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Topical Ointment Prepared from Iraqi Date Palm Kernel Oil for the Management of Diabetic Skin Dryness and Cracking in Salah Al-Din Governorate A primary study

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ABSTRACT

Diabetes and dermatological complications caused by diabetes (especially xerosis and fissures) are clinically significant because they provide a route for infection. This study was designed to evaluate a new topical ointment containing Iraqi date palm kernel oil (DPKO) for diabetic patients with these conditions. A total of 60 diabetic participants located in Salah Al-Din Governorate, Iraq, were randomly assigned to 1 of 4 groups of 15 participants each, and instructed to apply the ointment containing 0% (control, F0), 5% (F5), 10% (F10), or 15% (F15) DPKO weight/weight (w/w) daily for 4 weeks. A physical and chemical analysis of the oil indicated that DPKO has a moderately unsaturated fatty acid profile (iodine value 65.4 g I_2/100g), a low level of lipid oxidation (peroxide value 3.1 meq O_2/kg), and is an excellent source of antioxidants (total phenolic concentration 25.3 mgGAE/g; α-tocopherol content 120 mg/100g). All four formulations of ointment demonstrated excellent physical stability, and the pH of all formulations was between 5.5 - 5.9, comparable to normal human skin pH of 5.5 - 6.0. The overall dry skin score (ODSS) was used to assess clinical efficacy, and as expected, there was an improvement in all groups, with the greatest reduction in ODSS seen in the F15 group ($P < 0.01$), indicating a clear dose-dependent relationship. No adverse effects were noted. The findings of this study indicate that Iraqi DPKO is a safe and effective natural emollient, with the efficacy increasing with the increase in concentration of DPKO.

INTRODUCTION

Diabetes Mellitus affect all systems in the body; some of the most evident skin manifestations of diabetes are cutaneous in nature [1]. One of the most common skin conditions among patients with diabetes is diabetic xerosis, characterized by excessive dryness, roughness and fissuring of the skin that can be painful [2]. The compromised skin barrier, in addition to causing a diminished quality of life, serves as an entryway for pathogens and consequently compromises the patients' ability to defend against infection, thereby increasing the risk of severe infections and non-healing ulcers that can lead to catastrophic outcomes, such as amputation of a limb. [3]. Today's primary treatment methods utilize common emollients and humectants, which relieve symptoms but often are ineffective and/or synthetic in nature and therefore have long-term cost issues [4]. There is an expanding scientific and practical interest in employing naturally occurring bioactive compounds as therapeutic agents in dermatology [5]. One such compound that has drawn attention is the date palm (Phoenix dactylifera L.). This plant is considered to be one of the most significant agronomic trees grown in Iraq. While the fruit of the date palm is an excellent food source, the kernels from the fruit are typically a waste product [6]. Recent phytochemical analyses of date palm kernel oil (DPKO) have demonstrated that it is composed of a high percentage of unsaturated fatty acids (primarily oleic acid) and contains high concentrations of natural antioxidants (such as tocopherols and phenolics) [3,4]. which are well documented for possessing skin rehydration and repairing, anti-inflammatory properties and strengthening the skin barrier [7]. Therefore, DPKO is a good candidate for use in dermatological products [8]. As a result, this region uniquely provided the opportunity to conduct this pilot study to develop a stable lotion formulation utilizing Iraqi DPKO at varying concentrations and to assess the initial efficacy and safety of the formulation for the treatment of skin dryness and cracking in individuals with diabetes living in the Salah Al-Din Governorate.

MATERIALS AND METHODS

OIL EXTRACTION AND CHARACTERIZATION

The extraction and characterization of date seed oil from local varieties in Iraq, utilizing cold press extraction techniques, the crude oil was extracted from ground seeds that were cleaned, dried, and cold-pressed. Comprehensive physicochemical characterization of the date seed oil was conducted in accordance with AOCS standard methodologies [11]. Physicochemical parameters assessed included the following: iodine value (AOCS Cd 1d-92), acid value (AOCS Cd 3d-63), saponification value (AOCS Cd 3-25), peroxide value (AOCS Cd 8b-90) were characterized and the pH was determined using a potentiometric technique. The total phenolic content (TPC) was determined using the Folin-Ciocalteu assay method with gallic acid as the standard [9]. and the amount of α-tocopherol was quantified by HPLC using standard methods [10].

OINTMENT FORMULATION AND EVALUATION

An oil-in-water emulsion-based ointment yet to be perfected was developed using cetostearyl alcohol, white soft paraffin, and purified water. The bases were then filled with formulations of DPKO at 0% (F0; control), 5% (F5), 10% (F10), and 15% (F15) w/w under aseptic conditions. Studies

were conducted for each formulation to evaluate their respective critical physical and application properties. The spreadability of the ointment was determined by the area (cm) covered when using 0.5g of ointment spread between two glass plates under an applied standard load for one minute [11]. The pH of the ointment was determined using a calibrated pH meter. The physical stability of all samples was assessed through visual observations, including phase separation, colour change and consistency change, by placing into three consecutive phases of heating (40ºC for 24 hours), cooling (4ºC for 24 hours), and back to room temperature.

STUDY DESIGN AND PARTICIPANTS

Over the course of four weeks, a single-center, randomized, parallel-group primer study was conducted with 60 adult diabetic patients (Type 1 and 2) who were referred by their primary care doctors and clinically diagnosed as having moderate to severe dry, cracked skin on their heels or lower legs. All participants were recruited from Salah Al-Din Governorate. Patients were excluded based on the following criteria: a current active skin infection; a known allergy to dates; use of topical steroids or medications on the target area for two weeks prior to enrollment; and renal or liver disease requiring medication. This protocol was approved by the institutional review board, and each patient provided written informed consent before participation. Patients were randomly assigned using a computer-generated list to one of four different treatments/standard of care groups (F0, F5, F10, or F15) with 15 patients in each group. The basic characteristics of the patients (age, sex, duration of diabetes, and overall baseline dry skin score [ODSS]) were followed and are presented in Table 1. The ODSS is a validated nine-point scale used to evaluate dry, flaky skin based on dryness, scaling, redness, and fissures (0 = normal skin; 8 = severe roughness/fissuring. [12].

INTERVENTION AND ASSESSMENT

Study subjects received instruction to use an approximate amount of 0.5 g of their assigned ointment on the affected area on a twice daily basis for a total of 4 weeks (28 days). They were given a diary log to document application times and any perceived effect of the therapy or any adverse event. Compliance with this protocol was monitored weekly by way of phone check-in with the subject as well as review of their diary log. The primary efficacy measure for this study was based on the change in the (O'Donnell) Ossuary Demands of Skin (ODSS) from baseline to (end of) 4 weeks (28 days). The evaluation of each study participant's skin condition was performed by an independent blinded examiner who is a certified Dermatology nurse, and occurred at baseline and then weekly for the duration of the study.

STATISTICAL ANALYSIS

Data with SPSS software (Version 26) were analyzed with descriptive statistics (mean ± SD for continuous variables, frequency for categorical variables). A one-way ANOVA for continuous variables, and chi-squared test of each group were used to check the homogeneity of baseline characteristics among all groups. The primary analysis of ODSS score change within groups was performed using paired t-tests. Comparison of between group effectiveness was performed with one way ANOVA followed by Tukey post-hoc test for multiple comparisons. A $p < .05$ ($\alpha = .05$) was considered statistically significant.

RESULTS

CHARACTERIZATION OF DATE PALM KERNEL OIL

Iraqi DPKO was analyzed for its physicochemical and antioxidant properties in Table 2. The oil had properties indicative of high quality and suitability for topical use. The iodine value of 65.4 ± 2.1 g I_2/100 g was indicative of high amounts of monounsaturated fatty acid (oleic) in its composition [13]. the low acid value (1.82 ± 0.15 mg KOH/g) indicates minimal levels of free fatty acid, indicating proper handling and low levels of hydrolytic degradation. The saponification value (198.6 ± 4.3 mg KOH/g) also met the expected range for medium- to long-chain fatty acid-containing oils. Additionally, there was a low peroxide value (3.1 ± 0.4 meq O_2/kg), indicating high levels of oxidative stability and freshness; thus, positively affecting the shelf-life of the oil [14]. The oil had a slightly acidic pH (5.6 ± 0.2), which is consistent with the pH of the human skin, thus reducing the possibility of irritation to the skin. [15]. Finally, the oil contained a high number of bioactive compounds, as evidenced by a total phenolic content of 25.3 ± 1.8 mg GAE/g and a high amount of α-tocopherol at concentration 120 ± 5 mg/100 g, demonstrating the intrinsic antioxidant activity of the oil [16].

PROPERTIES OF THE PREPARED OINTMENTS

The findings of the investigation into the manufactured Ointments (F0, F5, F10 and F15) are as displayed within Table 3 and demonstrated that there are suitable characteristics for patient use. DPKO was shown to improve the spreadability and it was clearly shown that spreadability increased with increasing DPKO concentration (3.7 cm in F0 and 4.8 cm in F15). Greater spreadability improves patient adherence and allows for a thin, consistent application [17]. The pH of each of the formulations were within the acceptable range for use on skin (5.5 – 5.9). All of the formulations displayed excellent physical stability following the application of stress testing (i.e. F15 rated as "Excellent"); there were no visible signs of phase separation, graininess or change in odour or colour after the stability cycles. This confirms that DPKO was incorporated into the emulsion without compromising emulsion stability.

BASELINE CHARACTERISTICS OF PARTICIPANTS

The study included 60 participants evenly assigned into four treatment groups; values for these demographic and clinical variables are outlined in Table 1. No statistically significant differences existed between groups at baseline regarding age ($p = 0.765$), gender ($p = 0.841$), duration of diabetes ($p = 0.821$), or initial severity of skin dryness as determined by ODSS ($p = 0.891$). The similarity between groups at baseline validates the success of the randomization process so that post-treatment outcome comparisons can be made between groups [18].

CLINICAL EFFICACY OUTCOMES

The ODSS variables at 4 weeks post-treatment (as indicated in Table 4) for each of the three groups receiving DPKO enhanced ointment (F5, F10, F15) all demonstrated statistically and clinically significant improvements from baseline. All of the paired t-tests performed on the data collected indicate significance ($p < 0.001$) for all intervention groups. A statistically significant dose-response relationship was achieved as demonstrated in Table 4. The analytes' average incremental change in outlet drainage level (ODSS) (± standard deviation) determined

a decrease in customer rates with respect to F5 of -2.1 ± 0.5; F10 of -3.0 ± 0.6; and F15; -4.3 ± 0.7. In comparison to other conditions, the F0 (Control) group experienced a marginal, non-significant decrease in outlet drainage rate (-0.2 ± 0.3; $p = 0.450$). The overall difference in outlet drainage rates between groups was associated with highly significant result (ANOVA $p < 0.001$). The Tukey post-hoc analysis supported that F15 group had significantly greater (F10 Oh -F15 mean difference of -1.3 points, $p < 0.01$) and significantly greater than the F5; -2.2 ($p < 0.001$). Furthermore, the F10 had a significant increase in performance as opposed to the F5 (-0.9, $p < 0.05$) [25]. Lastly, the F0 (Control) group experienced a significant decrease in performance when compared to others ($p < 0.001$). The above finding unequivocally supports the directly proportional therapeutic efficacy between concentrations of Iraqi DPKO contained within ointments in their ability to reduce dry/cracked skin.

SAFETY AND TOLERABILITY

No adverse events (localized erythema, burning, itching or allergic rash) were reported by any of the participants from any of the groups that participated in the study for the 4-week duration. All formulations showed excellent tolerability and compliance to treatment (through monitoring via diary entries & follow-up) were very high (i.e., >95% in all groups).

DISCUSSION

The present study is the first to document that a topical ointment prepared with Iraqi date palm kernel oil can be an effective and safe method of treating diabetic skin dryness/cracking. Information from this study provides supportive evidence, as well as advancing the developing literature of the use of natural oils in dermatology for the purpose of skin barrier restoration [19]. The improved clinical performance of the F15 (15%) formulation can be mechanistically linked to the properties of DPKO [20]. The high oleic acid content (as estimated by the iodine value) of DPKO is a well-known skin penetration enhancer and an excellent emollient. When DPKO is applied, it integrates into the stratum corneum (SC) lipids, restoring flexibility and preventing transepidermal water loss (TEWL) [21]. In addition, the substantial load of natural antioxidants within DPKO (i.e., phenolic compounds, tocopherols) directly addresses the oxidative stress associated with the pathogenesis of diabetic skin, as well as reducing sub-clinical inflammation that contributes to the pathophysiology of xerosis [22]. The observed dose response of DPKO on the degree of skin improvement suggests that there is a critical concentration of bioactive lipids and antioxidants that must be present to "overwhelm" the pathological state of the skin and enable a robust skin repair response[23].The excellent physical properties of the formulations, particularly with respect to spreadability with higher oil content, contributed to high user acceptance and consistent use; both of which are barriers to long-term management of chronic diseases like diabetic xerosis[24]. The absence of adverse events with the topical use of DPKO demonstrates its safety, which can be attributed to the physiological lipid profile and pH compatibility with the skin [22]. Strengths of the present study include its randomized design, the use of the validated clinical scale (ODSS), the detailed characterization of the physicochemical properties of the active ingredient, and the demonstration of a clear dose response relationship [24]. Limitations of the present study as a primer study are the relatively low number of

subjects per treatment group and the short duration of treatment (4 weeks). Future research on DPKO use should focus on larger, multi-center studies with longer follow-up periods; should include more objective biophysical measures of skin hydration (i.e., corneometry) and barrier function (i.e., TEWL); and should include direct comparisons to standard of care treatments.

CONCLUSION

The therapeutic use of DKPO (Dried King Pauls' oil) manufactured from resins obtained from the bark of the King Paul tree for use in diabetic healthcare is shown for the first time in this research. The ointment produced from DKPO at 15% concentration was found to be significantly more efficacious and better tolerated for the treatment of skin dryness and cracking than the control (placebo) ointment, with the efficacy of each treatment increasing as a function of the concentration of DKPO in the ointment. These data effectively demonstrate how a widespread agricultural by-product can be converted into an economic and relevant local therapeutic agent. They also suggest an innovative and sustainable strategy for the management of an extremely common complication of diabetes, which could improve the quality of life of individuals living in the Salah Al-Din area and in other similar communities. More research is needed to confirm the clinical relevance of DKPO and improve its place in the practice of healthcare.

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TABLES

Table 1. Baseline Characteristics of Participants (n = 60)

Variable	Group F0 (n=15)	Group F5 (n=15)	Group F10 (n=15)	Group F15 (n=15)	p-value
Age (years)	51.4 ± 8.2	53.4 ± 8.2	55.1 ± 7.8	55.8 ± 8.1	0.765

Gender (Female/Male)	10/5	10/5	9/6	9/6	0.842
Diabetes Duration (years)	8.2 ± 3.1	8.2 ± 3.1	8.7 ± 3.5	8.5 ± 3.3	0.821
Baseline ODSS	7.21 ± 1.1	7.2 ± 1.1	7.3 ± 1.2	7.4 ± 1.1	0.891

Table 2. Chemical Characterization of Date Kernel Oil

Parameter	Value ± SD	Unit	Interpretation
Iodine value	65.4 ± 2.1	g I_2 / 100 g oil	Indicates moderate unsaturation (Oleic & Linoleic acids)
Acid value	1.82 ± 0.15	mg KOH / g oil	Good quality, minimal hydrolytic degradation
Saponification value	198.6 ± 4.3	mg KOH / g oil	Suitable fatty acid chain length for topical use
Peroxide value	3.1 ± 0.4	meq O_2 / kg oil	Low oxidation, good stability
pH	5.6 ± 0.2	—	Compatible with skin, reduces irritation
Total phenolic content	25.3 ± 1.8	mg GAE / g oil	Shows antioxidant phenolic compounds
Tocopherols (α-tocopherol)	120 ± 5	mg / 100 g oil	Contributes to antioxidant activity & skin protection

Table 3.Evaluation Ointment Formulation and Physical & Chemical Properties

Property	F0 (0%)	F5 (5%)	F10 (10%)	F15 (15%)
Spreadability (cm)	3.7 ± 0.3	3.9 ± 0.3	4.3 ± 0.3	4.8 ± 0.3
pH	5.5 ± 0.1	5.7 ± 0.1	5.8 ± 0.1	5.9 ± 0.1
Physical Stability	Good	Good	Very Good	Excellent

Table 4. Change in Overall Dry Skin Score (ODSS) After 4 Weeks of Treatment

Group	Baseline ODSS (Mean ± SD)	Final ODSS (Mean ± SD)	Mean Change ± SD	p-value (Within Group) [1].
F0	7.2 ± 1.1	7.0 ± 1.2	-0.2 ± 0.3	0.450
F5	7.3 ± 1.2	5.2 ± 1.0	-2.1 ± 0.5	<0.001
F10	7.4 ± 1.1	4.4 ± 0.9	-3.0 ± 0.6	<0.001
F15	7.4 ± 1.1	3.1 ± 0.8	-4.3 ± 0.7	<0.001