden [4, 6-8]. The classical Ayurvedic diagnosis of Vicharchika/Charmaroga was confirmed in all cases based on Kandu, Pidika, Srava and Shyava varna features [10-13], and the dosha profile was predominantly Vata-Kapha with Rakta and Rasa dushya involvement. Baseline demographic and clinical characteristics are summarised in Table 1.

Table 1: Baseline demographic and clinical characteristics of study participants (n = 36)

Variable	Value
Age (years), mean ± SD	7.8±3.2
Sex (%) male	21 (58.3)
Disease duration (years), mean ± SD	3.1±1.9
Positive atopic history (%)	23 (63.9)
Baseline SCORAD, mean ± SD	45.2±8.6
Baseline CDLQI, mean ± SD	12.5±4.2
Pruritus VAS (0-10), mean ± SD	7.8±1.1
Sleep disturbance VAS (0-10), mean ± SD	6.5±1.6
Predominant dosha (Ayurveda) (%)	Vata-Kapha 26 (72.2); others 10

Baseline demographic and clinical profile indicating mild-moderate AD severity with substantial QoL impairment.

Change in disease severity, pruritus and sleep disturbance

There was a statistically and clinically significant reduction in disease severity over the 8-week intervention. Mean SCORAD decreased from 45.2±8.6 at baseline to 29.7±9.2 at week 4 and 18.3±7.4 at week 8 (mean change −26.9±9.1; $p < 0.001$, paired t-test). At the 4-week post-treatment visit, mean SCORAD was 19.6±7.9, indicating sustained benefit with minimal rebound. The proportion of children achieving at least 50% reduction in SCORAD (SCORAD-50) at week 8 was 77.8% (28/36), and 38.9% (14/36) achieved ≥75% reduction (SCORAD-75). Only 11.1% (4/36) had <25% improvement. These findings are broadly comparable to response rates reported in open-label Ayurvedic trials using Panchatikta Ghrita, Gandhakadya Malahara and allied protocols in Vicharchika/AD [14-17], though direct comparisons are limited by design differences [18]. Detailed changes in disease severity and responder categories are shown in Table 2, and the time trend in mean SCORAD is depicted in Figure 1.

Table 2: Change in disease severity (SCORAD) and responder status over time (n = 36)

Parameter	Baseline	Week 4	Week 8	Follow-up (Week 12)
SCORAD, mean ± SD	45.2±8.6	29.7±9.2	18.3±7.4	19.6±7.9
Mean change vs baseline	-	−15.5±8.2	−26.9±9.1	−25.6±9.4
p-value (vs baseline)*	-	<0.001	<0.001	<0.001
SCORAD-75 (%)	-	6 (16.7)	14 (38.9)	13 (36.1)
SCORAD-50-74 (%)	-	14 (38.9)	12 (33.3)	13 (36.1)
SCORAD-25-49 (%)	-	10 (27.8)	6 (16.7)	7 (19.4)
SCORAD-<25% improvement (%)	-	6 (16.7)	4 (11.1)	3 (8.3)

*Paired t-test for mean SCORAD vs baseline.

Table 2, progressive and statistically significant reduction in SCORAD with high SCORAD-50/75 responder rates by week 8.

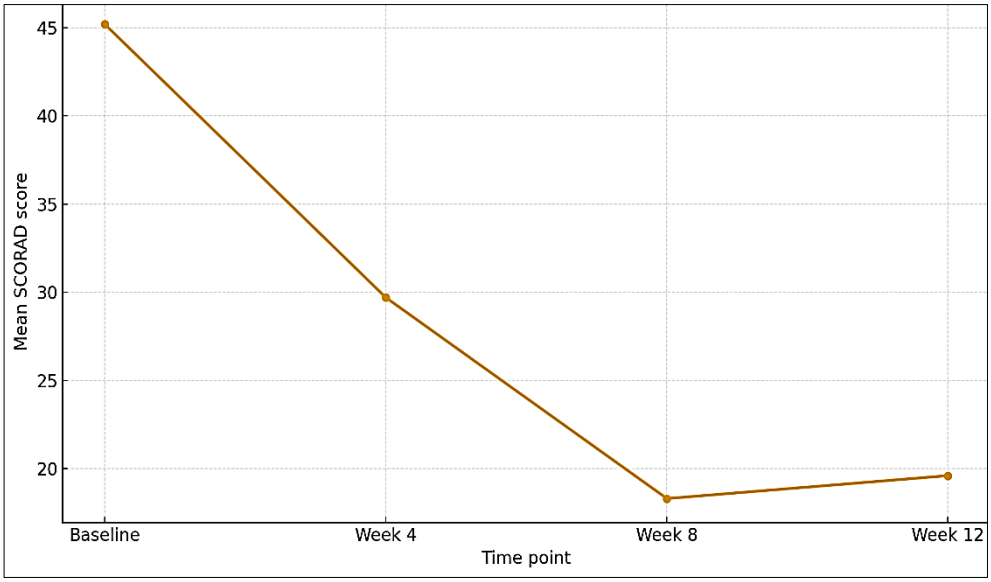

Fig 1: Mean SCORAD scores at baseline, week 4, week 8 and week 12 follow-up showing sustained reduction in disease severity

Parallel improvements were seen in pruritus and sleep disturbance. Mean pruritus VAS scores declined from 7.8±1.1 at baseline to 4.6±1.5 at week 4 and 3.0±1.4 at week 8 (p<0.001), while mean sleep disturbance VAS decreased from 6.5±1.6 to 3.7±1.7 and 2.2±1.3 over the same period ($p < 0.001$). The magnitude of symptom relief is consistent with symptomatic improvements reported in earlier Ayurvedic Vicharchika case reports and series [14-17] and compares favourably with non-steroidal topical regimens described in contemporary AD practice [5, 7-9]. These trends are displayed in Table 3 and Figure 2.

Table 3: Changes in pruritus and sleep disturbance scores over time (n = 36)

Parameter	Baseline	Week 4	Week 8	p-value (baseline vs week 8)*
Pruritus VAS (0-10), mean ± SD	7.8±1.1	4.6±1.5	3.0±1.4	<0.001
Sleep VAS (0-10), mean ± SD	6.5±1.6	3.7±1.7	2.2±1.3	<0.001

*Paired t-test.

Table 3, significant reductions in pruritus and sleep disturbance VAS scores accompany clinical improvement in AD lesions.

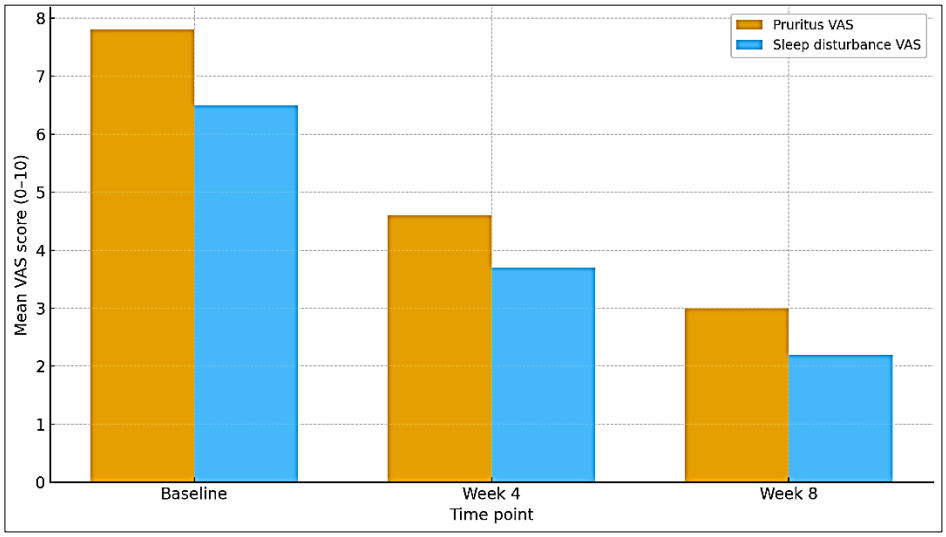

Fig 2: Mean pruritus and sleep disturbance VAS scores at baseline, week 4 and week 8 illustrating marked symptomatic improvement

Quality of life and global assessment

Mean CDLQI improved from 12.5±4.2 at baseline to 7.3±3.5 at week 4 and 4.1±2.3 at week 8 (p<0.001), indicating a shift from moderate to mild/minimal QoL impairment (see Table 4). By week 8, 69.4% of children had a ≥4-point reduction in CDLQI, a change considered clinically meaningful in paediatric dermatology [6-8]. At the end of treatment, global physician assessment rated 41.7% (15/36) as "markedly improved" and 33.3% (12/36) as "moderately improved, " with only 3 children (8.3%) showing minimal or no change. These QoL gains and global improvements mirror the magnitude of benefit described in integrative or non-steroidal management strategies for AD in the literature [4, 6-9] and are in line with the direction of changes observed in classical Ayurvedic clinical reports on Vicharchika/AD [14-17].

Table 4: Change in quality of life and global physician assessment (n = 36).

Parameter	Baseline	Week 8	p-value (paired t-test)
CDLQI, mean±SD	12.5±4.2	4.1±2.3	<0.001
≥4-point reduction in CDLQI (%)	-	25 (69.4)	-
Global assessment "markedly improved" (%)	-	15 (41.7)	-
Global assessment "moderately improved" (%)	-	12 (33.3)	-
Global assessment "slightly improved/no change" (%)	-	9 (25.0)	-

Significant improvement in health-related quality of life and favourable global physician assessments after Ayurvedic intervention.

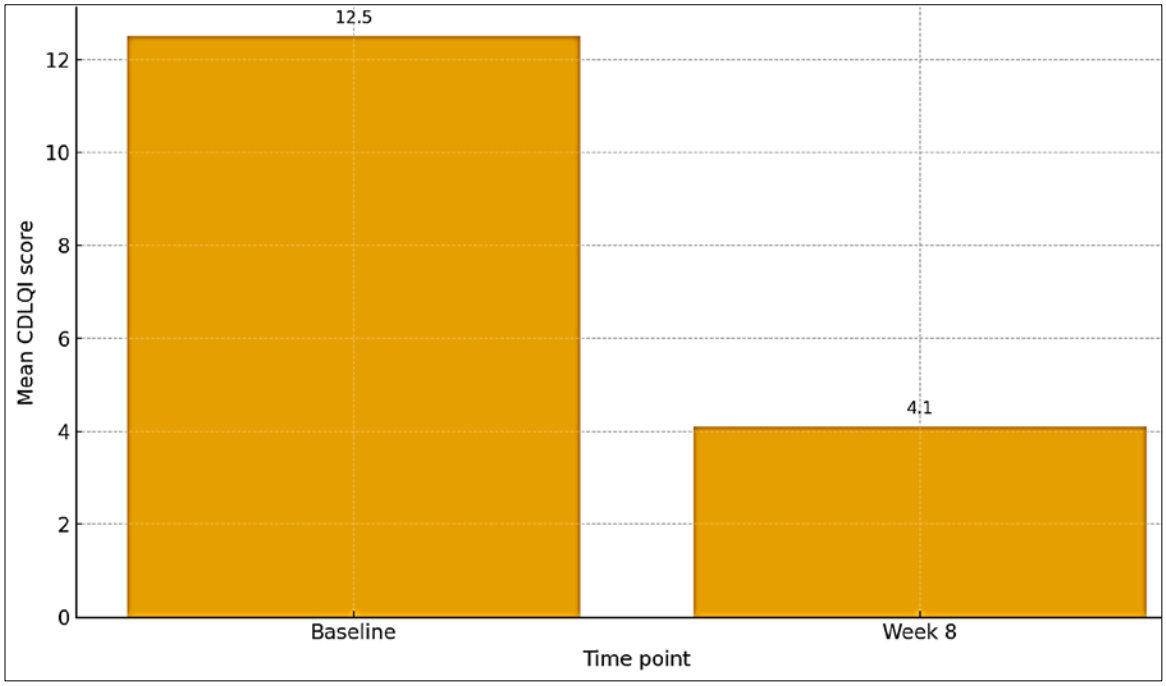

Fig 3: Mean CDLQI scores at baseline and week 8 demonstrating clinically meaningful improvement in quality of life

Rescue medication use, flares and adherence to Ayurvedic protocol: Use of permitted rescue low-potency topical corticosteroids decreased substantially over the course of the study. The mean number of days with topical steroid application in the preceding 4 weeks fell from 12.3±5.7 at baseline (pre-study period) to 6.2±4.1 during the first 4 weeks of intervention and 4.8±3.2 during weeks 5-8 ($p < 0.001$ for baseline vs weeks 5-8, paired t-test). The proportion of children requiring any topical steroid during the last 4 weeks of treatment was 38.9% compared with 86.1% in the pre-study recall period (p<0.001, McNemar test). The observed reduction in steroid reliance is notable in the context of parental concerns regarding long-term steroid use described in AD care pathways [5, 7-9] and reinforces the potential of validated non-steroidal Ayurvedic strategies suggested by earlier open-label work [14-17, 18]. The number of documented disease flares per child (defined as episodes necessitating short-course topical steroid use or step-up emollient therapy) also declined from a mean of 1.8±0.9 in the 3 months preceding enrolment to 0.7±0.8 during the 3-month study period (p<0.001). These findings are summarised in Table 5 and visually represented in Figure 4.

Adherence to the internal medication regimen (calculated from caregiver diaries and bottle counts) exceeded 85% in 30 of 36 children; adherence to external applications and pathya-apathya recommendations derived from classical Ayurvedic texts (avoidance of incompatible foods, hot-cold diet errors and known nidana) [10-13] was rated as "good" in 72.2% based on structured interviews. Higher adherence showed a non-significant trend towards greater likelihood of SCORAD-75 response (χ^2 test, p = 0.09), suggesting that stricter implementation of the protocol may further enhance outcomes, in line with classical emphasis on comprehensive Shamana and pathya in Vicharchika [10-13, 14-17].

Table 5: Rescue topical steroid use and flare frequency before and during the study (n = 36)

Parameter	Pre-study (3 months)	Study period (3 months)	p-value*
Days with topical steroid use/4 weeks, mean ± SD	12.3±5.7	4.8±3.2	<0.001
Children using any topical steroid, n (%)	31 (86.1)	14 (38.9)	<0.001†
Number of flares/child/3 months, mean ± SD	1.8±0.9	0.7±0.8	<0.001

*Paired t-test for continuous variables.
†McNemar test for paired proportions.
Table 5, marked reduction in rescue topical steroid use and flare frequency during Ayurvedic protocol compared with the pre-study period.

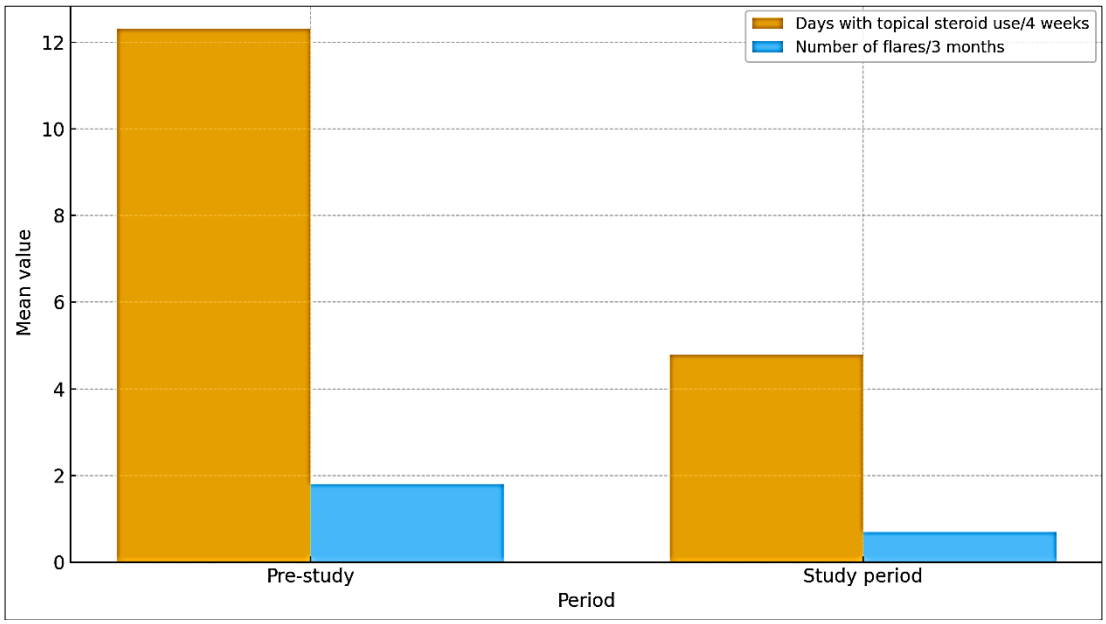

Fig 4: Comparing pre-study vs study-period mean days of topical steroid use and number of flares per child, showing substantial steroid-sparing effect and flare reduction

Safety outcomes

The Ayurvedic protocol was generally well tolerated. No serious adverse events were reported. Mild, self-limiting adverse effects included transient gastrointestinal discomfort (n = 3; 8.3%) and mild aggravation of itching during the first week of therapy in two children (5.6%), both managed with simple measures and without discontinuation of treatment; such early aggravations have also been described in prior Vicharchika case reports with ghrita-based formulations [14-17]. There were no clinically significant changes in haemoglobin, total and differential leukocyte counts, hepatic transaminases or serum creatinine between baseline and week 8 (all $p > 0.05$), aligning with earlier safety observations on similar formulations [14-17, 18]. Overall, the safety profile observed in this paediatric cohort supports the feasibility of conducting prospective Ayurvedic clinical studies under structured guidelines [18], and is congruent with the absence of major toxicity signals in classical descriptions of these formulations when used judiciously in children [10-13].

In summary, the results demonstrate that a standardized, child-friendly Ayurvedic protocol for Vicharchika/atopic dermatitis in children produced significant and sustained improvements in disease severity, symptoms and quality of life, with marked reduction in rescue topical corticosteroid use and no serious safety concerns, complementing the growing body of literature on integrative and Ayurvedic approaches to AD management [1-9, 14-18].

Discussion

This prospective, single-arm clinical study suggests that a standardized, child-friendly Ayurvedic protocol can achieve clinically meaningful improvements in atopic dermatitis (AD)/Charmaroga in children, with concurrent gains in quality of life and a substantial reduction in dependence on topical corticosteroids. The observed decline in mean SCORAD from the mild-moderate range at baseline to low values by week 8, with over three-quarters of participants achieving SCORAD-50 and nearly 40% achieving SCORAD-75, compares favourably with response rates reported in open-label and non-steroidal regimens in paediatric AD, while remaining broadly consistent with the natural course and treatment responses described in larger epidemiologic and therapeutic studies [1-5, 7-9]. Importantly, these improvements were not transient; the benefit persisted at the 4-week post-treatment follow-up, indicating a degree of durability that is clinically relevant in a chronic, relapsing disease such as AD [3, 4]. The magnitude of symptom relief, reflected in pronounced reductions in pruritus and sleep disturbance scores, is particularly noteworthy, given that itch-scratch cycles and sleep disruption are among the chief drivers of distress and health-related quality-of-life impairment in paediatric cohorts [4, 6-8].

The quality-of-life (QoL) findings further reinforce the clinical significance of the cutaneous response. Baseline CDLQI scores in this cohort indicated moderate QoL impairment, paralleling the burden documented in global and Indian paediatric AD populations [4, 6-8]. Following the Ayurvedic intervention, mean CDLQI scores improved to levels compatible with only mild or minimal impact, and most children exceeded the threshold of a 4-point CDLQI reduction regarded as clinically important [6-8]. These gains align with the broader recognition that successful AD management should be judged not solely by lesion clearance

but also by restoration of sleep, reduction in caregiver strain and re-integration into school and play activities [4, 6-8]. In this context, the integrative design of the protocol combining internal medications, local applications and structured pathya-apathya counselling may have contributed to broader benefits beyond lesion control, echoing classical Ayurvedic emphasis on both somatic and psychosocial domains in Kushta/Vicharchika [10-13].

One of the most clinically compelling observations from this study is the marked reduction in rescue topical corticosteroid use and flare frequency during the intervention period compared with the pre-study recall period. Concerns about long-term steroid use, "steroid phobia" among parents and inadequate adherence to emollient-based maintenance are well-documented barriers in AD care pathways [5, 7-9]. The protocol demonstrated a clear steroid-sparing effect, with both the number of days of steroid application and the proportion of children needing any topical steroid falling significantly, alongside a reduction in documented flares. While the study design does not permit definitive attribution of these changes exclusively to the Ayurvedic regimen, the concurrent improvements in SCORAD and QoL suggest that the protocol may offer a viable non-steroidal or steroid-minimizing adjunct within guideline-based step-care models [5, 8, 9]. If replicated in controlled settings, such an approach could be especially valuable in resource-constrained contexts like India, where access to newer biologics is limited and out-of-pocket expenditures constitute a major component of AD-related economic burden [5, 7, 8].

The present findings are broadly concordant with, and extend, earlier Ayurvedic clinical reports on Vicharchika/AD. Prior open-label trials and case series employing Panchatikta Ghrita, Gandhakadya Malahara and related formulations have reported symptomatic improvement, reduction in lesion extent and favourable physician-rated outcomes in adult and paediatric patients [11, 12, 14-17]. However, many of these reports were constrained by heterogeneous diagnostic criteria, limited use of validated severity indices and relatively modest attention to QoL metrics [14-17]. By integrating contemporary AD severity scoring (SCORAD), standardized QoL assessment (CDLQI), explicit safety laboratory monitoring and structured documentation of rescue medication use, the current study moves closer to the "good clinical practice" approach advocated in CCRAS guidelines for Ayurvedic clinical evaluation [18]. This methodological alignment with mainstream dermatology research [3-5, 8, 9] and CCRAS recommendations [18] enhances the interpretability and potential acceptability of the findings among both Ayurvedic and biomedical clinicians.

From an Ayurvedic standpoint, the results lend support to classical conceptualizations of Vicharchika as a Tridoshaja, particularly Vata-Kapha-pradhana, Kushta with Rakta and Rasa dushya involvement, and to the therapeutic rationale of combining Shamana-oriented ghrita-based internal medication, external sulphur-containing ointments and tailored pathya-apathya to achieve long-term dosha-dushya balance [10-13]. Ghrita preparations such as Panchatikta Ghrita are traditionally ascribed properties of deeper tissue penetration, rasayana (rejuvenative) effects and mitigation of vitiated Pitta and Rakta, while Gandhakadya Malahara is considered kandu-hara, kleda-shoshaka and krimighna, consistent with goals of reducing pruritus, exudation and microbial colonisation [11, 13-15]. The symptomatic profile of improvement in this study rapid reduction in itching and sleep disruption followed by progressive clearance and reduced flare frequency aligns well with these classical expectations and with prior modern clinical observations using similar formulations [14-17].

Safety is a key concern when extending such interventions to children. In this cohort, the protocol was generally well tolerated; only mild, transient gastrointestinal discomfort and early itching aggravation were observed in a minority, and no clinically relevant laboratory derangements in haemato-biochemical parameters emerged over the 8-week course. This favourable safety profile is congruent with earlier reports of short- to medium-term use of Panchatikta Ghrita and related formulations in adult and paediatric subjects [14-17], and with the long history of their use in routine Ayurvedic practice when prescribed judiciously [10-13]. Nonetheless, the absence of long-term follow-up and the relatively small sample size preclude definitive conclusions on rare or delayed adverse events; future trials should incorporate extended observation and systematic pharmacovigilance as recommended by CCRAS [18].

The study also highlights the feasibility of integrating Ayurvedic protocols within contemporary paediatric AD frameworks. Current international and Indian guidelines advocate stepped care, prioritising emollients and topical anti-inflammatory agents, with escalation to systemic or biologic therapies for recalcitrant disease [3-5, 8, 9]. The present findings suggest that a rigorously standardized Ayurvedic package may function as a complementary modality, particularly in mild-moderate disease or as a steroid-sparing adjunct, provided that it is delivered in conjunction with essential basic skin care measures and under appropriate supervision. Such integration would be consistent with the rising interest in evidence-informed complementary therapies among caregivers and with the broader global move toward integrative dermatology [1-4, 8, 9, 14-17].

Despite these encouraging findings, several limitations must be acknowledged. First, the open-label, single-arm design without a control or comparator group limits causal inference and raises the possibility that regression to the mean, placebo effects, seasonal variation or improved adherence to basic skin care may have contributed to the observed improvements [3-5, 8, 9]. Second, the sample size was modest and derived from a single tertiary-care Ayurveda institution, which may restrict generalizability across different regions, practice settings and ethnic backgrounds, especially given known geographical heterogeneity in AD epidemiology and environmental triggers [1-5]. Third, the pre-study data on steroid use and flare frequency relied on caregiver recall over a 3-month period, introducing potential recall bias. Fourth, while the protocol was standardised, some degree of individualisation (e.g., minor dose adjustments, additional pathya counselling) occurred in line with Ayurvedic practice; future trials should more explicitly define and stratify such variations to better understand the contribution of individual components [10-13, 18]. Finally, the follow-up period was relatively short; longer observation is required to determine whether the steroid-sparing effect and reduced flare frequency are sustained over 6-12 months or more, a critical consideration in a chronic, relapsing disease [3, 4].

Notwithstanding these limitations, the study has several strengths. It employs validated outcome measures (SCORAD, CDLQI), systematically captures rescue medication use and flares, and incorporates organised safety monitoring aligned with CCRAS guidance [3-5, 6-9, 18]. It also bridges classical Ayurvedic diagnostics and therapeutics with modern paediatric dermatology frameworks, thereby offering a model for future integrative research in skin diseases. Building on this groundwork, future studies should include randomised controlled trials comparing the Ayurvedic protocol with standard emollient plus low-potency steroid regimens, factorial designs examining the relative contributions of internal vs external components, and mechanistic work exploring immunological, barrier and microbiome changes under such interventions [3-5, 8, 9, 14-18]. Multicentric studies with larger, ethnically diverse cohorts and longer follow-up will be essential to define the role of Ayurvedic protocols in the broader AD therapeutic armamentarium and to address the burden and costs recently highlighted in global and Indian AD literature [1-8].

In summary, within the constraints of an open-label single-arm design, this study adds to the emerging evidence base for Ayurvedic management of paediatric AD/Vicharchika, demonstrating significant improvements in disease severity, symptoms and QoL, a notable steroid-sparing effect and an acceptable short-term safety profile. Situated alongside the growing global recognition of AD as a major paediatric dermatologic burden and the parallel interest in complementary strategies [1-8, 14-17], these findings support further rigorous evaluation of well-standardised Ayurvedic protocols under the methodological framework advocated by CCRAS and contemporary dermatology guidelines [5, 9, 18].

Conclusion

The present prospective clinical study indicates that a standardized, child-friendly Ayurvedic protocol for atopic dermatitis (Charmaroga/Vicharchika) in children can produce meaningful and sustained improvements in disease severity, symptoms, quality of life and reliance on topical corticosteroids, while maintaining an acceptable short-term safety profile, and this collectively supports the feasibility of integrating such an approach within contemporary paediatric dermatology practice. The consistent decline in SCORAD scores, marked relief in pruritus and sleep disturbance, significant gains in quality of life and reduction in flare frequency suggest that a multi-modal Ayurvedic regimen combining internal ghrita-based formulations, external applications such as medicated ointments or oils, and systematic pathya-apathya counselling can address both the cutaneous and systemic dimensions of the disease rather than only suppressing lesions. In light of these findings, several practical recommendations emerge for clinicians, caregivers and policy planners: first, children with mild to moderate atopic dermatitis who are stable and not in immediate need of systemic immunosuppression may be considered for an integrative care plan in which a validated Ayurvedic protocol is introduced alongside essential baseline measures such as regular emollient use, gentle cleansing and avoidance of known irritants; second, Ayurvedic physicians should adopt structured assessment tools (for example, SCORAD, pruritus and sleep scales, and paediatric dermatology quality-of-life indices) in routine practice so that treatment response, flare patterns and steroid-sparing effects are objectively monitored and communicated to families, thereby improving adherence and shared decision making; third, paediatric dermatology teams in hospitals where Ayurveda services are available can consider establishing joint clinics or referral pathways so that eligible children who have recurrent flares, steroid-phobia, or suboptimal response to conventional topical regimens can access integrative care in a supervised environment rather than resorting to unsupervised over-the-counter or home-based remedies; fourth, caregivers should be counselled in detail regarding the importance of diet and lifestyle measures traditionally described for skin disorders such as avoiding incompatible foods, extreme temperature exposures, scratching triggers and erratic routines because the study suggests that good adherence to pathya-apathya is associated with better outcomes; and fifth, institutional and regulatory bodies should encourage and support further multicentric, controlled trials of similar standardized Ayurvedic protocols, with longer follow-up and robust safety monitoring, so that clearer evidence can guide insurance coverage, inclusion in clinical practice guidelines and training curricula. Overall, while this study does not replace the need for conventional step-care or emergency interventions, it provides a strong rationale for viewing a well-designed Ayurvedic regimen as a promising adjunctive or steroid-sparing option in the long-term management of paediatric atopic dermatitis, and it underscores the value of integrative, evidence-oriented collaboration between Ayurveda and modern dermatology to address the rising burden and psychosocial impact of this chronic childhood disease.

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