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Ultrasonographic Response to Polarized Light Therapy in the Treatment of Atopic Dermatitis

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Abstract:

Purpose: : To evaluate the efficacy of polarized light therapy in atopic dermatitis patients through measuring the changes in the skin thickness by ultrasonography.

Methods: Active controlled trail, randomized, single blind design. 40 male patients with chronic atopic dermatitis were randomly split into two groups. The A group (20 patients) received Bioptron light therapy; B group (20 patients) received topical corticosteroid cream with (hydrocortisone 2.5%) only. Ultrasonography was used to evaluate skin thickness and SCORAD index was used to clinically estimate the degree of atopic dermatitis (AD).

Results: Comparing between two groups post treatment, skin thickness showed statistically nonsignificant difference between groups. Regarding SCORAD index there was statistically significant improvement in both group with better improvement in Polarized light group with percentage of improvement 518.6 % versus 260.7 % percentage of improvement in topical corticosteroids group.

Conclusion: Polarized light therapy is a simple, safe and effective procedure in treatment of atopic dermatitis which could reduce the need of long-term use of topical corticosteroid and avoid its associated side effects.

Key words: Polarized Light Therapy, Atopic dermatitis, Ultrasonographic Response, Skin thickness measurement.

1.Introduction

Atopic dermatitis (AD) is type of skin disorder that is inflammatory, chronic, extremely pruritic, and also most popular skin disorder in children (1).

AD is caused by an overreactive response of immune system to many environmental factors as well as dry, skin irritation. Skin lesions can aggravate psycho-social problem and have a great effect on

performance of daily living of patients and their family members.

AD is distinguished by its perturbations, possible reversibility, and unexpected progression throughout the patient's life (2). Stress, scratching, and contact allergens, among other things can cause skin problems. The occurrence of AD is believed to initiate allergic disorders facilitated by sensitization of immunoglobulin E (IgE) to environmental infectious agents, such as allergic conjunctivitis /rhinoconjunctivitis and asthma, known as atopic march (3). Furthermore, there is strong proof that AD has been linked to systemic disease and would be classified as a systemic disorder (4).

AD has an environmental and genetic etiology; the limited knowledge of AD pathophysiology focuses on deficiency of skin barrier mechanism and impairment of immune system. The interaction of these mechanisms results in the following signs and symptoms of AD: dry skin, pruritus, excoriations, edema, and oozing. The symptoms of AD can change based on the person 's age, extent of disease, and duration (5).

The first line of AD management is moisturizing skin cream which can help reduce loss of water and hydration of stratum corneum in inflamed areas, Emollients provide lipids and water, which aid in the reduction of inflammation. and occlusive agents minimize water evaporation, and new research suggests that they can boost production of antimicrobial peptide (6).

Treatment options for mild cases of the disease also provide topical calcineurin inhibitors and topical glucocorticosteroids (7). When used chronically, topical glucocorticosteroids can have serious side effects and, in rare cases, cause contact allergy (8).

The hazard of adverse reactions from corticosteroids is determined by several variables, such as the steroid's potency, the use of occlusion, the amount of steroid selected, and the skin's integrity. The highest penetration develops when steroids are applied to the face and groin; the least penetration occurs when steroids are applied to the soles and palms (9).

UVA (wavelength is 320-400 nm) and UVB (wavelength is 280-320 nm) have received the most attention in the dermatological field. Several photochemical and phototherapeutic methods utilizing UVA and UVB have been successfully used in the management of many inflammatory disorders such as atopic dermatitis and psoriasis (10).

Bioptron polarized light (Bioptron, AG, and Switzerland) is created using a special multilayered mirror, and it has the following properties: Polarization: All emitted waves oscillate (move/spread linearly across a plane). Incoherence occurs when each light wave oscillates at its own amplitude and wavelength. Waves are not coordinated in space or time, which means that waves, and so their own intensities, were either modified or added (11).

Polychromacy: The polarized light wavelength range extends from 480 to 3.400 nm, that is, it is entirely visible light (400780 nm) and with trace of infrared radiation (780-1,500 IRA and 1,500-3,400 IR B). Ultraviolet is classified as chemical active radiation, the specific energy density of bioptron polarized light is 40 mW: cm. The light is moved to target area and applied at a fixed intensity and with minimum energy consumption. However, it remains unchanged at 2.4 joule cm2 for every minute (11).

Polarized light had a significant effect on cell membrane activities, increasing mitochondrial adenosine triphosphate creation. Furthermore, it reduced inflammation by increasing vascularization, collagen production, fibroblast proliferation, tissue oxygenation and new tissue formation. This method was promising for accelerating wound healing because it improved these functions (12).

The need of this study arises from lake of study examined the polarized light therapy on dermal thickness. So, this study was designed to examine the effectiveness of polarized light therapy on SCORAD index including erythema, oedema/papulation, excoriations, lichenification, oozing/crusts, dryness, and size of lesion areas with special infancies on the ultrasonographic skin thickness.

2.Patients and Methods

2.1.Study participants and recruitment criteria:

Between July 2021 and October 31, 2021, the practical project was finished. Over this period, forty male subjects with atopic dermatitis who are complaining from atopic dermatitis disease for the past 3 years were recruited from the dermatology out-clinic department at Sheikh Zayed Hospital. In this

study, subject were included if they suffered from itching, inflammation, and skin thickness in the arm, wrist, hand or leg and their ages varied from 20 to 30 years. Subjects were excluded from the study if they have skin cancer in the skin's surface, patients with a history of diabetes, vascular or sensory disorders, and patients with an active infection of treated area.

The diagnosis, inclusion and exclusion criteria were assessed by dermatologist staff using physical and clinical assessment techniques using ultrasonography for skin thickness measurement and the SCORAD index.

2.2. Study Design:

The research was designed as active controlled trail, randomized, single blind, superiority, parallel clinical study with 1:1 allocation ratio with 40 patients suffering from chronic atopic dermatitis. Each participant provided written informed consent. ClinicalTrials.gov Protocol Registration and Results System (PRS) ID: NCT04955951 was assigned to this project. Also, this study follow declaration of Helsinki recommendations in dealing with human subject studies .

2.3. Methods:

Patients are randomly selected and mainly categorized into two equal-sized groups via one-on-one correspondence with dermatologists: Polarized light therapy was administered to Group A (20 patients), while topical corticosteroid therapy was administered to Group B (20 patients) using block randomization method, with blocks of 2X4. Sealed randomization blocks envelopes were opened by a research assistant not involved in the treatments to allocate subject to treatment sessions schedules according to treatment group.

A statistician who's not related to data collection or analysis prepared the randomization blocks. The selected volunteers were not notified which group they were given to, study or control. Before initial assessment, each subject was given a detailed explanation of the treatment protocol, and they all agreed to sign a written informed consent paper, indicating their clear agreement to participate in the study and have the results published.

Study group (Polarized light therapy) received three sessions per week, phototherapeutic Bioptron light therapy (Bioptron AG, Wollerau, Switzerland) for four weeks with 5 cm treatment diameter (BIOPTRON MedAll®, 480-3400 nm, 95 percent of polarization level, energy density 2,4 J/cm2 per minute, power density 40 mW/ cm2) with total number of 12 sessions. Bioptron was placed vertically at 90° to the surface and kept at range 10-cm distance from the cleaned skin area, for 10 minutes per section. No emollient was used before and after the light exposure (13, 14, 15).

Control group (Topical corticosteroid therapy) received topical corticosteroid cream (hydrocortisone 2.5%) only. According to the dermatologist prescription, subjects informed to apply topical corticosteroids once or twice per day according to severity of case, for four weeks, with us of emollients multiple times per day before or after topical corticosteroids application (16).

2.4.Outcome measures:

The first session included gathering medical history and assessment of tow outcome measures, ultrasonographic assessment of skin thickness and SCORAD index before and after 4 weeks of treatment.

Primary Outcome Measure:

1) Ultrasonography

Using a 7.5-megahertz ultrasonography device, ultrasonography was used to evaluate skin thickness associated with atopic dermatitis changes (Toshiba Xario prime ultrasound, made by Toshiba Canon Medical Systems Corporation, Japan). For both study groups, throughout the procedures, the same radiologist performed ultrasonography measurements. To achieve greater efficiency, an ultrasound gel with 1 mm thickness was used as a coupling medium. The device's printed paper examines the skin thickness (17).

Secondary Outcome Measure:

2) SCORAD index was used to clinically estimate the degree of AD. Law of nines is attributed to back/front diagram of the patient's inflammatory lesions using the SCORAD (Index). The degree was scaled between 0 to 100. The SCORAD intensity section includes six parts: erythema, papulation/ oedema, excoriations, lichenification, crusts/ oozing, and dry skin. Also, every item is based on standards of 0 to 3. Frequent pruritus and insomnia are two of the subjective items. A/5 + 7B/2 + C is used equation to calculate the SCORAD Index.

A reflects the severity (0-100), B measures the intensity (0-18), and C defines the clinical symptom in this formula (0-20). The SCORAD Index has a maximum score of 103. The extent and severity items comprise the objective SCORAD; the equation is A/5 + 7B/2. 83 points are the highest outcome SCORAD scoring system (Additional 10 marks for critical serious underlying eczema of hands and face) (18).

To eliminate type II error, a preliminary power analysis was performed [power (1 −α error P) = 0.95, = 0.05, effect size = 1.42]. in this study, a sample size of 28 was determined for two groups (20 subjects in each group) using the suggested sample size. This effect size was determined based on a pilot test study of 12 volunteers, every group contains 6 volunteers, with the skin thickness index serving as the primary outcome.

3.DATA ANALYSIS:

Calculation of sample size:

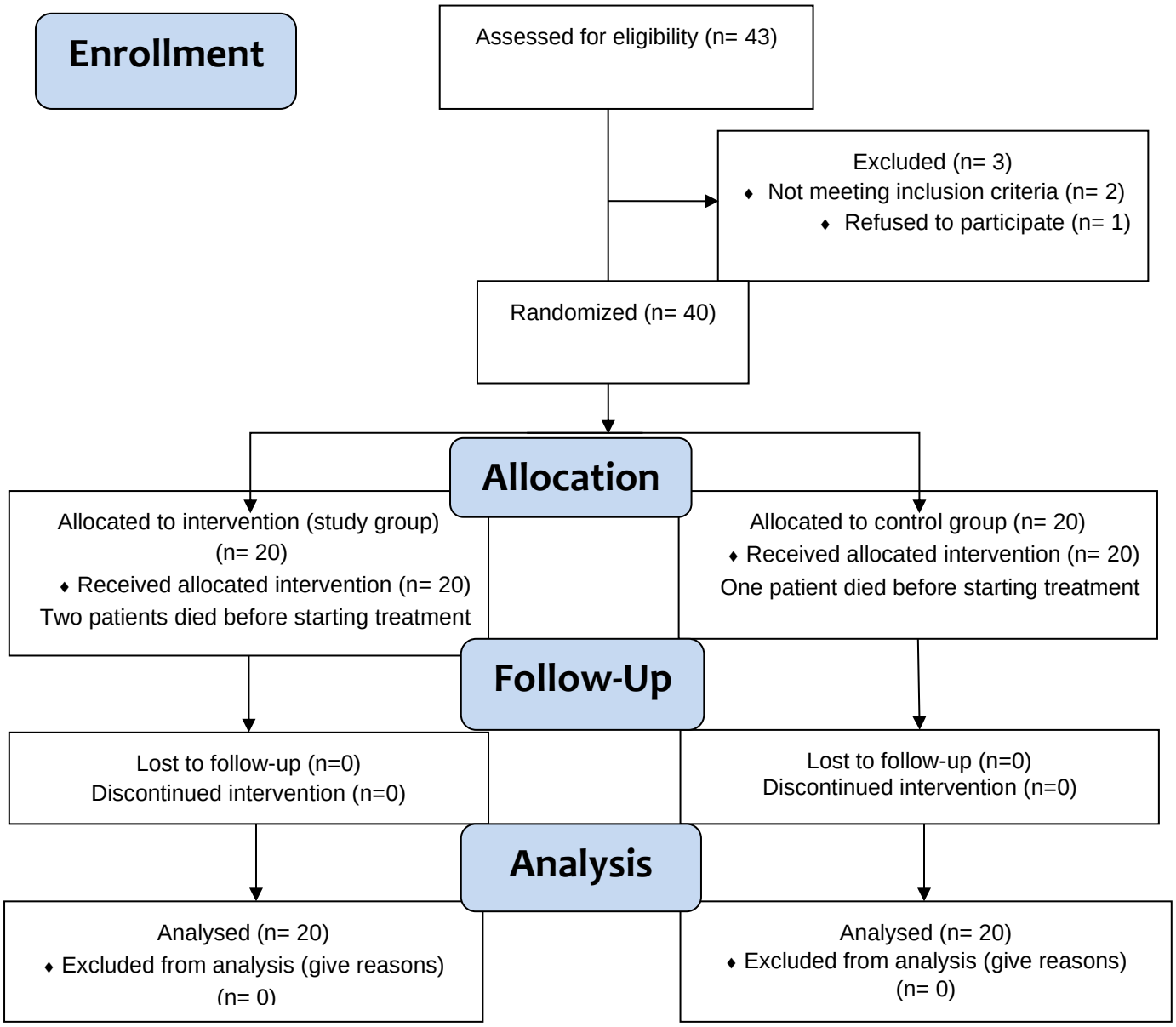

Figure (1): Study flow chart.

The data analysis method was carried out using the G*Power 3.1.9.2 software, which included the t-test family, and the statistical test was used in mean difference between two dependent variables (matched pairs) in study group.

Statistical Analysis:

SPSS for Windows, version 26 was used to identify data analysis (SPSS, Inc., Chicago, IL). Just before to the final analysis, information was examined for the presence of extreme values and the assumption of normality. This investigation was carried out as a prerequisite for parametric study of different measurements. The analysis of descriptive data that used histograms which contained normal distribution curve and data normality testing that used Shapiro-Wilk test revealed that BMI, age, skin thickness, and SCORAD index data in both groups were distributed normally and did not conflict with parametric assumption.

2×2 designs that are mixed for each dependent variable, MANOVA was applied to evaluate the examined parameters across multiple test groups (between groups) and durations (within group). Two independent variables were used in the test. The first was the (examined group; among subject factor with two levels) (Polarized light and Topical corticosteroid group), another one was the (monitoring times; within subject factor with two phases) (before treatment & after treatment). The coefficient alpha was 0.05.

4. Results

Our primary analysis was conducted using an intent to treat approach and therefore included all randomized patients. A total of 43 people were qualified to participate. The final statistical analysis included 40 patients, 20 of whom were assigned to the Polarized light group and 20 to the Topical corticosteroid group (**Fig 1**)

At baseline (**Table 1**), statistically there was Nonsignificant difference between both groups related to age, and BMI (P>0.05).

Post hoc tests (Multiple pairwise comparison tests) demonstrated a statistically significant lowering in skin thickness after intervention in both groups (P-value < 0.01), with percentage of improvement in the Polarized light group being 82.3 percent and the percentage of improvement in the Topical corticosteroid group being 78.1 percent.

Considering the impact of examined group (first independent variable) on tissue skin thickness, Post hoc tests (Multiple pairwise comparison tests) shows no significance difference in skin thickness values between the two groups (Polarized light group and Topical corticosteroid group). before treatment with (P-value = 0.929) and after treatment (P-value = 0.464) (**table 2**).

Table (1): Demographic data of patients in both groups

Qualitative variables	Polarized Light group	Topical corticosteroid group	P-value
	Mean ± SD (Median)	Mean ± SD (Median)	
Age (years)	23.8 ± 6.144	23.33 ± 6.207	0.8111
BMI	28.54 ± 0.919	27.8 ± 1.471	0.218

SD: Standard deviation.

Multiple pairwise comparison tests (P-value 0.0001) revealed a statistically significantly improve in SCORAD index post treatment in two groups (P-value < 0.01), with 518.6 percent improvement in the Polarized light group and 260.7 percent improvement in the topical corticosteroid group.

Multiple pairwise comparison tests (P-value = 0.828) show that there was no statistical difference in mean SCORAD index values before treatment among examined groups (Polarized light group and Topical corticosteroid group). After treatment, there was a significant variation (Polarized light group and Topical corticosteroid group) in favor of the Polarized light group (P-value < 0.01).

5. Discussion

Ultrasound is a non - invasive method that detects any morphological changes in both healthy and pathologic skin. It provides a broad range of diagnostic information that aids in disease assessment in a different way, it was used in a range of skin conditions for different reasons, including objective assessment of treatment effect in pressure ulcers, distinguishing blister sites in blistering skin diseases, and others (19,20).

Table (2): Comparison between (Mean ± SD or Median) values of outcome measured variables pre- and post-treatment within and between groups:

Variable		Polarized light group	Topical corticosteroid group	Between groups comparison (P value)
		Mean ± SD (Median)	Mean ± SD (Median)	
Skin thickness	Pre	16.027±1.557	16.073±1.285	Non-sig
	Post	8.793±0.753**	9.027±0.955**	Non-sig
SCORAD index	Pre	32.6±4.388	32.93±3.918	Non-sig
	Post	5.27±1.71**	9.13±2.066**	Sig

****: Statistically significant difference within in comparison to pretreatment values P-value <0.01.**
SD: Standard deviation. Pre: before treatment measures. Post: after 4 weeks of treatment measures.

The polarized light emitted by the Bioptron machine has several features, including the fact that the waves of polarized light fluctuate on parallel planes and have a high transfer speed, its wavelength ranged from 480 to 3400 nm, incoherent, has a low energy density, and enters the skin with a sufficient intensity. This density has bio-stimulant properties (21).

Even though there is a limited research on the accurate influence of BLT in management of skin disorders, It effectively improves the management of these kind of diseases due to its anti-inflammatory action, which reduces elevated proinflammatory cytokines which including IL-2, TNFα and IFN-I (22). It improves and alters tissue repair and regeneration pattern, or even the stimulation of human defense mechanisms, by acting to encourage the body's regenerative abilities and thus assisting the body in producing its own healing capabilities (23).

The application of low-level light intervention to treat a variety of clinical conditions is gaining popularity. Before, it was mostly used for healing wound, reducing multiple rheumatic situations, and pain management. Even though it was discussed in terms of photo-biomodulation, the underlying mechanism is unclear. Biomodulation is mechanism of altering a cell's or tissue's normal biochemical reaction within the range of normal of its activity to encourage cell's natural metabolic ability to reply to stimulation (24,25). Once one photon transmits an own energy toward a chromophore, it causes biomodulation, which is known as photo biomodulation. It has been discovered to stabilize the harmed cellular medium in a variety of disease conditions and to encourage natural healing. Recent research has shown that photo-biomodulation can regulate inflammatory processes (25).

The current results are supported with those of Pinheiro et al., who discovered that application of polarized light at 685 nm and treatment dosage 20 J/cm2 have ability to accelerate healing process by improving collagen deposition and number of myofibroblasts (26).

These outcomes back up to previous results which found that daily Bioptron polarized therapy facilitated recovery of wound in twenty-two cases with severe 2nd burn degree, greatly accelerated time of healing, decreased scarring, and enhanced long-term functional status (27).

This study's findings were consistent with other studies that investigated the impact of Bioptron intervention in addition to standard care on 55 in-patients with pressure ulcers. After the 1st and 2nd weeks, statistically significant differences between experimental and controlled group ulcers were discovered. The lesions in experimental group shrank by 10.56 percent on average, especially in contrast to 0.95 percent in the placebo group (28).

A recent case report that used Polarized UV-free polychromatic light treatment (Bioptron light therapy) for intervention of 67-year-old Caucasian female complaints of infrequent moderate non-atopic dermatitis for the last 20 years confirms our findings. After three weeks of polarized light therapy, there was a marked

improvement without any adverse reactions (29).

Limitations and recommendations

Despite the fact that polarized light therapy has been shown to be effective in the treatment of many conditions, including septic wounds, diabetic foot complicated by atherosclerosis, ulcer healing and acne vulgaris management, there has not been enough investigations on its influence on atopic dermatitis. Furthermore, because the majority of our patients were males, our study was restricted to male participants only. As a result, we recommend future experiments include both sexes and different polarized light therapy treatment parameters. Even if our findings show promising results, more clinical research are needed to give better understand about the therapeutic potential of polarized light and to recognize its advantages.

Conclusion

According to previous discussions of these results and reviews of academic research associated with the current study, it is possible to state that polarized light therapy is a simple and effective procedure for treating of atopic dermatitis with no noticeable side effects specially those associated with long-term use of topical corticosteroid.

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