

# The value of diclofenac gel 1 % in the treatment of pityriasis versicolor in a sample of Iraqi patients

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## ABSTRACT

One of the commonly encountered skin disorders seen in daily clinical practice is the benign superficial fungal skin infection known as tinea versicolor or pityriasis versicolor. Clinically it presents as macules with fine scales that are either hypopigmented or hyperpigmented involving most often the neck, upper extremities, and the trunk. However, because of the high rate of recurrence and frequent failure of response accompanying usual mode of treatment, several agents are tried now and then, and one of these agents that have been evaluated for treating tinea versicolor is topical 1% diclofenac gel. In the current randomized controlled clinical trial we are aiming to compare the response of tinea versicolor to diclofenac gel in comparison with clotrimazole cream in a sample of Iraqi patients suffering the disease. The present randomized controlled clinical trial included 40 tinea versicolor patients with an age range of 19 to 42 years. Those patients were randomly selected from the pool of patients visiting the dermatology department at Al-Diwaniyah teaching hospital in Al-Diwaniyah province, Mid-Euphrates region of Iraq. Patients were diagnosed by dermatology specialist and were randomly allocated into two groups, 20 patients each. The first group served as a study group, and the patients received 1% diclofenac gel based on two times a day for one month. Patients in the second group, the control group, were given the usual clotrimazole cream, two times daily for one month. There was a highly significant difference in response to treatment between both groups two weeks after surgery in such a way that clotrimazole resulted in more complete response than diclofenac gel, 65 % versus 20 %, respectively ( $P = 0.008$ ). Moreover, there was a significant difference in response to treatment between both groups four weeks after treatment in such a way that clotrimazole resulted in more complete response than diclofenac gel, 90 % versus 50 %, respectively ( $P = 0.019$ ). It appears that diclofenac topical 1% gel is fairly effective in the treatment of pityriasis versicolor; however, other agents such as clotrimazole are more effective, and hence diclofenac topical 1% gel may be used as an adjuvant form of treatment rather than the sole treatment modality.

**Keywords:** Diclofenac 1 % gel, pityriasis Versicolor, clotrimazole

## INTRODUCTION

One of the commonly encountered skin disorders seen in daily clinical practice is the benign superficial fungal skin infection known as tinea versicolor or pityriasis versicolor. Clinically it presents as macules with fine scales that are either hypopigmented or hyperpigmented involving most often the neck, upper extremities, and the trunk [1-3]. The diagnosis is often clinical; however, doubtful cases may be approached by the use of skin scraping with microscopical evaluation or black ultraviolet light [4-5]. The etiology of this dermatological disorder is a normal skin fungal flora belongs to *Malassezia*, and the main causative agents isolated from skin lesions are *Malassezia furfur*, *Malassezia sympodialis*, and *Malassezia globosa* [3]. Although the disease is globally distributed, warm and humid environments are the main areas where it can be seen very often. Therefore, the prevalence of the disease is highly variable and ranges from as low as 1.1 % in cold climates such as some European countries to as high as 50 % in a number of tropical countries. No age is immune; however, young adults and adolescents are the principal age groups to be affected by the disease, possibly because of high sebum production. There is usually neither gender nor ethnic

predilection by the disease [6-7]. From pathophysiological perspective, *Malassezia* undergo a pathogenic transformation in order to cause the skin disorder, but the exact way by which this conversion occurs is not completely understood; however, several risk factors have been implicated such as environmental predisposition, genetic susceptibility, pregnancy, oily skin and immune deficiency [8-10]. Patients may consider the disease contagious; therefore, the commensal nature of the causative agent should be clarified to them, in addition, they should be reassured that the disease will never cause scarring or a pigmentary permanent disorder and that the disease has a high rate of recurrence [4,11-12]. The first-line treatment for tinea versicolor includes topical medications which are either specific antifungal agents that have fungistatic or fungicidal effects such as ketoconazole 2%, clotrimazole 1%, and isaconazole, or nonspecific antifungal agents that removes primarily dead tissues and prevent further invasion such as zinc-pyrithione, selenium sulfide 2.5% and sulfur plus salicylic acid [4,13]. Severe, widely spread, and resistant lesions may be treated by oral medications [4,13]. However, because of the high rate of recurrence and frequent

failure of response accompanying usual mode of treatment, several agents are tried now, and the, and one of these agents that have been evaluated for treating tinea versicolor is topical 1% diclofenac gel [14]. Therefore, in the current randomized controlled clinical trial, we are aiming to compare the response of tinea versicolor to diclofenac gel in comparison with clotrimazole cream in a sample of Iraqi patients suffering the disease.

### Patients And Methods

The present randomized controlled clinical trial included a cohort of 40 patients with tinea versicolor with an age range of 19 to 42 years. Those patients were randomly selected from the pool of patients visiting the dermatology department at Al-Diwaniyah teaching hospital in Al-Diwaniyah province, Mid-Euphrates region of Iraq. The study started on February 2<sup>nd</sup>, 2019, and extended to June 15<sup>th</sup>, 2019. Patients were diagnosed by dermatology specialist and were randomly allocated into two groups, 20 patients each. The first group served as a study group, and the patients received 1% diclofenac gel on the basis of 2 times a day for one month. Patients in the second group, the control group, were given the usual clotrimazole cream, 2 times daily for one month. Treatment response was evaluated 2 weeks and 4 weeks later and categorized into no response, partial response, and complete response. The evaluation also included skin scraping examination 2 weeks and 4 weeks later. Data about age and gender were included in the questionnaire form.

### Statistical analysis

Data were then transformed into an SPSS (version 23) spreadsheet and analyzed. Data were expressed as mean, standard deviation, range, number, and percentage. Independent samples t-test was used to compare mean values between two groups; whereas, the chi-square test was used to compare the difference in frequency between two groups. The level of significance was considered at  $P \leq 0.05$ .

### Results

The current study included 40 patients with pityriasis versicolor. Their age ranges from 19 to 42 years, with a mean of  $27.55 \pm 6.90$  years. They included 25 (62.5 %) male patients and 15 (37.5 %) female patients with a male to female ratio of 1.67: 1. They were randomly allocated into 2 groups according to treatment; each group consisting of 20 patients and received either Diclofenac gel 1 % (study group) or Clotrimazole (control group). Each group included 20 patients. There was no significant difference in mean age between either group,  $28.60 \pm 6.95$  years versus  $26.50 \pm 6.87$  years, respectively ( $P = 0.343$ ), as shown in table 1. In addition, there was no significant difference in the distribution of patients according to gender between study and control groups. Therefore, both groups were statistically matched with respect to age and gender. Treatment response was categorized into no response, partial response, and complete response and was evaluated 2 weeks and 4 weeks after initiation of therapy. There was a highly significant difference in response to treatment between both groups 2 weeks after treatment in such a way that clotrimazole resulted in more complete response than diclofenac gel, 65 % versus 20 %, respectively ( $P = 0.008$ ). Moreover, there was a significant difference in response to treatment between both groups 4 weeks after treatment in such a way that clotrimazole resulted in more complete response than diclofenac gel, 90 % versus 50 %, respectively ( $P = 0.019$ ), as shown in table 2. Skin scraping results were also contrasted between the two groups 2 weeks and 4 weeks after initiation of treatment, as shown in table 3. Clotrimazole resulted in more negative skin scraping results than diclofenac, 70 % versus 20 %, 2 weeks after treatment; the difference was highly significant (0.001). On the other hand, Clotrimazole resulted in more negative skin scraping results than diclofenac, 90 % versus 65 %, 4 weeks after treatment; the difference was not significant ( $P = 0.058$ ), but very close to the level of significance of 0.05, as shown in table 3.

**Table 1: Demographic characteristics of patients with pityriasis versicolor**

Characteristics	Total <i>n</i> = 40	Diclofenac gel 1 % <i>n</i> = 20	Clotrimazole <i>n</i> = 20	<i>P</i>
<b>Age (years)</b>				
Range	19 - 42	19 - 42	19 - 40	0.343 † NS
Mean ±SD	27.55 ± 6.90	28.60 ± 6.95	26.50 ± 6.87	
<b>Gender</b>				
Male, <i>n</i> (%)	25 (62.5 %)	13 (65.0 %)	12 (60.0 %)	0.744 ¥ NS
Female, <i>n</i> (%)	15 (37.5 %)	7 (35.0 %)	8 (40.0 %)	
Male: Female	1.67: 1	1.86: 1	1.5:1	

*n*: number of cases; SD: standard deviation; †: independent samples t-test; ¥: Chi-square test; NS: not significant

**Table 2: Response to treatment**

Response		Diclofenac gel 1 % n = 20		Clotrimazole n = 20		P
		n	%	n	%	
At 2 weeks	No response	3	15	0	0	0.008 ¥ HS
	Partial	13	65	7	35	
	Complete	4	20	13	65	
At 4 weeks	No response	2	10	0	0	0.019 ¥ S
	Partial	8	40	2	10	
	Complete	10	50	18	90	

n: number of cases; ¥: Chi-square test; HS: highly significant at  $P \leq 0.01$ ; S: significant at  $P \leq 0.05$

**Table 3: Skin scraping results**

Skin scraping		Diclofenac gel 1 %		Clotrimazole		P
		n	%	n	%	
After 2 weeks	Negative	4	20	14	70	0.001 ¥ HS
	Positive	16	80	6	30	
After 4 weeks	Negative	13	65	18	90	0.058 ¥ NS
	Positive	7	35	2	10	

n: number of cases; ¥: Chi-square test; HS: highly significant at  $P \leq 0.01$ ; NS: Not significant at  $P \leq 0.05$

### Discussion

Tinea versicolor color is frequently encountered in our community in daily dermatologic practice. Despite very good response upon treatment initiation, a high rate of recurrence makes affected individual unsatisfied with usual and conventional mode of available topical treatment. For that reason, dermatologists now and then seek another mode of treatment in order to get better results with respect to recurrence. Based on previous reports of the use of topical diclofenac in the treatment of tinea versicolor[14], we planned and conducted the current study to test the validity of such approach in the treatment of a sample of Iraqi patients suffering from skin disfigurement due to pityriasis versicolor. The current study revealed that topical diclofenac gel was significantly less effective than the traditional topical clotrimazole cream in the treatment of tinea versicolor. The rate of complete response was significantly less, and the skin scraping negative results were also significantly less in the group of diclofenac in comparison with clotrimazole. However, a rate of 50 % complete response and 65 % negative skin scraping results is fairly accepted in daily dermatological practice but does not justify the use of diclofenac alone as the sole treatment, instead it can be used as an adjuvant treatment option in cases with a high recurrence rate of resistant to usual

form of treatment. However, the later suggestion should be evaluated in another future randomized controlled clinical trial. These results are comparable to that of Sharquiea et al., who stated that "both diclofenac gel and clotrimazole cream were effective in clearing the lesions of pityriasis versicolor; at 2 weeks of therapy, diclofenac gel cleared 16% of the patients while clotrimazole cream cleared 56% of patients. After 4 weeks of therapy, diclofenac gel cleared 56% of patients while clotrimazole cream was more effective, which cleared 92% of patients" [14]. Probably, the negligible side effects associated with the use of diclofenac topical gel are encouraging, especially when compared with that resulted from the application of nonspecific fungal agents.

### Conclusion

In conclusion, it appears that diclofenac topical 1% gel is fairly effective in the treatment of pityriasis versicolor; however, other agents such as clotrimazole are more effective, and hence diclofenac topical 1% gel may be used as an adjuvant form of treatment rather than the sole treatment modality.

### Conflict of interest

The authors declare no conflict of interest.

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### Ethical clearance

The study was approved by the institutional ethical approval committee, and verbal consent was obtained from each patient following a full illustration of the aims and procedures of the current study.

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