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Topical Therapy of Acne Vulgaris Using Ciprofloxacin Solution 1.5% in Comparison With Clindamycin Solution 1.5%

Dr. Dalila Mohammed Al. Jabory

M.B.Ch.B., F.I.C.M.S, Baghdad Health Office/Al-Rasafa/,Al-Nu'man Teaching Hospital

Abstract: ***There are many topical therapies that have been used in the treatment of mild to moderate acne vulgaris, yet there is no optimal therapy is defined. The aim of this study is to assess the efficacy and safety of topical 1.5% ciprofloxacin solution in the treatment of mild type of acne vulgaris in comparison with topical 1.5% clindamycin solution.Sixty eight patients with mild acne vulgaris were included in this single-blind comparative therapeutics clinical trial which was conducted in the Department of Dermatology-Baghdad Teaching Hospital from February 2016 -March 2017. The patients were divided into two groups and applied the following solutions twice daily on the face for eight weeks: Group A used 1.5% ciprofloxacin solution, while Group B used 1.5% clindamycin solution in the same manner as Group A. Full clinical assessment was carried out. Scoring system was done every two weeks till the end of the therapy to record the clinical improvement of the lesions and any topical or systemic side effects. Follow up was done for another four weeks after cessation of therapy to record any clinical relapse. Sixty one patients with mild acne vulgaris completed the course of treatment, their ages ranged from 17-25 (19.3 ± 1.9) years, thirty patients in Group A with mean ages 18.8 ± 1.8 years and thirty one in Group B their mean ages 19.8 ± 2.1 years. Both topical ciprofloxacin and topical clindamycin solutions cleared the lesions in mild acne within 8 weeks of therapy and when compared the results of the two groups with each other there was no statistical differences between the groups, but topical ciprofloxacin solution was more effective in the clearance of papules, while topical clindamycin was more effective on pustules. In conclusion; topical 1.5% ciprofloxacin solution was as effective as topical 1.5% clindamycin solution in the treatment of mild acne vulgaris, with negligible side effects.***

Keywords: Ciprofloxacin, Clindamycin, Acne Vulgaris

1. Introduction

Acne vulgaris is a very common disorder affecting virtually every adolescent at some point in time[1]. Acne is a disorder of pilosebaceous follicle; characterized by increased sebum production, follicular keratinization, colonization by *Propionibacterium acne* (*P. acne*)and localized inflammation [2]. Effective treatment is essential to prevent facial deformity and to deter psychologic and physical scarring[3]. The most widely used topical drugs for acne treatment are benzoyl peroxide, retinoids, topical antibiotics and azelaic acid either as monotherapy or in combination with their action at different steps of acne pathogenesis. Ideal treatment must affect all of these pathogenic mechanisms. There is no such ideal therapy; therefore, clinicians usually combine several topical and systemic agents to achieve best result [4].

Ciprofloxacin is a member of quinolone family and represents a particularly important therapeutic advance,it is a second generation floroquinolone antimicrobial, it is a bactericidal drug acts by inhibiting the action of bacterial topoisomerase II (DNA gyrase) and IV during bacterial growth and reproduction which lead to impaired DNA replication, transcription and repair, topoisomerase IV is required by bacteria for cell division, it has broad spectrum activity that cover both gram negative and gram positive bacteria[5-7]. It has relatively few side effects and microbial resistance to their action does not develop rapidly[8, 9]. So the aim of the present work is to evaluate the efficacy of topical 1.5% ciprofloxacin solution in the treatment of mild type of acne vulgaris in comparison with topical 1.5% clindamycin solution.

2. Patients and Methods

This single-blind comparative therapeutic clinical trial was conducted in Department of Dermatology and Venerology in Baghdad Teaching Hospital from February 2016 - March 2017. Sixty eight patients with mild acne vulgaris on the face were included in this study. Full history was taken from each patient including: age, sex, duration of disease, previous treatment and ensured that every patient had stopped any systemic and topical treatment at least 2 months before starting the present therapy. Close physical examination was done to evaluate the severity of acne. Scoring the severity of acne was determined according to the following rules[10]:

1) Mild acne in which the count of pustules is less than 20 and the count of papules is less than 10.
2) Moderate acne in which the count of pustules is ranging between 20-40 and the count of papules ranging between 10-30 papules.
3) Severe acne in which the count of pustules is more than 40 and the count of papules is more than 30.

Comedonal, severe and nodulo-cystic acne, patients aged 16 years and less, pregnant and lactating females, patients with immunosuppression conditions, patients on systemic drugs that induced acneiform eruption and patients with post-epilation acne, acne cosmetic, those with polycystic ovary and menstrual irregularities were excluded from this study.

Formal consent was taken from each patient after full explanation of nature of the disease, course, treatments, prognosis and its complications, the target of the present

work regarding the drug, its efficacy, side effects, the method and duration of treatment and follow up. Also, ethical approval was performed by the Scientific Council of Dermatology and Venerology-Iraqi Board for Medical Specializations. Color photographs for each patient were performed at baseline, at 2 weeks, 4 weeks, 8 weeks and 12 weeks. Frontal, right and left views were taken using Sony-digital, high sensitivity, 12.1 megapixel camera in the same place with fixed illumination and distance.

Thirty-three patients with mild acne vulgaris assigned to be the first group (Group A) using topical ciprofloxacin solution 1.5% which prepared as one and half gm ciprofloxacin [(Sarf.)^{R} Produced by: Julfur-Gulf pharmaceutical industries, Ras Al-Khaima, U.A.E, 500mg, three tablets crushed by coffee grinder, dissolved in 75ml rectified spirit and 25ml distilled water] and mixed in dark glass container. In the second group (Group B) 35 patients were treated with topical clindamycin solution 1.5% prepared as one and half gm clindamycin [(clindamyl) ^{R} as HCL produced by: APM industries, 150mg, ten capsules dissolved in 75ml rectified spirit and 25ml distilled water] then mixed in dark glass container. In both groups the patients were instructed to apply the solution twice daily by using cotton wool applicator for eight weeks. The clinical evaluation was done every two weeks till the end of the eight weeks. Then the patients were asked to stop the use of medication to be re-evaluated again after four weeks without any treatment. The assessment carried out by counting the inflammatory lesions including papules and pustules depending on the scoring and watching for any side effects.
Statistical analysis were done using SPSS version 19 (Statistical Package for Social Sciences). Comparison between the two groups done by using independent sample t-test. Comparison before and after treatment in each group was done by using paired t-test, comparison of the patient response to treatment in the two groups done by using chi-square, and P-value < 0.05 was considered as level of significance. F-test (ANOVA) was applied to measure the significance differences between and within groups.

3. Results

Sixty eight patients included in this study, 7 (10.2%) patients did not complete the treatment, one of them from ***Group A*** because of the side effects which was severe burning sensation and 6 (8.8%) considered defaulted for unknown reasons (3 in ***Group A*** and 3 in ***Group B***). Sixty one patients completed the course of treatment, their ages ranged from 17-25 years with a mean ± SD of 19.3± 1.9 years. Thirty patients in ***Group A*** their mean ages ± SD was 18.8 ± 1.8 years, 18 (60%) females and 12 (40%) males, with female to male ratio 1.5:1 and thirty one patients in ***Group B*** their mean age ± SD was 19.8 ± 2.1, 18 (58.1%) females and 13 (41.9) males, female to male ratio 1.4:1. The duration of the disease ranged between 6 months-8 years.

In both groups, the means of inflammatory lesion counts (papules and pustules) within each group diminished significantly at each visit when compared to the baseline starting from the second visit (after two weeks) in ***Group A*** and in ***Group B*****(Table-1)**, **(Figure 1, Figure 2).**

There were no statistically significant differences between the two groups in the total means of the inflammatory lesions (papules and pustules) at the baseline and at each visit and there is no relapse rate after the stopping of the treatment **(Table-2).**

In ***Group A***, 4 (13.3%) patients had burning sensation, while in ***Group B***, 6 (19.3%) patients had burning sensation and one (3.2%) patient had itching that did not need to discontinue the therapy.

Table 1: The mean ± SD of papules and pustules counts within the groups

	1st visit (before therapy)	2 wks	4 wks	8 wks	ANOVA	P- value
Clindamycin						
Papules	3.23±2.63	2.58±2.34	1.97±2.03*	1.39±1.31*	4.27	0.006
Pustules	9.16±4.61	6.00±4.49*	5.39±4.35*	4.32±3.74*	7.23	0
Total	12.39±4.54	8.58±4.56*	7.35±3.95*	5.71±4.14*	13.52	0
Ciprofloxacin						
Papules	4.93±2.80	2.60±2.34*	1.67±1.71*	1.53±1.85*	16.53	0
Pustules	8.60±4.99	5.93±4.02*	5.23±4.29*	3.87±3.20*	6.81	0.0002
Total	13.53±5.25	8.53±4.18*	9.90±3.82*	5.40±3.32*	19.28	0

***significantly different from the 1st visit (p<0.05)**

Table 2: Total mean (papules and pustules) difference between the 2 groups at each visit

	Group A Mean± SD	Group B Mean ± SD	t-test	P-value
(1st visit)	13.5±5.2	12.3±4.5	0.913	0.365*
(2 wks)	8.5±4.1	8.5±4.5	0.042	0.966*
(4wks)	6.9±3.8	7.3±3.9	0.457	0.649*
(8 wks)	5.4±3.3	5.7±4.1	0.322	0.749*
4 wks after therapy	6.3±4.6	5.3±4.3	0.890	0.377*

*p-value ≥ 0.05

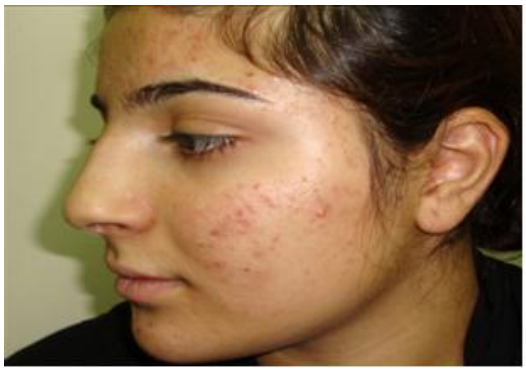

Figure 1: Eighteen years old female with mild acne vulgaris before treatment with topical ciprofloxacin solution.

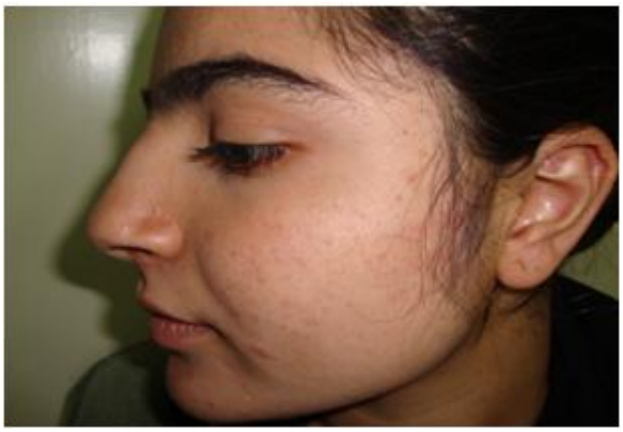

Figure 2: The same patient 8 weeks after treatment with topical ciprofloxacin solution.

4. Discussion

Acne vulgaris is a major health problem among youth and although it is self limiting disease but in many cases if left without treatment cause scarring which has psychological and cosmetical impacts on the patients. There are many topical therapies that have been used in the treatment of acne vulgaris such as benzoyl peroxide, azelaic acid, retinoic acid, erythromycin and clindamycin[11-13].

Clindamycin has been used for long time in the treatment of acne vulgaris and proved its effectiveness[14-16]. Ciprofloxacin gel has been introduced as a topical therapy for acne vulgaris in 2006 by Iraqi study and showed that 72.8% of patients had good improvement, 22.7% had partial improvement, and 4.5% had no improvement[17]. Since then topical ciprofloxacin has been used in daily clinical practice and proved its efficacy and safety (Sharquie personal observations).

The aim of the present work is to reassess the efficacy and safety of topical ciprofloxacin solution in the treatment of acne vulgaris and to be compared with topical clindamycin solution which is one of the standard acne treatments. The result was as follow: Regarding topical ciprofloxacin 63.3% of patients showed good improvement, 30% showed partial improvement, and 6.6% had no response. When this study using ciprofloxacin solution compared with previous Iraqi study used ciprofloxacin gel, the result was almost comparable but using solution is much simpler in formulation of the drug and cost of therapy, in addition the gel form need highly sophisticated tool and need to be kept in special environment. Regarding clindamycin solution 58.0% of patients showed good response, 35.4% had partial response, and 6.4% had no response. Clindamycin also proved its effectiveness by the present study and was closely comparable to Al-Zubaidy et al study[18].

Both clindamycin and ciprofloxacin cleared the lesions in mild and moderate acne within 8 weeks of therapy (58.0% and 63.3% respectively) and when compared the results of the two groups with each other there was no statistical differences between the two groups, but topical clindamycin solution was more effective in the clearance of pustules better than topical ciprofloxacin solution (p= 0.0001), in contrast to topical ciprofloxacin solution which was more effective in the clearance of papules (p= 0.0009).

Both drugs showed mild side effects in the form of burning sensation and itching and considered safe when compared with other topical therapy that commonly associated with more severe side effects like tretinoin and benzoyl peroxide [19].

5. Conclusion

This study proved that topical ciprofloxacin solution is as effective as topical clindamycin solution and without side effects.

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