Emollient and antipruritic effect of Itch cream in dermatological disorders: A randomized controlled trial

Topical therapy is one of the foundations of a dermatologist's therapeutic armamentarium as it is used either for symptomatic relief, control, or cure of the underlying disease. Emollients provide symptomatic relief in xerotic skin diseases like ichthyoses, xeroderma, disorders of keratinization, and atopic dermatitis.[1],[2] They act by softening the stratum corneum by increasing its hydration. Currently marketed emollients often cause adverse effects like irritant or allergic contact dermatitis, cosmetic acne, and pigmentary disorders.[1],[2] Pruritus being the most common presenting symptom in xerotic disorders, systemic antipruritic drugs like antihistamines are routinely prescribed to patients. There are few effective yet safe topical antipruritic agents available for treatment of such clinical conditions and the availability of such an agent could be of immense value.

Topical polyherbal formulations are the latest additions to the dermatologist's repertoire of treatment. Scientific efforts to unearth their therapeutic utility and safety in some dermatological disorders have been documented.[3],[4]

Itch cream, a topical proprietary polyherbal formulation, is marketed for its antipruritic and emollient properties in xerotic and pruritic skin disorders. It contains the following ingredients (v/w basis): Extracts of Turmeric 16% (*Curcuma longa*), Saffron 0.025% (*Crocus sativus*), Sandalwood 8% (*Santalum album*), Vetiver 0.5% (*Veteveria zizanioides*), Lata kasturi 0.1% (*Abelmoschus moschatus*), Mehendi 3% (*Lawsonia inermis*), Tulasi 3% (*Ocimum sanctum*), Yastimadhu 0.5% (*Glycyrrhiza glabra*), Turmeric oil 0.1%, Surasar 0.5%, and *Swarna bhasma* 0.00032% in a nongreasy cream base q.s. Reports on the therapeutic utility of many of these plants in skin disorders are available in the traditional medical literature.[5]–[8]

The present study was a prospective, unicentric, open label, randomized, controlled study conducted at the dermatology OPD of SSKM Hospital, Kolkata with prior approval from the Institutional Ethics Committee.[9]

The objectives were to assess the efficacy and safety of Itch cream as an emollient and topical antipruritic for symptomatic relief in various xerotic and pruritic dermatological disorders like atopic dermatitis, senile pruritus, and ichthyosis. Inclusion criteria: (a) children (2–12 years) of either sex with atopic dermatitis, ichthyosis vulgaris, and impetigo. (b) Adults (>12–70 years) of both sex with senile pruritus, ichthyosis vulgaris, or other xerotic diseases.

Only cases with involvement of ≤30% body surface area were recruited. Exclusion criteria: (a) severe cases with ≥30% body surface area involvement; (b) cases concomitantly receiving/received the following medications: topical or systemic corticosteroids within the last 1 month, systemic antiallergic medication in the last 7 days, and any topical emollient preparation in the last 14 days; (c) participation in other clinical trials within the past 1 month; (d) known hypersensitivity to study medications/excipients in the formulations; (e) pregnant women; (f) cases suffering from systemic diseases where pruritus is a presenting symptom like obstructive jaundice, diabetes, hypothyroidism, or chronic renal failure were excluded.

After screening, eligible subjects were randomized using random number table into: Group A (Test drug i.e. Itch cream) or Group B (Comparator drug i.e. *Moisturex* cream (Croslands) containing the following constituents (w/w basis) – Urea i.p. 10%, Lactic acid i.p. 10%, Propylene glycol i.p. 10%, Light liquid paraffin i.p. 10%, Cream base q.s.).

Both the formulations were dispensed by the physician in identical containers containing 15 g to the respective groups. The manufacturing date and batch number of the entire consignment of each formulation were identical. Subjects were advised to apply either test/comparator cream topically twice daily as a thin film over the affected area only and not to vigorously rub or massage. In case of severe burning pain/redness/swelling appearing within a few hours of application, they were advised to discontinue and report at the earliest.

Systemic antihistaminic drugs like prochlorperazine, hydroxyzine, cetrizine, levo-cetrizine, fexofenadine, desloratidine, or any other systemic/topical medication for therapy of the underlying skin disease were not allowed. Topical application of any corticosteroid in the form of cream, ointment, gel, lotion, or any emollient like paraffin containing preparation were not allowed.

However, topical/systemic antibiotics were allowed in impetigo cases. Rescue medication was advised either as systemic antihistaminic or topical emollient etc. as applicable if symptoms were not adequately controlled.

Study parameters

The primary efficacy parameters were: (a) severity of pruritus assessed subjectively by a pruritus scale (0–3). Score 0 – no pruritus; 1 – mild but not causing any significant impairment of daily activities; 2 – moderate, causing impairment of daily activities; 3 – severe pruritus causing sleepless night. (b) A composite score (0–3) scale on the basis of clinical assessment of keratinization, excoriation, and fissuring. Score 0 – no such features; 1 – mild features present; 2 – moderate features present; 3 – severe features. (c) The secondary efficacy parameters were global assessment of improvement of symptoms and clinical well being by the subject

on the basis of whether there was dryness/roughening/scaling of skin and relief of other presenting complaints on a four-point scale (0–3). Score 0 – complete relief of symptoms and feeling of well being; 1 – significant improvement; 2 – mild improvement; 3 – No improvement/feeling of well being. All adverse events (serious and nonserious AE) reported spontaneously by the subject were noted by the investigator during each visit.

Time schedule of visits

The baseline scores were recorded after enrollment and subjects were instructed to attend three weekly follow-up visits. History, clinical examination, and the efficacy scores were recorded in the case record form. Drugs were dispensed as per the schedule and compliance ensured. The final end-of-study visit was 1 week after withdrawal of study medication to note any residual therapeutic or adverse effects.

The efficacy data were analysed on the basis of intention to treat. Nonparametric numeric data were compared by Wilcoxon matched pairs signed rank test with 2 – tailed $P<0.05$ as the cut-off level for statistical significance. Between-group comparison of means was done using the Mann–Whitney *U* test. Analysis of adverse events and rescue medication was done using Fisher's exact test. $P<0.05$ was considered significant. Results show that 64 subjects were recruited for the study adhering to the subject selection criteria. Cases with similar site affections were enrolled and then randomized to the two treatment groups. The sites affected were: senile pruritus and ichthyosis – extremities and/or trunk; atopic dermatitis – flexures and the extensor aspect of the limbs. Facial involvement was not present in any of the trial subjects recruited. Only 25/36 (69.4%) recruited subjects in group A completed the study, and 21/28 (75%) in group B. Others were lost to follow-up. No subjects were withdrawn from the trial because of adverse events or protocol violation. The demographic pattern of cases: The mean age (SD) was 32.1(27.9) yr for Group A and 30.76(29.9) yr for Group B. Female patients constituted 48 and 42.8% in groups A and B, respectively.

Analysis of the efficacy parameters is depicted in Table 1. A statistically significant reduction in the mean pruritus and patient's global assessment of well being scores ($P<0.005$) was noted in patients of atopic dermatitis, ichthyosis vulgaris, senile pruritus, and xerotic skin disorders when compared with the baseline mean scores. Similarly, a statistically significant reduction in the composite scores ($P<0.05$) was detected when compared with baseline values. Rescue medication in the form of systemic antihistamine was required only in two out of twenty five cases in group A and in two cases in group B. Between-group comparison of the efficacy parameters and rescue medication requirement showed no statistically significant difference.

Adverse events like mild local skin irritation and burning sensation at the site of application were reported in only three out of twenty five cases in group A but no serious adverse events were encountered. In Group B, contact dermatitis was reported in two out of twenty one cases. No statistically significant difference was noted.

Table 1

Antipruritic and emollient effects of topical application of Itch cream *Vs* Moisturex

Score	*Treatment group*	*Baseline score*	*Final score*
Pruritus score	Group A	2.32 ± 0.69	1.40± 0.91**
	Group B	2.52 ± 0.51	1.48± 1.03**
Composite score	Group A	2.24 ± 0.59	1.72± 0.84*
	Group B	2.24 ± 0.70	1.43± 0.87**
Patient's global assessment of well being score	Group A	2.36 ± 0.48	1.44± 0.96**
	Group B	2.29 ± 0.56	1.23± 0.99**

Values are mean±SD. Group A – Itch cream group, *n* = 25 in each group; Group B – Moisturex (comparator) group, n = 21 in each group. **P≤0.005, *P≤0.05 significance in comparison with baseline scores using Wilcoxon signed rank test.

The results suggest that Itch cream has antipruritic and emollient effects in patients of atopic dermatitis, ichthyosis vulgaris, and other xerotic diseases of mild severity. Its efficacy as an emollient was comparable to the nonherbal comparator. The symptomatic benefits achieved could be attributed to the herbal ingredients of the product that have been quoted to possess efficacy in different dermatological conditions in traditional medicinal literature. However, there is no evidence to support that this formulation has any curative potential in the treatment of the above diseases and it can only be used as an add-on therapy to the existent treatment modalities.

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