Efficacy and safety of virgin coconut oil and king coconut oil compared to liquid paraffin as a moisturizer for mild atopic dermatitis: A pilot study

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Abstract

Atopic dermatitis is a chronic skin condition due to altered skin barrier. There is no cure for the condition, but it can often be managed with proper care and treatment. Application of a moisturizer is a mainstay of treatment to manage the condition. Therefore, this study assessed the effectiveness and safety of virgin coconut oil (VCO) and king coconut oil (KCO) compared to liquid paraffin as a moisturizer for mild atopic dermatitis. The study was conducted as a pilot study of a randomized, double-blind, parallel group comparison trial on patients with mild atopic dermatitis. Patients were randomized to receive VCO, KCO or liquid paraffin. The outcome measures were SCORing atopic dermatitis (SCORAD) index and Patient Oriented Eczema Measure (POEM) score and instrumental measurements of skin moisture and skin lipid levels at two weeks intervals for 3 times. The results showed a significant improvement of eczema was seen in relation to SCORAD index and POEM scores in all three arms. Significant improvement of moisture levels was seen in KCO and liquid paraffin arms. However, no improvement of lipid levels was seen in all three arms. It was concluded that, this pilot study shows that VCO, KCO and liquid paraffin are equally effective moisturizers for the treatment of mild atopic dermatitis. VCO and KCO can be used instead of hydrocarbon-based liquid paraffin in the treatment of mild atopic dermatitis as those vegetable oils are relatively inexpensive and widely available in Sri Lanka.

Keywords: atopic dermatitis, virgin coconut oil, king coconut oil, liquid paraffin

Introduction

Atopic dermatitis (AD) is a chronic pruritic skin disease that occurs due to defects in the epidermal barrier function and cutaneous inflammation[1]. The lesions have ill-defined erythema, with oedema, and vesicles which are predominantly seen in skin flexures. In the chronic stage of AD, the skin becomes lichenified[2]. AD can occur at any age, but the prevalence is high in children[3].

There are several aetiological factors in AD. They include genetic factors, allergens like house dust mites, foods, *Staphylococcus aureus* infections and exposure to excessive heat and irritants[3]. Due to the defects in epidermal barrier function, AD patients are more prone to allergic sensitization, microbial colonization and infections[4.5]. When the epidermal barrier function is defective trans-epidermal water loss (TEWL) will be increased and water retention capacity will be reduced leading to dry skin. There are low levels of skin lipids and ceramides in patients with AD[6].

The diagnosis of AD is essentially clinical. The Hanifin and Rajika diagnostic criteria for AD are widely used to confirm the diagnosis of AD for research purposes[2].

Moisturizers should be considered as the mainstay of AD management[7].

With the use of moisturizers, dry skin, itching and the penetration of skin by irritants and allergens are reduced leading to a significant improvement in appearance and the symptoms of dry skin[2.8]. Moisturizers have ingredients to achieve hydration and improve skin barrier properties such as occlusives, humectants and emollients[9]. Humectants

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are water-attracting substances with a low molecular weight[10]. Occlusive prevent trans-epidermal water loss (TEWL) by forming a hydrophobic barrier over the skin. Emollients fill the gaps and fissures and help to improve the skin texture[11].

The inflammatory component of AD is usually managed with the use of corticosteroids[8] Antihistamines are often used for symptomatic relief.

The use of moisturizers has been shown to enhance the response to treatment with topical corticosteroids in AD[12].

Topical calcineurin inhibitors such as tacrolimus and pimecrolimus also can be used as other treatment options.

In selected patients, antibiotics, systemic immuno-modulators and ultra-violet light are used[2].

Skin is composed of two main layers known as epidermis and dermis. The epidermis prevents water loss from the skin and acts as a protective barrier for various allergens. The stratum corneum is the protective outer layer that is responsible for preventing TEWL.

The most significant risk factor for AD is mutation in the human filaggrin gene (FLG) which codes for skin barrier protein filaggrin[13]. Filaggrin is a major structural histidine-rich protein localized in the stratum corneum of the skin. Filaggrin aggregates filaments catalyzing the formation of disulfide bonds between keratin fibers. These aggregated fibers maintain the flattened shape characteristic of corneocytes. Once the keratin fibers are formed, filaggrin is degraded.

The natural moisturizing factor (NMF) components in the corneocytes are the breakdown products from the proteolysis of filaggrin. NMF components act as humectants and keep the corneocytes hydrated by attracting and binding to atmospheric water[14]. The degradation process of filaggrin depends on the water content within the corneocytes. If the water content is low the hydrolytic enzymes will not be able to degrade filaggrin and therefore the levels of NMF are reduced[15].

Decreased levels of filaggrin lead to increased TEWL and the reduction in stratum corneum hydration[16]. The softness and flexibility of the stratum corneum are maintained by water and when there is reduced water, the stratum corneum becomes hard and brittle[17].

Lipids that are found in the stratum corneum help to maintain the water barrier of the skin as well as help to retain NMF within the corneocytes. Lipid levels in the stratum corneum vary with factors such as genetic variation, age, diet and environmental factors. Therefore, reduced lipid levels in the stratum corneum may predispose to dry skin[14].

Various natural and synthetic agents are used as moisturizers to improve the skin barrier function.

Virgin coconut oil (VCO) is a safe, non-toxic, natural moisturizing agent used in the traditional systems of medicine. VCO is extracted from the fresh and mature kernel of the coconut[18]. VCO is colourless and has the aroma of fresh coconut. It can be used for cooking and cosmetic purposes.

VCO has many clinically useful phytochemicals and physicochemical properties[19].

VCO consists of triglycerides >99% and it is rich in medium-chain fatty acids. The chemical composition of VCO is shown in Table 1.

Table 1: The chemical composition of VCO

Fatty acid	Lipid number	Composition %
Caproic acid	C6:0	0.2
Caprylic acid	C8:0	7.8
Capric acid	C10:0	6.5
Lauric acid	C12:0	50.6
Myristic acid	C14:0	19.5
Palmitic acid	C16:0	6.5
Stearic acid	C18:0	1.9
Oleic acid	C18:1	4.5
Linoleic acid	C18:2	2.5

In addition to triglycerides, VCO contains phenolic acids and polyphenols that have antioxidative, anti-inflammatory, antibacterial, and wound-healing properties[20].

VCO, by forming an occlusive film on the skin, significantly reduces TEWL and improves skin hydration[1]. The anti-inflammatory effect is provided by the medium-chain fatty acids (produced as a

result of the degradation of triglycerides by the lipases of skin flora), phenolic acids and polyphenols of VCO[1].

The antibacterial effects of VCO are mainly due to monoglycerides. *Staphylococcus aureus* in infected lesions of AD produces lipases that hydrolyse triglycerides in VCO to monoglycerides. Monoglycerides and medium-chain fatty acids in VCO prevent bacterial growth[20].

A study on the in-vitro anti-inflammatory and skin protective properties of VCO has found that topical application of VCO increases the filaggrin level in corneocytes and improves the barrier function (21). This finding supports the use of VCO to treat AD, in which defective barrier function is a major contributory factor[21].

Another study has shown a 68.23% reduction in the SCORAD index and an improvement of post-treatment mean TEWL of 7.09 from a baseline mean of 26.6[1].

KCO is extracted from the fresh, mature kernel of the king coconut. It is colourless and has the aroma of fresh king coconut.

KCO has a high iodine value which indicates the presence of high amounts of unsaturated fatty acids in KCO. When the iodine value is high, the drying property of a particular oil will also be high. A drying oil hardens to form a tough solid film on exposure to air through a chemical reaction with oxygen in the air but not through the evaporation of water. Therefore, the drying property of oil is an advantage in producing cosmetic products because it improves the occlusive function of the epidermis. Comparatively higher levels of free fatty acids are found in KCO[22].

Liquid paraffin is a standard base in most of the moisturizers. It can also be used alone as a moisturizer. Liquid paraffin is a colourless, almost odourless, oily liquid composed of complex saturated hydrocarbons obtained from petroleum[23].

The appearance, colour and odour of VCO, KCO and liquid paraffin are so similar that they cannot be distinguished from each other. Therefore, we used the liquid paraffin as a comparator in our study.

Materials and methods

Study design

The pilot study was conducted as a part of a randomized, double-blind, parallel-group, comparison trial assessing the efficacy and safety of VCO and KCO compared with liquid paraffin as a moisturizer for mild AD. Ethical approval was taken from the Institutional Ethics Review Committee of Faculty of Medicine, University of Peradeniya (2020/EC/62) and the Clinical Trial registration number is SLCTR/2021/006. Written informed consent was obtained from all subjects and the study was conducted in accordance with the Declaration of Helsinki.

Preparation of coconut and king coconut oils

Preparation of VCO and KCO done at Coconut Research Institute Sri Lanka as follows,

Seasoned Coconut/ King Coconut
Dehusking
Deshelling
Paring
Splitting
Washing with potable water
Disintegrating
Drying (at less than 650C)
Feeding into cold pressing oil expeller (Cold Pressing Oil Expeller is an expeller that operates ~ 600C)
Extraction of virgin coconut oil/ virgin king coconut oil (~ 600C)
Raw virgin coconut oil/ Raw virgin king coconut oil
Sedimentation
Filtration or centrifugation
Storage
Bottling and sealing
Labelling
Storage of VCO and KCO

Liquid paraffin was purchased from the State pharmaceutical corporation Sri Lanka.

Participants

The study population was the patients with mild AD (SCORAD index of 0-24) aged more than two years. The following categories of patients were excluded from the study: patients with presence of AD only on the face, patients with significant mental and physical disabilities, pregnant or lactating women, patients who had used topical or oral steroids during past two weeks, patients who had used topical calcineurin inhibitors during past two weeks, patients who had used systemic immunosuppressive therapies (methotrexate, cyclosporine, azathioprine, mycophenolate mofetil) during past two weeks, patients with currently infected lesions that require antibiotics, patients with other dermatological conditions in addition to AD (e.g. Psoriasis) patients with known hypersensitivity to VCO, KCO or liquid paraffin, patients with any concomitant medication that could aggravate AD (retinoids, diuretics, lipid-lowering agents, calcium antagonists, beta blockers) patients with known comorbidities that could aggravate AD (heart failure, chronic kidney disease, diabetes mellitus, chronic liver diseases, hyperparathyroidism, hypo or hyperthyroidism, iron deficiency).

The patients were recruited from the outpatient dermatology clinic "Skin Center", Sirimavo Bandaranayake Mawatha, Kandy, Sri Lanka. The study was conducted at the Department of Pharmacology, Faculty of Medicine, University of Peradeniya as a single-center study.

Sample size

The study was conducted as a pilot study (phase III clinical trial) with three study arms with a total sample size of 35 (Table 2).

Table 2: Three study arms with a total sample size of 35

Study arm (moisturizer treatment for AD)	Sample size
VCO	11
KCO	12
Liquid paraffin	12

Randomization

Patients were assigned to the three treatment arms equally using a block randomization method.

Allocation concealment and blinding

VCO, KCO and liquid paraffin which are similar in colour, odour and consistency were packaged in identical bottles by the pharmacist and labelled as "A", "B" or "C". Only the pharmacist knew what type of oil was filled in each bottle labelled as "A", "B" or "C and the allocation sequence was kept secret in a sealed envelope until the end of the study. The co-investigator who did the randomization informed the pharmacist to dispense the relevant bottles of oil to the patient. The pharmacist recorded the letter assigned to each subject.

Intervention

Study interventions were the use of VCO and KCO as a moisturizer. A comparison intervention was the use of liquid paraffin as a moisturizer.

The trial was conducted for a total period of four weeks including a recruitment visit and two follow-up visits. Screening was done by the principal investigator (PI) using the Hanifin and Rajka criteria for diagnosis of AD and eligibility of the subjects was assessed and informed written consent was taken from eligible subjects.

Outcome measures

At the recruitment visit baseline severity of the disease was assessed clinically by using SCORAD index and POEM score and baseline instrumental measurements of skin moisture level and skin lipid level. SCORAD index ranges from 0 to 103 and POEM index ranges from 0 to 28. The lowest means the lower severity of the disease in both scores. At each follow-up visit done at 2 and 4 weeks, the severity of the disease was assessed as in baseline. Occurrence of adverse events and compliance were also assessed at each follow-up visit.

Statistical methods

A series of linear mixed-effects models were fitted to assess the outcome variables, including differences in SCORAD scores, POEM scores, lipid levels, and moisture levels between visits. The treatment arm was modelled as a random effect in these models, and they were compared to corresponding intercept-only fixed effect base models using ANOVA.

To compare SCORAD scores, POEM scores, lipid levels, and moisture levels across visits within each treatment arm, Wilcoxon signed-rank tests were conducted. A p-value less than 0.05 was considered statistically significant.

Results

Sixty-one patients were recruited and thirty-five patients between age three and 66y with mild atopic dermatitis completed the study. Eighteen (51%) of them were females whereas 17 (49%) were males. Patients were divided into three groups (X=12, Y=12, Z=11) and were given KCO, liquid paraffin and VCO respectively and were followed up for a total of three clinic visits. Baseline data are shown in Table 3.

Table 3: Baseline data of outcome measures

Arm	SCORAD (median of the first visit)(IQR)	POEM (median) (IQR)	Moisture level (median) (IQR)	Lipid level (median) (IQR)
X(KCO)	18.83 (23.02)	9.5 (7.75)	33(1.5)	2(1)
Y (liquid paraffin)	19.97 (10.83)	10.5 (7.5)	33(4.5)	2(2)
Z(VCO)	23.8 (19.5)	12 (8)	33(1.5)	2(0.5)

The comparison of the improvement of the SCORAD index, POEM score, moisture level and lipid level between the first and third visits using the Wilcoxon test which is a paired nonparametric test.

A significant improvement was shown in the SCORAD index of all three arms ($p < 0.01$). POEM score also showed a significant improvement in the disease in X (p=0.03), Y (p=0.01) and Z (p=0.01) arms. Significant elevation of moisture level was shown in the X (p=0.03) and Y (p=0.005) arms. No statistical significance was shown in the lipid level in all three arms (Table 4).

Table 4: The summary of the data at the end of the third visit

Arm	SCORAD	POEM	Moisture level	Lipid level
X(KCO)	P<0.01	P=0.03	P=0.03	Not significant
Y(liquid paraffin)	P<0.01	P=0.01	P=0.005	Not significant
Z(VCO)	P<0.01	P=0.01	Not significant	Not significant

The linear mixed-effects models, with treatment arms treated as random effects, did not demonstrate a significant improvement over the base models.

There was no statistically significant difference across different treatment arms in our previous analysis when compared with generalized linear models.

Regarding adverse events, one patient had itching when applying the liquid paraffin and another one had a burning sensation and erythema when applying KCO, however none has stopped the treatment due to adverse effects of the treatments.

Discussion

We were unable to achieve the intended sample size as most patients were reluctant to be treated only with a local application. There was about a 50% dropout rate. If the topical application could be combined with an oral tablet (placebo), the patients would have been more compliant with the trial. Therefore, we are planning to conduct a larger trial with oral placebo to achieve our main objective, which was to evaluate the efficacy and safety of VCO and KCO compared to liquid paraffin as a moisturizer for mild atopic dermatitis.

This is the first study of this nature comparing vegetable oils with hydrocarbon-based oils in Sri Lanka.

Another drawback of the study is not including the patients with facial eczema to the study. Most of the

patients with mild eczema have facial lesions. As we have not come across any adverse effects related to those three oils, next time perhaps we can include patients with facial eczema as well.

This study will be further extended on a larger scale to assess the ability of VCO and KCO to treat atopic dermatitis.

Conclusion

This pilot study shows that VCO, KCO and liquid paraffin are equally effective for the treatment of atopic dermatitis. As VCO and KCO are relatively inexpensive and widely available in Sri Lankan setup, this pilot study shows that they can be used instead of liquid paraffin in the treatment of mild atopic dermatitis in Sri Lanka.

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