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COMPARE THE EFFICACY OF OLIVE OIL WITH ALTERATIVE (PLACEBO) IN THE TREATMENT OF PENILE LICHEN PLANUS

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Abstract:

Objectives: *Compare the efficacy of olive oil and placebo (alterative) in the topical treatment of penile lichen planus.*

Methods: *A randomized, double-blind, placebo (alterative)- controlled trial was designed. Thirty patients were randomized into two groups to receive olive oil or placebo for 12 weeks.*

Results: *Thirty consecutive male patients participated in the study. We found annular ring like pattern as a single or multiple lesions and ulcerative lesions with and with out pain in 69% and 31%, respectively. The most common site of penile lichen planus was the tip of penis. Six out of fifteen patients treated with olive oil (40%) had a good response after 12 weeks of treatment, while two of fifteen alternative-treated patients (14%) had a similar response ($P < 0.001$). Furthermore, one patient treated with olive oil (7%) had a complete clinical remission. Clinically penile lichen planus improved by at least 40% (good response) in six patients treated with olive oil and in two patient treated with placebo (alternative) 14% (good response) ($P < 0.001$). No side-effects were found in both groups.*

Conclusions: *Olive oil is significantly more effective for clinical improvement of penile lichen planus than placebo (alternative). Therefore, olive oil can be considered as a safe treatment for patients with penile lichen planus.*

Key words: *Olive oil, lichen planus, penile, randomized controlled trial.*

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INTRODUCTION:

Lichen planus is a chronic, common, benign, recurrent inflammatory skin disorder of generally unknown cause, presented as an itchy, non-infectious rash of small, polygonal flat-topped reddish purple lesions (bumps) on the arms and legs. Other parts of the body may also be affected, including the mouth, nails, scalp, vulva, vagina, and penis.

Penile lichen planus is a chronic inflammatory disorder of mucosal surfaces; there are flares and partial remission but no tendency for complete remission, it can affect the glans penis or occur on the penile shaft, as a single lesion or multiple lesions in a ring like pattern, it is not a sexually contracted disease, seen in middle aged men from 30- 60 years of age, individuals of all races effected equally [1,2]. Prevalence and causes of penile lichen planus is still unknown (idiopathic) in majority of cases, but there is evidence to suggest that in some cases [6] it is immunologically mediated abnormal cell mediated immunity may be the potential cause, 10 and according to literature certain medications, including thiazide diuretics, anti malarials and phenothiazines (a group of tranquilizing drugs with anti-psychotic actions) can induce lichen planus [9,12] A higher-than-normal percentage of people with hepatitis C [5] and some other liver diseases have lichen planus, its not a sexually transmitted disease presentation of penile lichen planus can be variable, patients typically presents with marked mucosal fagility, erythema and agglutination of glans penis and shaft of penis, but the most common site of involvement is glans, usually glans may have annular (ring-shaped) lichen planus [6]. There are clumps or patterns of shiny, raised, red/pink/purple, flat-topped papules (bumps), papules are approximately 3mm to 5mm in diameter, sometimes there may be white streaks on the papules, called Wickham's striae, size of lesions may vary from 1mm to 10mm, severity of lichen planus of penis may vary [7].

The disease causes lot of pruritus, which seriously affects the patient's quality of life [3,4]. However, a minority of patients may be asymptomatic or have minimal symptoms.

Clinical presentation varies from annular lesions to ulcerative and reticular forms, sometimes may present with erosions, atrophy and ulcerations.

The classical lesions consist of reticulated papules with violaceous discoloration, but hypertrophic, ulcerative and erosive forms can also occur. The erosive lesions hardly ever remit spontaneously and may lead to confusion with other vesiculo bullous or autoimmune mucosal diseases which share similar clinical manifestations [8,10].

Squamous cell carcinoma is highly associated with penile lichen planus, the possible relationship between HPV and penile lichen planus is currently remains open for discussion, prognostic importance of these overlapping diseases is still unclear [5].

Lichen planus is self- limiting disorder that requires no treatment but multiple topical and systemic treatments are available for patients with penile lichen planus but therapeutic responsiveness may differ between patients [3,4].

Olive oil is a liquid fat obtained from olives (the fruit of olea europaea; family Oleaceae) oil is produced by pressing whole olives. It's commonly used in cooking but now also used in cosmetics, pharmaceuticals.13 It consist of oleic acid up to (83%), fatty acids including linoleic acid up to (21%) and palmitic acid up to (20%) since long olive oil is used for skincare [14]. Egyptians used it as cleanser, moisturizer and an anti- bacterial agent. Olive oil is used for massaging infants, toddlers; sportsmen one analysis of olive oil v/s mineral oil can found that olive oil can be considered more protective for skin. Another trial found that olive oil lowered the risk of dermatitis when compared with emollient creams olive oil is a natural and self-lubricant. 15 Virgin olive oil produced by the mechanical means without chemicals [16].

To the best of our knowledge, no studies available to compare the olive oil and placebo in the treatment of penile lichen planus. Therefore, the objective of our study was to compare the efficacy of topically applied olive oil and placebo for the treatment of penile lichen planus in a double-blind, randomized trial.

Patients and methods:

Patients with penile lichen planus attending the Isra University Hospital Out Patient Department during July 2016- June 2017 were asked to participate in our study. The inclusion criteria were as follows: (1) clinically patients have penile lichen planus. The exclusion criteria were: (1) any treatment taken during last 4 weeks for genital region as well as for penile lichen planus. A randomized, double-blind, placebo-controlled study was designed. Local Isra University Hospital's ethical committee approval was taken before the trial started and all patients gave verbal informed consent.

The virgin olive oil was prepared by Borges

Mediterranean Group Spanish company based in Tarrega available in pakistan. It consisted of 100% virgin olive oil, it's a premium oil obtained from first cold pressing and has a acidity levels of less than 0.8%, which conforms to these standards. The placebo contained simple liquid paraffin. The study medications were packed in identical jars and the code of the jars was kept at the Department of Physiology until completion of the study.

A randomized controlled trial was performed; randomization was done by using random number table. Patients were randomly divided into two groups, the first group of patients received olive oil, whereas the second group of patients received placebo. Both medications, which were used, were unknown to the patients and physicians. The patients were instructed to apply the medication twice daily and were prohibited from using any emollient during the applications of study medication. Each patient was examined at the beginning of treatment, and then after 2, 4, 6 and 8 weeks of therapy.

The clinical data were scored according to the criteria used by Thongprasom et al.:[10] 0, no lesion; 1, mild white striae, no erythematous area; 2, white striae with atrophic area
< 1 cm; 3, white striae with atrophic area > 1 cm; 4, white striae with erosive area < 1 cm; 5, white striae with erosive area > 1 cm or ulcerative lesion.

Treatment response was graded as complete when the scores according to Thongprasom et al.[10] Good when scores decreased by 50% from baseline, poor when scores decreased by < 50% from baseline, and as no response when the lesions were unchanged.

RESULTS:

Thirty men patients were enrolled in the study. No patients were dropped from the study. There were no significant differences between the two groups with regard to age and clinical scores at baseline. The mean age of patients in olive oil group is 40 years and same 40 years in placebo treated group. The mean duration of the disease before participating in the study was 12 months in the olive oil treated group and 12 months in the placebo-treated group. We found annular lesions (ring like pattern) in 24 patients (80%) (17 patients in olive oil group and 7 patients in placebo group), ulcerative lesions in 9 patients (20%) (six patients in olive oil group and three patients in placebo group) and reticular lesions in all patients (100%). (Table 1).

The most common site of involvement in our study was the glans penis (86%) 26 patients (13 in olive oil group and 13 in placebo group), followed by the shaft of the penis six patients (14%) 4 patients (two in olive oil group and two in placebo group). (Table 2).

Eight of 30 patients also had cutaneous lichen planus (27%). Regarding clinical signs at the end of therapy, four of the 15 patients treated with olive oil had complete response (26%), while none of the placebo-treated patients had complete remission. Improvement of the lesions by a decrease of the clinical scores by 50% (good response) was noted in the 11 patients (73%) in the olive oil group and in two patient (13%) in the placebo group. The difference was statistically significant (P < 0.001). Four patients (27%) in the placebo group had poor response (improvement of < 50% from baseline). No change of the lesions after 12 weeks of therapy was observed in nine patients (60%) receiving placebo. The difference was statistically significant (P < 0.001) (Table 3).

Table 1: Type of lesions

Agent	Annular lesions	Ulcerative lesions	Reticular lesions
Olive oil Group	17	6	15
Placebo Group	7	3	15
Total	24	9	30

Table 2: Location of lesions

Agent	Glans Penis	Shaft of Penis
Olive oil (n== 15)	13	4
Placebo (n== 15)	13	2
Total (n == 30)	26	6

Table 3: Comparison of clinical response in both group of patients

Response	Olive oil (n== 15)	Placebo (n==15)
Complete response	4 (26%)	0 (0%)
Good response	11 (73%)	2 (13%)
Poor response	0 (0%)	4 (27%)
No response	0 (0%)	9 (60%)

No side-effects of olive oil or placebo were recorded, no significant complaint was reported in the olive oil group and placebo group.

DISCUSSION:

Lichen planus of penis can affect the glans penis or occur on the penile shaft, as a single lesion or multiple lesions in a ring like pattern. It is not a sexually contracted disease, in general, man in the 30 to 60 years age group are affected the most. Most lesions are asymptomatic, however some may ulcerate and cause pain condition occur worldwide individuals of all racial and ethnic back ground may be affected. The risk factors for penile lichen planus are unknown or unidentified.1 Penile lichen planus has a slow onset, it may take days and weeks for the signs and symptoms to develop, the lesion may be present on the glans penis or shaft of the penis, single or multiple lesions may be present as a ring like pattern (annular lesion) the lesion may ulcerate and cause pain, size of lesion may vary from 1mm to 10 mm, chronic itching skin become thick, discolored and leathery presence of lesions can make sexual intercourse uncomfortable, diagnostic method used for penile lichen planus are physical examination, complete medical history, dermoscopy, tissue biopsy, complication of penile lichen planus are bacterial and fungal infections, rarely [2]. Squamous cell carcinoma can develop from the lesion, individuals may have stress and anxiety which may lead to depression and social isolation, penile lichen planus has good prognosis, penile lichen planus is a unique chronic inflammatory mucous membrane reaction, it can present with or without cutaneous lichen planus, 5 very less number of patients with cutaneous lichen planus can develop penile lichen planus, generally. Current treatments for penile lichen planus are aimed at alleviating itching and eliminating the lesions. Many treatments have been tried but there is a lack of strong evidence supporting their efficacy. Even though no therapy of penile lichen planus is curative, clinical relief can be achieved in the majority of patients with topical treatment such as corticosteroids, ciclosporin, retinoic acid, pimecrolimus and tacrolimus [3,4].

Many systemic agents have been used in the treatment of penile lichen planus, e.g. acitretin, azathioprine, dapsone and systemic corticosteroids [4].

Many factors were suggested to be involved in the etiology of penile lichen planus, including HLA association, infectious agents, drugs, diabetes, hepatic diseases, graft versus host disease, and psychological factors, but none of these was proved [9,12]. It is now believed to be an immune-mediated disease. Penile lichen planus is a T cell-mediated disease in which cytotoxic CD8+ T cells trigger apoptosis of penile epithelial cells. Upregulation of intercellular adhesion molecules and cytokines secreted by activated lymphocytes and keratinocytes such as interleukin (IL)-2, IL-4, IL-10 and tumour necrosis factor (TNF) can play a role in the pathogenesis of lichen planus [10].

Olive oil has a long history of being used as a home remedy for skin care, ancient Greeks used olive oil during massage to prevent sports injuries, relieve muscle fatigue and illuminate lactic acid build up [16]. It is a natural and safe lubricant, olive oil has many vitamins including A, D, K, E vitamin it has an antioxidant properties, studies showed 19 that it might have to prevent cancer causing ultraviolet radiations, it has anti-inflammatory, anti-bacterial and anti-fungal properties, olive oil also known to moisturize and hydrate the skin. Recent data suggest that olive oil also has anti-inflammatory effects by the reduction of leucocyte adhesion and tumor necrosis factor level [14,15].

Study done in UK 13 in which olive oil and sun flower oil used for the prevention and treatment of dry skin in babies with atopic eczema, 2nd study done in University of Moracco [17] in which they use organ oil in post-menopausal women to maintain the skin elasticity of face during 60 days of application they caught an anti- aging effect on skin of 30 post-menopausal women, study done in university of Janain in China 2015 [18] they use an olive oil to prevent the radio dermatitis in patients of nasopharyngeal carcinoma they got superior therapeutic effects of olive oil on other general skin care regime, 77.8% of patient with radio dermatitis were cure by an anti-oxidative and anti-inflammatory effect of olive oil.

In our study, we found white reticular lesions in

every patient, annular lesions in 24 patients and ulcerative lesions in nine patients. The glans was the most common site of involvement in twenty six patients. In the present study, olive oil was effective in the treatment of penile lichen planus when compared with placebo. We found 100% of the olive oil treated patients significantly improved (improvement of at least 50% from baseline) after 8 weeks of therapy where as only 13% of placebo-treated patients had a similar response ($P < 0.001$). In particular, 26% of the olive oil treated patients had complete remission of the lesions (according to the criteria of Thongprasom et al.), [10] while none of the placebo group had such a response.

CONCLUSION:

The effect of olive oil on penile lichen planus was significantly better than that of placebo. The results showed decreases in clinical sign and symptoms. No side effects were noted and olive oil was generally well tolerated.

Thus, olive oil can be used a safe and effective treatment for penile lichen planus.

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