



Research Article

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CLINICAL EVALUATION OF CUTFAR OINTMENT IN THE DERMATOLOGICAL DISORDERS

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ABSTRACT

An open label non-randomized Phase-III study was conducted to assess the safety and efficacy of Cutfar Ointment in patients of chilblain, cracked heels, rough skin, cuts and wounds. Three hundred fifty patients suffering from chilblain, cracked heels, rough skin, cuts and wounds, scaling, pruritus, wrinkles, were included in the study. Patients with history of peripheral vascular disease, known dermatological disease, use of any topical steroids or moisturizers on the feet in previous 2 weeks were excluded in the study. All the patients were instructed to wash the affected part with lukewarm water and gently apply Cutfar ointment twice a day, massaging properly until it gets fully absorbed. All the patients were checked after 03 and 06 days treatment. A significant recovery was observed after the treatment. The study concluded that, Cutfar an Ayurvedic medicine, is an effective treatment for various skin problems such as chilblain, cracked heels, rough skin, cuts and wounds, scaling, pruritus, wrinkles, pigmentation, and laxity of skin. Cutfar soothes and softens the skin, has tissue repair property and enhances healing. Cutfar also possess keratolytic and emollient action.

Key Words: Keratolytic, Emollient, Skin softening, Antiseptic, Antibacterial.

INTRODUCTION

Cutfar ointment is an Ayurvedic formula containing *Vipadikahar Malam RSSPS 25.00% w/w* and *Jatyadi oil AFI 1.00% v/w*. It has been developed to treat various dry skin abnormalities.

Composition:

Sanskrit/Hindi Name	Scientific or Botanical Name	Part of plant used	Properties	Quantity Per dosage unit	Reference
<i>Jatyadi Oil</i>	Classical preparation	Taila	<i>Varna Ropak, Dagdha Varana</i>	1 % v/w	AFI- Ayurvedic Formulary of India, P1, E2, P – 135
<i>Vipadikahar Malam</i>	Classical preparation	Malham	<i>Vipadika, Charma Kushtha, Kittibha</i>	25 % w/w	RSSPS-Rasatantra Sara Siddha Prayog Sangraha – 475

Ointment Base: Q.S. to 100 %

There are numerous skin diseases and they are amongst the frequently occurring health problem, affecting population of all ages. Some wild plants and their parts are frequently used to treat skin diseases. The use of plants is as old as the mankind, natural treatment is cheap and claimed to be safe¹.

Crack foot is considered as a cosmetic problem that occurs due to age, fashionable high heels and improper shoes, excessive walking, involvement in athletic activity, psoriasis, thyroid disease, diabetes, dust, skin allergies and house hold heat especially in kitchen²⁻³.

Burn can be defined as tissue damage caused by a variety of agents such as heat, chemicals, electricity, sunlight, or nuclear radiation. Managing burns is important because they are common, painful and can result in disfiguring and disabling scarring or amputation of affected parts. Most of the early treatment modalities include use of an appropriate dressing, particularly to reduce pain and to help prevent infection.

Wound healing is the process of repair that follows injury to the skin and other soft tissues. It involves a complex series of interactions between different cell types, cytokine mediators, and the extracellular matrix⁴⁻⁵.

Pruritus is intermittent or prolonged over hours and days, and becomes worse at night. Emollients have been shown to be beneficial in patients with Chronic Kidney disease associated pruritus. Recent advances in pathophysiology of itch and treatment for Chronic Kidney disease associated pruritus have improved this condition remarkably⁶.

Ayurvedic herbs have shown to prove effective in treating skin diseases. They are devoid of side effects and equally effective in comparison to their modern counterparts. The use of bioactive ingredients in cosmetics influence biological functions of skin and provides nutrients necessary for the healthy skin⁷.

Aging is universal process that probably began with the origin of life. Accumulation of the diverse deleterious changes

produced by aging throughout the cells and tissues progressively impairs function and can eventually cause death. The most common amongst visible signs of skin aging are wrinkles. Wrinkles are formed and promoted by both internal and external factors. As we age our skin becomes looser, it is called laxity. Essential fatty acids (EFAs) are building blocks of cellular membranes which allow efficient transportation of nutrients from the extracellular space into the intracellular environment where metabolism takes place⁸.

Cosmeceuticals are topical cosmetic-pharmaceutical hybrids that enhance the beauty through constituents that provide additional health-related benefit. Cosmeceuticals are commonly used for hyperpigmentation. These agents selectively target hyperplastic melanocytes and inhibit key regulatory steps in melanin synthesis⁹.

Hyper pigmentation is characterized by darkening of areas of skin caused by overproduction of pigment in the skin known as melanin. Ayurvedic medicines used to treat skin disease are safe and gives complete relief¹⁰⁻¹¹.

The skin care kit for rough skin, tanning, sunburn, polymorphic light reaction, CAD, insect bite reactions, chilblain, and frostbite are cold cream, body lotion, coconut or olive oil, sunscreen¹².

Scaling skin is the loss of the outer layer of the epidermis in large, scale-like flakes. The skin appears dry and cracked, though skin dryness isn't always to blame. Scaling skin can be embarrassing, particularly if it occurs on the hands, feet, face, or other visible areas¹³⁻¹⁷.

Charaka Samhita contains a number of modified pharmaceutical preparations such as *Asava, Arista, Churna, Avleha, Vatika, Varti, Taila, Ghrita, Lepa, Mantha, Arka* etc. Microorganisms are ubiquitous in nature and are vital components in the cycle of Life. Those agents which are used to kill or inhibit the growth of microorganism are called Antimicrobial agents (AMA). These can be synthetic or natural.

In traditional Indian medicinal treatise Jatyadi Taila (JT) is medicated oil having good wound healing property and

popularly used in the treatment of various topical wounds and cuts¹⁸⁻²³.

Vipadikahar malam RSSPS contains boric acid, Salicylic acid and Lanoline as described in the Rastantra Sara Siddha Prayog - II - 485.

Boric acid is a weak, topical, bacteriostatic, and fungistatic agent; however, the exact mechanism of action is unclear. Boric acid is not readily absorbed through intact skin. It is however, absorbed rapidly in damaged skin and especially granulation tissue; the absorption is rapid when the substance is administered as the pure powder or in aqueous media such as solutions or gels but is poor from hydrophobic preparation or from talcum powder²⁴⁻²⁸.

Salicylic acid is a keratolytic agent that dissolves the intracellular matrix and softens the stratum corneum, thereby enhancing the shedding of scales. Skin desquamation is the result of loss of cohesion between coenocyte's. Moreover it penetrates in the inflammatory lesions where it has astringent, antibacterial and anti-inflammatory activities. Salicylic acid tends to loosen and lift the scales of psoriasis on the body or the scalp. Salicylic acid can be used as a long-term treatment²⁹⁻³⁴.

Medical-grade lanoline has occlusive properties. Lanoline penetrates through the stratum corneum down to the stratum granulosum. Once there, it apparently spontaneously emulsifies skin moisture and holds it in the form of an emulsion, rather like a sponge soaking up water. This moisture can then be released to the dry outer layers of the skin when required, thus reducing the skin's tendency to crack³⁵⁻³⁶.

MATERIALS AND METHODS

Three hundred fifty patients were enrolled in the study, ages ranged from 18 to 60 years.

Inclusion criteria: The patients with chilblain, cracked heels, rough skin, cuts and wounds, scaling, pruritus, wrinkles, pigmentation, and laxity of skin were included in the study. Each type of above disease were enrolled in 30 numbers each.

Table 1: Classification of Patient according to the observed symptoms for the treatment with Cutfar Ointment (Demographic)

Indications	Patient demographic classification		
	Male patients	Female Patients	Total No. of patients
Chilblain	15 (50%)	15 (50%)	30
Cracked heels	05 (6.25%)	75 (93.75%)	80
Cuts and wounds	15 (50%)	15 (50%)	30
Pruritus	13 (43.33%)	17 (56.67%)	30
Pain	10 (33.33%)	20 (66.67%)	30
Wrinkles	10 (33.33%)	20 (66.67%)	30
Pigmentation	17 (56.67%)	13 (43.33%)	30
Rough skin	14 (50%)	16 (50%)	30
Laxity of skin	12 (40%)	18 (60%)	30
Scaling skin	11 (36.67%)	19 (63.34%)	30

Exclusion criteria: Patients with history of peripheral vascular disease, pre-existing immunosuppressive disease, known dermatologic diseases such as psoriasis, eczema, ichthyosis vulgaris, use of any topical steroids or moisturizers on the feet in previous 2 weeks, known hypersensitivity to topical preparations, presence of erysipelas and vasculitis. Patients who had participated in a clinical study with a moisturizing product within the previous 4 weeks or who had a history of poor compliance with medical treatment also were excluded.

Preclinical examination: The history was noted by interviewing the parent/guardian. Thorough clinical examination and symptomatic evaluation was carried out and was noted down in the Case Report Form (CRF). The written and informed consent was obtained from all the patients.

Present study was carried out in accordance with ethical principles by following International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP).

All the patients were instructed to wash the affected part with lukewarm water and gently apply Cutfar ointment twice a day, massaging properly until it gets fully absorbed.

The patients suffering from cracked heel were instructed to soak their feet in lukewarm water for half an hour and rub the feet with brush prior to the application of ointment.

RESULTS

Table 2: Showing % recovery in skin problems after treatment with Cutfar ointment periodically

Indications	No. of patients	% Recovery		
		Initial Day visit	Visit 1 (Day 03)	Visit 2 (Day 06)
Chilblain	30	Nil	60%	80%
Cracked heels	80	Nil	62%	91%
Cuts and wounds	30	Nil	70%	90%
Pruritus	30	Nil	28%	58%
Pain	30	Nil	35%	55%
Wrinkles	30	Nil	27%	57%
Pigmentation	30	Nil	30%	60%
Rough skin	30	Nil	58%	70%
Laxity of skin	30	Nil	34%	62%
Scaling skin	30	Nil	40%	65%

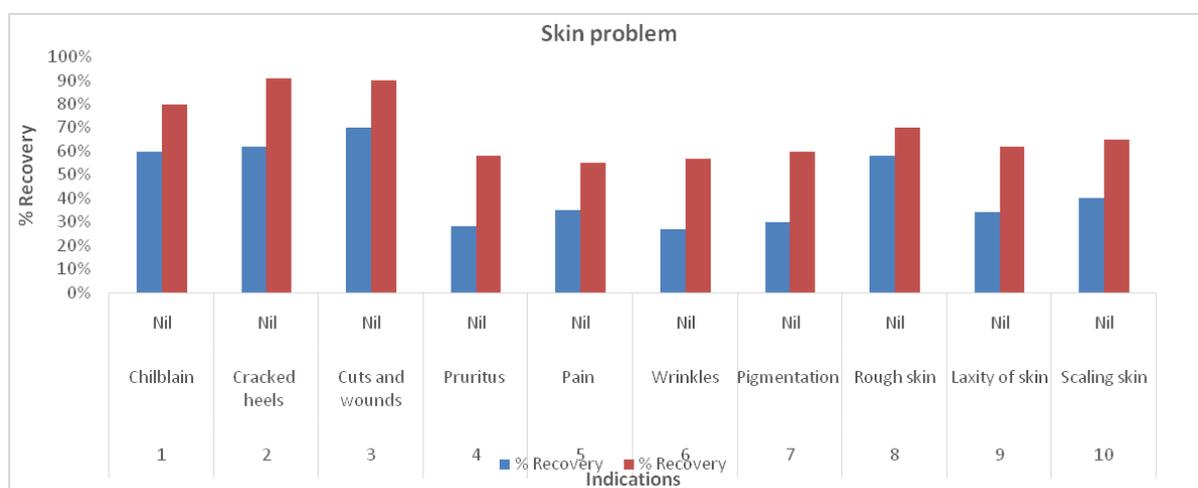


Figure 1: Graph representing % recovery after the treatment with Cutfar ointment

DISCUSSION

All the patients were checked after 3rd and 6th day of the treatment. A significant recovery was observed after the treatment with Cutfar ointment. Cutfar ointment contains Vipadikahar Malam *RSSPS* and Jatyadi oil *AFI*. Vipadikahar malam *RSSPS* contains Boric acid, Salicylic acid & Lanoline. These ingredients possess topical, bacteriostatic, fungistatic, keratolytic, occlusive properties. According to Indian medicinal treaties Jatyadi Taila (*JT*) *AFI* is a medicated oil having good wound healing property and popularly used in the treatment of various topical wounds and cuts.

CONCLUSION

Cutfar is an Ayurvedic medicine effective for the treatment of various skin problems such as chilblain, cracked heels, rough skin, cuts and wounds, scaling, pruritus, wrinkles, pigmentation, and laxity of skin. Cutfar soothes and softens the skin, have tissue repair property and enhance healing. Cutfar also possess keratolytic and emollient action. Cutfar contains *Vipadikahar Malam RSSPS* and *Jatyadi oil AFI* it has following properties: *Vipadikahar malam*: Keratolytic, skin softening activity, *Jatyadi oil*: Antiseptic, antibacterial.

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