A Randomized Double-Blind Controlled Trial Comparing Extra Virgin Coconut Oil with Mineral Oil as a Moisturizer for Mild to Moderate Xerosis

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ABSTRACT (Email Abstract) Background

Xerosis is a common skin condition (1) characterized by dry, rough, scaly, and itchy skin, (2) associated with a defect in skin barrier function, and (3) treated with moisturizers. People in the tropics have effectively used coconut oil as a traditional moisturizer for centuries. Recently, the oil also has been shown to have skin antiseptic effects. A moisturizer with antiseptic effects has value, but there are no clinical studies to document the efficacy and safety of coconut oil as a skin moisturizer.

Objective

This study aimed to determine the effectivity and safety of virgin coconut oil compared with mineral oil as a therapeutic moisturizer for mild to moderate xerosis.

Methods

A randomized double-blind controlled clinical trial was conducted on mild to moderate xerosis in 34 patients with negative patch-test reactions to the test products. These patients were randomized to apply either coconut oil or mineral oil on the legs twice a day for 2 weeks. Quantitative outcome parameters for effectivity were measured at baseline and on each visit with a Corneometer CM825 to measure skin hydration and a Sebumeter SM 810 to measure skin lipids. For safety, transepidermal water loss (TEWL) was measured with a Tewameter TM210, and skin surface hydrogen ion concentration (pH) was measured with a Skin pH meter PH900. Patients and the investigator separately evaluated, at baseline and at each weekly visit, skin symptoms of dryness, scaling, roughness, and pruritus by using a visual analogue scale and grading of xerosis.

Results

Coconut oil and mineral oil have comparable effects. Both oils showed effectivity through significant improvement in skin hydration and increase in skin surface lipid levels. Safety was demonstrated through no significant difference in TEWL and skin pH. Subjective grading of xerosis by the investigators and visual analogue scales used by the patients showed a general trend toward better (though not statistically evident) improvement with coconut oil than with mineral oil. Safety for both was further demonstrated by negative patch-test results prior to the study and by the absence of adverse reactions during the study.

Conclusion

Coconut oil is as effective and safe as mineral oil when used as a moisturizer.

Complementary and alternative medicines (CAMs) are now being subjected to efficacy and safety studies by well-respected academic centers using vigorous scientific methods.1 In the tropics, the coconut (*Cocos nucifera L.*) has a long history of medicinal use. For centuries, people have used the oil to soften, moisturize, protect, and heal dry skin and hair among adults and even among children.2

Coconut oil is extracted by various methods. The more common commercial coconut oil is from copra, which is coconut meat that is dried, often outdoors, and then shipped to processing plants. The obvious risk of mycotoxin contamination is high.3 Producers of virgin coconut oil (VCO) avoid this contamination by processing the coconut meat shortly after harvest. In the traditional wet process, the coconut milk is squeezed from the meat and is then subjected to low heat. Three distinct layers form. The clear, colorless, and somewhat dense but lighter VCO separates and rises above the water, which settles to the bottom of the heating vessel, and also separates from the solid residue, which rises above the oil., 3 The research group of Espino and colleagues at the National Institute of Molecular Biology and Biotechnology (BIOTECH) of the University of the Philippines in Los Baños adapted a technology for enzyme-catalyzed extraction of coconut oil from freshly grated coconut meat.4 Natural enzymes (pectinase, neutral protease, and amylase) and

commercial cellulose act on the fibrous component of the meat and release the oil (fig1). The residues of the enzymes, which are all water soluble, separate from the oil into the aqueous effluent., 5,6 We named this heat-free extracted oil "extra virgin coconut oil" (EVCO).

Figure 1
Schematic diagram of procedure for extraction of oil from freshly grated coconut meat.

Analyses done at the Industrial Technology Development Institute (ITDI) and Department of Science & Technology (DOST) showed the absence of the enzymes in EVCO and the comparable physicochemical properties of VCO and EVCO (Table 1).

Table 1
Comparison of Physicochemical Properties of Three Types of Coconut Oil

Previous studies showed that lauric acid (the major fatty acid of coconut oil) and (especially) its monoglyceride monolaurin (Lauricidin, Med-Chem Laboratories, Inc., Galena, IL) have antiseptic properties.7–11 In two skin studies, Lauricidin eradicated *Serratia marcescens* applied to volunteers' hands12 and also eradicated bacteria cultured from the hands of health personnel going off duty., 13 Another preliminary study showed that this monoglyceride and the coconut oil itself show antiviral activity against human immunodeficiency virus (HIV)., 14

Verallo-Rowell, the senior author, recognized the value of an oil that has a long tradition of safe use and that is now shown to apparently have broad-spectrum antiseptic action. At her general dermatology and psoriasis day care clinic, VCO and EVCO have been prescribed for patients with moderate to severe xerosis from chronic psoriasis, atopic contact dermatitis, and miscellaneous other causes since 2000.

Of clinical significance is that there were no reports of pruritus, erythema, frank contact dermatitis, or worsening of skin dryness, and EVCO prescriptions were frequently refilled. A review of the charts of 40 of these patients indicated improved appearance, less skin roughness or dryness, and high patient acceptance. (This was submitted to the ethics committee by the authors, as part of the justification for the study.)

Searches in the MEDLINE and Health Research and Development Information Network (HERDIN) databases revealed no formal clinical studies on the use of coconut oil as a therapeutic moisturizer. The purpose of this study was to assess, by objective and quantifiable ways, whether VCO can be used as an alternative to mineral oil, a commonly used commercial moisturizer. VCO is available at organic oil food sections and from CAM suppliers.

We asked the following study question: among patients with mild to moderate xerosis and aged 16 to 70 years, how does VCO, as a moisturizer, compare with mineral oil on quantitative measures for treatment effectivity and safety and on qualitative severity scores for xerosis, response rates, and side effects? The null hypothesis was that there is no difference in regard to skin hydration, skin sebum levels, transepidermal water loss, hydrogen ion concentration (pH), and severity scores for xerosis, response rates, and side effects when VCO is used and when mineral oil is used. The alternative hypothesis was that there is a difference in regard to skin hydration, skin sebum levels, transepidermal water loss, pH, and severity scores for xerosis, response rates, and side effects when VCO is used and when mineral oil is used.

The general objective of the study was to determine the effectivity and safety of EVCO as compared to mineral oil when used as a therapeutic moisturizer for mild to moderate xerosis. The specific objectives for effectivity were the biophysical profiles of skin hydration and skin sebum levels and, for safety, transepidermal water loss and pH. Qualitative clinical response rates were graded with severity scores for xerosis and a visual analogue scale (VAS). The study also observed any irritancy, allergy, general acceptability, or other side effects on the skin when the oils were applied to xerotic skin.

In terms of study design, this study was a randomized double-blind controlled clinical trial comparing mineral oil and EVCO.

The hospital's Institutional Review Board approved the study. Written informed consent was obtained from each patient, and all data were kept confidential. Patients understood that the investigator would treat any adverse reactions without cost and that they could withdraw from the study at any time. Patients were also informed that all nonresponders would be shifted to an effective standard moisturizer at no cost after the study.

Materials and Methods Subjects

A total of 34 subjects were enrolled in the study. Demographic data, medical histories, and baseline photographic documentation were obtained prior to treatment. Included were adult patients aged 16 to 70 years and seen at the dermatology outpatient department who suffered from dry skin conditions (senile xerosis, atopic dermatitis, contact dermatitis, or xerosis from change in weather conditions), had mild to moderate xerosis on the legs according to the grading by Wehr and colleagues15 (Table 2), had negative skin patch-test results for both mineral oil and coconut oil, and who had given written informed consent. All patients were instructed to discontinue applications of moisturizers for at least a week prior to the start of the trial.

Table 2
Criteria for Grading of Xerosis*

Patients were excluded if they had (1) a mental or physical handicap affecting compliance, (2) concomitant skin infections, (3) eczematous skin reactions, or (4) other acute skin diseases.

Patch testing for irritant and allergic contact dermatitis from mineral oil and coconut oil was conducted among 34 patients. Patients were instructed to not take steroids for at least 2 weeks prior to patch testing. With 8 mm aluminum Finn Chambers (Epitest Ltd Oy, Tuusula, Finland), 0.025 mL of the test materials were applied under occlusive patches to skin sites on the scapular back. After 48 hours, the patches were removed and initial readings were made. Patients returned the following day for the reading at 72 hours.

The International Contact Dermatitis Research Group grading system was used for irritant or allergic reactions, as follows: 0 for no reaction, plain erythema; + for erythema and edema; ++ for erythema and vesicles; +++ for erythema, edema, and bullae.

Method

EVCO and mineral oil were packaged in identical dark bottles numbered 1 to 34, according to a computer-generated random allocation sequence. The hospital pharmacy director kept the codes secret in a sealed envelope until the end of the study. A blinded pharmacist dispensed the bottles of oil and recorded the number assigned to each subject, and a blinded investigator saw patients at each follow-up.

The patients applied the oils twice a day on the legs for 2 weeks. They were asked not to apply any other topical agents during the duration of the study, to use only a prescribed mild cleansing soap provided by the investigator, and to bring the bottles to each follow-up visit so that the patients could be assessed for compliance. Patients were also instructed not to apply the oils on the follow-up days.

Assessment

Patients were seen on days 0 (baseline), 7, and 14 of treatment. Quantitative outcome parameters for effectivity, measured on each visit, were the level of skin hydration as measured with a capacitance meter (Corneometer CM825, GOJO Industries, Inc., Akron, OH) and the level of skin lipids as measured with a Sebumeter SM 810 (Courage + Khazaka, Cologne, Germany). For safety, transepidermal water loss (TEWL) was measured with an evaporimeter (Tewameter TM210, GOJO Industries), and skin surface pH was measured with a Skin pH Meter PH900 (Courage + Khazaka). The biophysical investigations were made on the left and right dorsal aspects of the legs (midtibial) and left and right backs of the calves (midcalf), and the mean of the measurements was obtained. All measurements were conducted under constant room conditions of temperature (20°C) and air humidity (40–60%) and a premeasurement rest period of 15 minutes.

At each visit, patients recorded their self-evaluation of skin symptoms (dryness, scaling, roughness, pruritus), using a VAS with a scale ranging from 0 (absent) to 10 (most severe). The investigator likewise evaluated the patients for xerosis at each visit, according to the grading of Wehr and colleagues[15] (see Table 2).

Standard photographs were taken for documentation during each visit, and patients were asked about erythema, stinging, itching, and other side effects after applications. During the last week of treatment, patients were asked to rate the ease of application, the absorbency, and the smell of the oils as acceptable or unacceptable.

Data Analysis Outcome Measures

Intention-to-treat analysis was done. Outcome measures used in this study included changes in the Corneometer CM825 and Sebumeter SM 810 measurements (for effectivity), Tewameter TM210 and Skin pH Meter PH900 measurements (for safety), qualitative clinical responses using the patients' VAS self-evaluations, and the investigator's grading of xerosis.

Statistical Analysis

To determine if there was a significantly different treatment outcome from the baseline to the end of the treatment period, a paired *t*-test was applied to the Corneometer CM825, Tewameter TM210, Sebumeter SM 810, and Skin pH Meter PH900 measurements.

To determine if there was a significant difference when comparing the mean change of biophysical measurement values between the coconut oil and mineral oil groups, an unpaired *t*-test was applied. A *t*-test for ranks was applied to determine any difference in mean change of the VAS and xerosis scores between the two treatment groups. The clinical response of subjects receiving the coconut oil was compared with that of those using the mineral oil, with a 95% confidence interval. Treatment success (responder) was defined as a reduction of 50% or greater in dryness, scaling, roughness, and pruritus from baseline as recorded by patients on the VAS. Treatment failure (nonresponder) was defined as no change or a worsening of VAS scores. An improvement of xerosis grading was considered a treatment success. No change or worsening of xerosis grading was considered a treatment failure.

Results

All 34 patients had negative patch-test results at 24 and 72 hours and were included in the study. All completed the study. Table 3 lists the baseline demographic characteristics of the study groups. All the patients were women ranging from 17 to 65 years of age (mean, 41 years).

Table 3
Baseline Demographic Characteristics of Study Groups

Table 4 refers to the baseline values of both treatment groups. The two groups were balanced at baseline. At the start of the treatment, 61% (11 of 18) of the mineral oil treatment group were graded as having moderate xerosis, and 39% (7 of 18) were graded with mild xerosis. In the coconut oil treatment group, 31% (5 of 16) were graded with mild xerosis, and 69% (11 of 16) were graded with moderate xerosis.

Table 4
Mean Values for Study Groups at Baseline

All patients were followed up on days 7 and 14. There was a general trend toward improvement for both study groups; Corneometer CM825 values increased for almost all patients (fig2). The paired *t*-test showed a significant increase in values for both the mineral oil ($p = .000$) and coconut oil ($p = .000$) treatment groups at the end of the treatment period. Sebumeter SM 810 values likewise showed a significant change for both groups ($p = .002$ and $p = .000$, respectively) (fig3).

Figure 2
Corneometer values for mineral oil and coconut oil groups.

Figure 3
Sebumeter values for mineral oil and coconut oil groups.

The paired *t*-test showed no significant changes in Tewameter TM210 values ($p = .74$ and $p = .75$, respectively) and Skin pH Meter PH900 values ($p = .53$ and $p = .20$, respectively) from baseline for both mineral oil and coconut oil groups. The unpaired *t*-test applied to the Corneometer CM825, Tewameter TM210, Sebumeter SM 810, and Skin pH Meter PH900 measurements and the *t*-test for rank applied to the VAS and grading of xerosis showed no significant differences when comparing mean change between both treatment groups (Table 5).

Table 5
Comparisons of Mean Change in Values between Mineral Oil and Coconut Oil Groups

Overall, by the end of the study, 72% (13 of 18) of the subjects in the mineral oil group and 81% (13 of 16) of the subjects in the coconut oil group showed an improvement of at least one level in xerosis grading. VAS response rates of the mineral oil and coconut oil groups, respectively, were 44% (8 of 18) and 56% (9 of 16) for dryness, 33% (6 of 18) and 50% (8 of 16) for scaling, 44% (8 of 18) and 62% (10 of 16) for roughness, 25% (4 of 16) and and 22% (4 of 18) for pruritus. There appears to be a trend for EVCO to be better than mineral oil, but the 95% confidence intervals for all differences in response rates did not exclude 0 (Table 6).

Table 6
Rates of Response to Treatment

All patients had negative skin patch-test reactions to both mineral oil and coconut oil, indicating no irritant and allergic contact dermatitis effects from the test oils. Likewise, no patient experienced any adverse effects for the duration of the trial although three patients in the coconut oil group claimed lightening of their skin tone as a side effect.
All patients found both oils acceptable with regard to ease of application, smell, and absorbency.

Discussion

Among the protective mechanisms of the skin is its function of protecting against water loss. If this barrier (a two-compartment system of corneocytes in a lipid-enriched matrix) is disrupted and not repaired, a dermatologic condition known as dry skin ensues.16 One outcome parameter of effectivity was epidermal hydration, tested through skin capacitance measurements made with a Corneometer CM825. This assessment is based on the principle that capacitance increases in parallel with skin water content. For both oils, there was a significant (and nearly equal) improvement of epidermal hydration at the end of the treatment period.
The generally accepted view that the water content of the stratum corneum is the major factor in determining the appearance of skin can be traced back to Blank17 and to Sato and colleagues., 18 It is now appreciated that the balance between water content and skin lipids forms the still-current “bricks and mortar” model of the stratum corneum as the barrier to the environment. Equimolar mixtures of ceramides, cholesterol, and nonessential free fatty acids (including those found in coconut oil) form extracellular membranes, riveted into parallel structures by linoleic acid-bearing o-hydroxy-esterified ceramides (acylceramides)., 19
Each of these key lipids, supplied together, are required for barrier homeostasis and recovery. Many moisturizers try to mimic the role of epidermal lipids in the skin barrier by producing an occlusive film that prevents water diffusion and loss. These emollients increase the hydration of the stratum corneum, making the skin soft and pliable. Mineral oil, a synthetic hydrocarbon, is an example of a moisturizer with occlusive and water-insoluble characteristics providing an inert and immediate protective hydrophobic barrier to the stratum corneum.
Coconut oil consists of triglycerides (made up of glycerol), combined with stable saturated medium-chain fatty acids (49% C12 lauric acid, 7% C10 capric acid, and 8% C8 caprylic acid). Coconut oil has the same occlusive and hydrophobic characteristics that mineral oil has. Unlike with mineral oil, fatty acids found in the coconut are found naturally in the skin, and the breakdown products, particularly of coconut's lauric acid, have been found to have antiseptic properties.
To test for skin surface lipids, a Sebumeter SM 810 was used. This test is based on a photometric method for lipid content measured as micrograms of lipids per square centimeter of skin. After treatment with both test oils, skin surface lipids were equally and significantly increased.
In regard to outcome parameters of safety, the PH900 meter gave skin pH readings that showed no significant change from baseline at the end of treatment with either oil. This signifies that the skin pH remained at optimum acidic levels, a beneficial state since in vitro studies have shown that the formation of the horny layer lipids requires an acidic pH level.20
The Tewameter TM210 measures TEWL. The pressure built up by diffusion of the body-specific water is measured as grams per hour meter squared. This measurement evaluates the efficiency of the skin's water barrier function. There was no significant change in TEWL with either oil. This may indicate that in the long term, the barrier function of the skin was not repaired by either of the oils; however, it may also indicate that both oils caused no contact irritant effects that would have resulted in significantly increased levels of water loss. This will be clarified by follow-up studies. The conclusion drawn from the objective instrumental determinations (made with the Corneometer CM825, Sebumeter SM 810, Skin pH Meter PH900, and Tewameter TM210) is that there was no significant difference, indicating that the two products had comparable effects.
Subjective measures used were Wehr's qualitative grading of xerosis by the investigator and a VAS for self-assessment by the subject.
Response rates based on the grading of xerosis were 81% for the coconut oil group and 72% for the mineral oil group. It appears that there was better response in the coconut oil group, but with the 95% confidence interval of -0.26 to 0.29, the two groups had the same response.
Response rates based on VAS scores (see Table 6) likewise appear to show a generally better response from the coconut oil group; but again, given that the 95% confidence intervals did not exclude 0, the null hypothesis that the two treatment groups were the same in this regard cannot be rejected.

Conclusion

Coconut oil is as effective as mineral oil when used as a moisturizer. Coconut oil is safe for use; it caused no reactions on patch testing, and no reported adverse effects were noted. Patients found the oil acceptable in terms of smell, ease of application, and skin absorbency. (Since 2000, studies on safety, efficacy, contact dermatitis and other adverse reactions,

microbial analysis, and effects on chronic skin diseases often aggravated by secondary infections have been under way with patients using coconut oil.)

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