DOI: 10.12923/cipms-2025-0013 Curr. Issues Pharm. Med. Sci., Vol. 38, No. 2, Pages 85-89

Current Issues in Pharmacy and Medical Sciences
Formerly ANNALES UNIVERSITATIS MARIAE CURIE-SKLODOWSKA, SECTIO DDD, PHARMACIA

journal homepage: https://czasopisma.umlub.pl/curipms

Topical use of *Cannabis sativa* L. – based emulsion for management of atopic dermatitis persisting from infancy in a 23 year-old male – a case study

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ARTICLE INFO

Received 27 December 2023
Accepted 20 May 2024

Keywords:
atopic dermatitis,
xerosis,
hemp oil.

ABSTRACT

In today's industrialized and quickly developing world, the prevalence of atopic dermatitis in children and adults alike continues to grow. Epidemiological studies conducted over the past 35 years indicate a 2-fold rise in incidence, linked to environmental factors, among others, growing atmospheric pollution, rising socioeconomic status and increasing popularity of the so called western lifestyle. Emollient therapy is the mainstay of proper skincare and treatment for atopic dermatitis (AD) patients.

Our experimental (interventional) study was conducted from June to October. The subject of the study was transdermal delivery of an emulsion compounded with cholesterol ointment, *Cannabis sativa* L. (hemp) seed oil, white petroleum jelly, purified water and urea to the skin of hands of a 23-year old male patient suffering atopic dermatitis (eczema) since infancy. The emulsion was applied to the skin once daily before sleep and covered with cotton gloves for the night for the occlusion effect for a period of 3 months.

In our observational study, regular, 3-month application of the emulsion based on *Cannabis sativa* L. oil considerably reduced inflammation, erythema, pruritus, xerosis and scaling of the skin, soothing excoriations and lichenification.

INTRODUCTION

Atopic dermatitis (AD), a skin condition formerly referred to as allergic dermatitis, eczema, Besnier's prurigo, neurodermatitis or dairy allergy rash, is a chronic, relapsing, non-infectious form of dermatitis involving the cuticle and the dermis [1-3].

Atopic dermatitis, along with allergic rhinitis, bronchial asthma and allergic conjunctivitis, falls into the atopic conditions group, induced by a combination of internal (genetically predisposed), and external or environmental factors (including inhaled, ingested and contact allergens), which either cause or exacerbate the symptoms. The condition is characterized by alternating flare and remission periods and severe itching (pruritus), leading patients to scratch uncontrollably, especially during sleep [4-13].

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Symptoms in AD vary according to patients' age. In infancy and early childhood, lesions are especially severe on protuberant body areas such as the forehead, chin and cheeks. In later life, concave areas ten to be involved, such as the cubital and popliteal fossa, skin folds, palms and back of the hands, neck and chest. The most common clinical manifestations of AD include erythema, excoriations, erosions and lichenization [14,15].

AD is becoming a globally pressing problem, as apart from its genetic, immunological, microbiological and environmental aspects, its mental health implications are a considerable burden for many patients. They may range from social isolation to suicidal thoughts, depressive disorders, anxiety (frequently linked to school and work absence) and sleep deprivation due to severe nighttime itching, resulting in a poor quality of life and overall wellbeing [13-18].

Over the past 35 years, a 2- or even 3-fold increase in the incidence of AD has been noted in industrialized countries. Populational studies carried out in the United States have shown AD to affect 10.7% of the total paediatric and 7.2% of the entire adult population. According to a 2014 cohort study of patients with mild-to-moderate AD, at any age, including up to 26 years of age, 80% of all participants with ≥5 years of follow-up continued to have symptoms or continued using medications (systemic and topical) for their AD [2,3,10,19].

According to literature, comorbidities are common in AD patients and primarily include allergic rhinitis (34% of all AD patients), bronchial asthma (20-35%) and food allergies (15%). Moreover, 60-70% of all AD patients have positive family history [3,20].

AD is also an economic burden on the patients, as proper AD skincare tends to be costly. A 2018 report by the European Federation of Allergy and Airways (EFA) estimated the average annual cost of private medical care, prescription medications and specialist skincare products at 927 euros. According to a study by the Polish Association of Atopic Conditions, carried out in a group of 1068 patients, daily skincare products, such as emollients and anti-prurient therapeutics, account for the largest portion of the costs (48%) incurred in relation to the suffered condition. Medical, including diagnostic, appointments account for 20% of the expenses, whilst specialist devices aiding skin treatment and dedicated dietary products make up 32% of the entire cost. With regard to the EFA report, only 5% of all AD patients do not incur additional expenses related to their condition [20].

For proper hydration of the corneal layer, daily skincare of atopic skin relies on occlusive agents (e.g., found in petroleum jelly, paraffin and waxes, such as lanoline and Carnauba wax), humectants (hyaluronic acid, urea, glycerol, amino acids) and synthetic and plant-based products such as evening primrose oil, hemp oil and starflower oil [21,22].

A growing number of studies found in the Journal Citation Reports (JCR) database are devoted to the properties of hemp oil, derived from the seeds of *Cannabis sativa* L. Its chemical composition depends on the actual strain/variety and the farming conditions, such as temperature, humidity and UV exposure. Hemp oil has a characteristic nutty flavour derived from terpenes (primarily myrcene) and a greenish hue owed to its chlorophyll content. It has a high percentage of essential unsaturated fatty acids, between 75-80%, including polyunsaturated omega 6 acids (linoleic acid 54%, gamma-linolenic acid, arachidic acid), polyunsaturated omega 3 acids (alfa-linolenic acid 17%), as well as monounsaturated omega 9 acids (oleic acid 19%). Gamma-linolenic acid (GLA) plays an important role, as it is a physiological component of phospholipids forming cell membranes, affecting the transport of nutrients. GLA is also incorporated into ceramides. GLA deficiency typically leads to xerosis, skin roughness, loss of elasticity and skin aging, Among the most common skin conditions resulting from GLA deficiency are atopic dermatitis, acne, seborrheic dermatitis and dandruff [23-25].

The vitamins found in hemp oil primarily include fat-soluble vitamins A, D, E and K. Additionally, hemp oil contains constituents of plant cells such as phytosterols, phospholipids and chlorophyll, all of which exhibit photoprotective properties [23-25].

Thus, the main objective of our study was to show correlation between the application of an emulsion formulated with cholesterol ointment, hemp seed oil, urea, purified water and white petroleum jelly to the hand skin of a 23-year-old male AD patient and the severity of his skin lesions, reduction of itching and improvement of his quality of life.

Case Report

The experimental (interventional) study ran from June to October. It was approved by the Bioethics Committee (decision of 18.05.2021, ID No. PCN/0022/KB1/40/2). The study was conducted using financial resources allocated for the maintenance and development of research potential from the portion designated for educational and research grants for the year 2022 – under the agreement to carry out a research task of a Young Scientist at the Silesian Medical University in Katowice (project number PCN-2-023/N/2/F). The study covered a 23-year old male suffering from AD since infancy. The patient was deemed eligible for the study based on a physical examination and interview, along with an assessment of the skin conducted by a dermatologist. The patient met the following inclusion criteria: he was over 18 years old, consented to participate, was aware of the risk related to the study, and signed an informed consent form.

Aim of the consultation

The 23-year old male presented for a dermatologist consultation due to xerosis and aggravated erythema, multiple papules, some oozing lesions and excoriations and moderate lichenification involving the cubital fossa, the palms and the back of the hands. He reported his dermal manifestations to occur in autumn-to-winter and summer seasons and to undergo cyclical exacerbation followed by remission. The patient is a university full-time student completing his Master's programme and leads a sedentary lifestyle, with his symptoms exacerbating during the exam season under stress. Additionally, allergens such as dust mites, citrus fruit and cow milk induce severe itching. The patient is allergic to ketoprofen. In the period of 6 months preceding the study, the patient did not undergo any surgeries or receive any hormonal or oncological therapies. His family history is negative for oncological conditions and no indication for cancer suspicion was identified. He has no implants or implanted electronic devices such as a heart pacer, hearing aid or defibrillator. He receives systemic medication, as well as topical glucocorticoids (mGks). The patient has never been treated with calcineurin inhibitors, nor has he received biological therapies, phototherapy, or sodium hypochlorite baths (dilute bleach baths). He reports uncontrollable scratching during sleep, leading to the formation of weeping and crusting lesions.

The patient has been managed pharmacologically for many years, depending on his current severity of symptoms, receiving oral antihistamine therapy and applying topical corticosteroids. For some time, he used customized Eucerin-based ointments compounded to order, containing hydrocortisone in different strengths, ranging from 0.5% to 2%, and 3% boric

acid solution. He also used emollients for daily skincare three times a day. He does not smoke, drink alcohol, take drugs or psychoactive substances. His medical history is negative for personality disorders or any mental health disorders that could affect doctor-patient collaboration or the reliability of the findings of a medical experimental study. The patient relies on over-the-counter medications, as well as specialist dietary products. His history is negative for chronic and systemic conditions, generalised malaise, fever, shivers, difficulty breathing, sore muscles or joints, excessive sweating. He has never undergone a skin biopsy. He is followed-up by a dermatology outpatients clinic. The patient takes hot baths which he finds effective for short-term relief of his itching.

The severity of the patient's AD was evaluated in a physical examination, using SCORAD validating system (Scoring Atopic Dermatitis), with a total score of 44.1.

Prior to beginning the study, 48-, 72- and 96-hour patch tests were performed, applying hemp seed oil to the patient's skin to rule out an allergy (result: negative). The patient was therefore deemed eligible for an experimental (interventional) one-patient study involving application of a *Cannabis sativa* L. oil-based formulation to the skin over a period of 3 months. He applied the emulsion once daily, before sleep, and put on cotton cosmetic gloves for the night.

The exact content of the formulation is listed in Table 1 below. It was compounded in accordance with the guidelines set out in the Polish Pharmacopoeia 12 (Farmakopeia Polska, FP XII) in the Compounded Preparations monograph. A compliance audit showed no irregularities [26-28]. The compounded medication is presented in Figure 1 below.

Table 1. Composition and preparation method of a compounded medication.

Composition of a compounded medication		
	Compound	Weight (g)
Formulation content and weight in grams (g)	*Oleum Cannabis sativa* L.	5.0
	Ung. cholesteroli	25.0
	Vaselinum album	70.0
	Aqua destilata/aqua purificata	10.0
	Urea	10.0
Oil phase – phase A	*Oleum Cannabis sativa* L.	
	Ung. cholesteroli	
	Vaselinum album	
Aqueous phase – phase B	*Aqua destilata/aqua purificata*	
	Urea	
The method of preparing the compounded medication	1. After preparing the appropriate pharmacy utensils, the preparation of the prescription medicine began. For this purpose, 10.0 g of distilled water (*Aqua pro usu officinale*) and 25.0 g of hemp oil (*Oleum Cannabis sativa* L.) were weighed into tared beakers. Then, 5.0 grams of urea (urea) were weighed on a tared parchment disc and 10.0 grams of *Vaselinum album* and 70.0 grams of cholesterol ointment (*Ung. cholesteroli*) were weighed on cards 2. 5.0 grams of urea were added to the beaker with distilled water and afterwards stirred until completely dissolved. The solution was filtered and weighed 3. The lipophilic phase (*i.e. Vaselinum album* and *Ung. cholesteroli*, previously homogenised) was introduced into the mortar, subsequently hemp oil (*Oleum Cannabis sativa* L.) was introduced into the phase and the whole mixture was gently mixed with a pestle until a uniform consistency was obtained 4. **After homogenization of the lipid phase, the previ**ously prepared urea solution was gradually added to the mortar. The mixture was mixed gradually with a pistol so as not to break the emulsion 5. The finished emulsion was transferred to a pharmacy box and marked with an orange signature	

Figure 1. In-house study: Hemp seed oil-based emulsion (*Cannabis sativa* L. var. indica)

DISCUSSION

Hemp is a lipophilic bioactive component. When delivered topically in skincare products, active substances do not reach the bloodstream and therefore the brain, excluding a psychoactive effect [29].

These days, it is possible to use high quality hemp seed oil for the formulation of creams, emulsions, gels, micellar water and pharmaceutical ointments. The concentration in different types of cosmetic products varies, *e.g.* hemp oil content in skincare creams is 5-7%, in body balms up to 30%, in hair products 0.1-1%, in bath products 0.1-1%, in massage oils 3-25%, whilst in some specialist skincare products it may be as high as 25% [25].

Due to its low freezing temperature (-10°C), owed to its high gamma-unsaturated fatty acids content, hemp seed oil is used in cold weather creams, fatty creams, nourishing creams and specialist skincare creams for athletes, hikers and skiers [25].

According to the available literature of the subject, topical delivery of hemp seed oil is safe and effective. Many studies report that hemp seed oil-based therapies significantly improve the quality of life of patients suffering from conditions such as atopic dermatitis, psoriasis and acne [23,30,33].

As per a study by Stemmann, oral delivery of 2-3 tablespoons of hemp seed oil combined with direct application to skin lesions in paediatric AD patients led to elimination or reduction of pruritic lesions. A similar study by Simonsohn found a deficiency in gamma-linolenic acid in the blood of AD patients as the potential cause of their condition [30].

Grinspoon and Bakalar report a case of a 60-year old patient suffering from AD since the age of 19, for whom vaporised hemp proved the only effective therapy preventing formation of skin lesions and itching. Our study had a similar outcome [31].

A Polish study carried out in a group of patients with uraemic pruritus demonstrated relief achieved with topical application of hemp seed oil-based creams [32]. Another study conducted by the Dermatology Department of the University of Wrocław in 2005 also showed the use of hemp seed oil-based cream to significantly reduce uraemic pruritus and xerosis. According to the data from this study, itching decreased in 38% of all the patients, whilst xerosis resolved completely in 81% of the entire studied group. Initial research points to reduced hornification of the skin in haemodialysis patients using hemp seed oil-based topicals, yet additional studies are necessary to explore, explain and document the usefulness of cannabinoids for the management of various forms of dermatitis [33]. In a study by

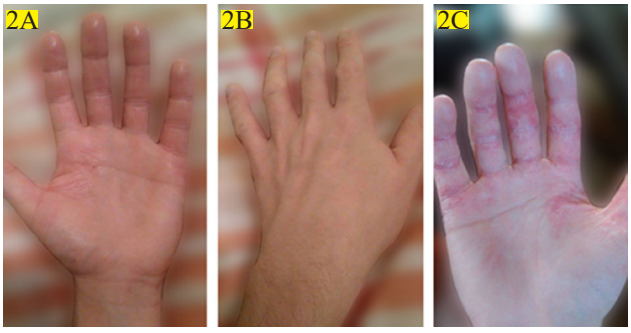
Palmeri et al. involving a group of 5 AD patients, topical delivery of an ointment containing cannabidiol (CBD) significantly improved the biophysical parameters of the skin [34,35].

In AD, xerosis occurs due to altered activity of delta-6-desaturase, an enzyme participating in the metabolism of polyunsaturated fatty acids affecting the composition of the cellular membranes of keratinocytes and the intercellular lipid matrix, or "cement", of the corneal layer. The deficiency leads to an increased permeability of the skin, manifesting in excessive loss of water [23].

Hemp contains exogenous amino acids, i.e. tryptophan, histidine, isoleucine, leucine, lysine, methionine, cystine, phenylalanine, tyrosine, threonine and valine, all contributing to homeostasis processes. Histidine mediates tolerance of allergens, leucine promotes growth of muscle and bone tissues and promotes healthy skin microbiota. Lysine, in turn, has antiviral effects, primarily against outbreaks of herpes simplex virus (HSV), as well as aids wound healing. Sulphur-containing amino acids methionine and cysteine are building blocks of the integument and prevent premature skin aging. Cystine found in hemp has anti-inflammatory properties. Threonine is essential for the production of collagen and elastin, which are key to skin elasticity and its regenerative ability [23,30].

RESULT

Despite the numerous reports pointing to the potential of hemp seed oil in cosmetology and dermatology, its effectiveness is far from explored. The case studies found in the JCR database are not fully comprehensive sources of information, omitting to identify the exact parameters of the used formulations, such as their concentration. In our experimental study, topical delivery of emulsion compounded with *Oleum Cannabis sativa* L. 25.0, Urea 5.0, *Aqua destilata* 10.0, *Vaselinum album* 10.0, *Ung. Cholesteroli* 70.0, led to significant reduction of irritation, erythema, xerosis, pruritus and scaliness, and soothed lesions such as excoriations formed due to itching and lichenization. (Figure 2). It may be concluded, therefore, to have been effective in decreasing inflammation of the skin (Figure 2).



(Figure 2A and Figure 2B show the skin on the palm and the back of the hand respectively following treatment. Figure 2C shows the palm of the hand prior to treatment)

Figure 2. The outcome of 3 months of therapy with the emulsion

As an additional benefit, no hypersensitivity of the skin to UV radiation was observed in the summer months as the result of the therapy, yet this needs further validation in a larger group of patients. The fatty acids present in hemp seed oil manifest nourishing, anti-allergic, regenerative, anti-aging and immuno-stimulating properties. Hemp oil is easily absorbed, without leaving a fatty film on the skin [23,29,30]. The outcome achieved in our experimental study corresponds to the findings of other studies, confirming the effectiveness of hemp-derived products delivered transdermally for the management of atopic dermatitis.

CONCLUSIONS

Our case study is in line with other available literature reports regarding the potential of hemp seed oil for the management and skincare of AD patients. In our 23-year old male patient, remission of dermal lesions on the palms and the dorsal parts of both hands was achieved within 3 months, with the patient also reporting improved mental wellbeing and social interactions. Further studies exploring the use of hemp seed oil-based emulsion for the management of AD symptoms are required, including double-blind trials.

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