Original Article

Topical Clindamycin in the Treatment of Acne Vulgaris

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Abstract

This study was conducted to evaluate the efficacy, safety and adverse effects of topical clindamycin phosphate 1% lotion in treating acne vulgaris in a group of Bangladeshi people. This prospective study was undertaken in skin & VD out patient department of Rajshahi Medical college Hospital, Rajshahi. A total of 30 patients, 15 (50%) males and 15 (50%) females between ages 15 and 35 years (mean 18 years) with acne of grades I, II and III of duration <3 years to 10 years (mean 3.33 years) were studied. Clindamycin phosphate 1% lotion was administered twice daily for 12 weeks to each patient. Response was excellent in 73.33%, good in 20%, fair in 3.33% and poor in 3.33% of cases. Clinical adverse effects were noted in 20% of cases where oiliness was in 6.67%, irritation and burning in 3.33%, puritans in 3.33%, erythema i3.33% and peeling in 3.33% of cases. None of the reactions was severe, all were mild and well tolerated and most occurred within the first month of initiation of treatment and resolved with continued use of drug and completely cured after the treatment completed. No body had to discontinue the therapy for side effects. 80% of the total patients had no side effects. This study confirms that clindamycin is safe and effective topical therapy for mild to moderate acne vulgaris.

Introduction

Acne vulgaris is the most common disease.1 Acne vulgaris is mostly a disease of the adolescent.2 Acne is common problem in adolescents and young adults. Acne and its associated problems affects as many as 80% of adolescents and young adults. Only one third affected teenagers could consult with their physician about acne.3 A good number of male and females teenagers suffer from acne vulgaris in our country and suffer from high degree of morbidity and psychological trauma due to post acne scar. Depending on the severity and extent of involvement, treatment varies from application of topical medications to systemic therapy with antibiotics or retinoids.2

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All correspondence to: Shahnaj Sultana Medical Officer Skin & VD Department Rajshahi Medical College Hospital Topical preparations constitute the sole treatment in many patients with acne and are part of the therapeutic regimen in almost all patients.3Topical acne therapies are widely used for the treatment of mild to moderately severe acne vulgaris. However, many available treatments have limitations associated with their use, including lengthy time to response, cosmetic acceptability and photosensitivity.4Topical treatment is sufficient in most patients with acne, but systemic therapy is required in patients who have deep acne with nodules and cysts.3 The major topical agents now in use are vitamin A derivatives and antimicrobials such as benzoyl peroxide and topical antibiotics.5 The topical retinoid class, which includes tretinoin , adapalene and tazarotene, and the topical antibacterials, clindamycin and erythromucin, are regulated by prescription in most countries. Topical clindamycin has no systemic toxicity except diarrhoea rarely nd there have been 2 cases of pseudo membranous colitis reported.6Though topical clindamycin is being used in many countries for the treatment of acne vulgaris but it was not being used in our country due to non-availability of the drug. Very recently topical clindamycin in the name of CLINEX LOTION (clindamycin 1%) is being produced and marketed in our country but its efficacy and safety has not been studied in our population yet. Here, an endeavour has been made to do such a study.

Aims and Objectives

a. To evaluate efficacy of topical clindamycin in treating acne vulgaris among Bangladeshi people.

b. To monitor the adverse effects encountered during the therapy.

c. To assess the safety and tolerance of drug.

Materials and Methods

Study population

It was a cross-sectional type of descriptive study carried out among 30 patients (15 male and 15 female) suffering from acne vulgaris in skin OPD, Rajshahi Medical College Hospital. It was carried out for a period of 12 weeks. Informed written consent was taken from the patients of the study subjects. Patients data was recorded in pre designed case record sheet. At the base line visit, history of acne regarding duration, relationship to pregnancy, hormonal therapy, sun exposure, food habit and cosmetic use were taken. Patients were asked about previous use of clindamycin and any hypersensitivity to these agents. Family history of acne was also taken.

Inclusion criteria

1. Acne patient of both sex group of age varies from 15 to 35 years.
2. Patient who had not received any treatment for acnes (both systemic and topical) in previous 1-month time.
3. Female who was not on oral contraceptive pill.

Exclusion criteria

1. Patients those who refused to be included in the study.
2. Pregnant and lactating mothers.
3. Known case of clindamycin hypersensitivity.
4. If patients were taking or required any antibiotics and steroids.
5. Married women who were taking oral contraceptives.

Procedure

The diagnosis was made on the clinical basis by assessing morphology of the lesions, age of onset and eir distribution sites. To reach a cilnical diagnosis, detailed history, thorough physical examination ncluding comedone expression, and identification of pupule, pustule on the face, neck, trunk or shoulder region were done. The cases were graded as Grade I - only comedones, Grade II - comedones, papules and pustules (<5), Grade III -comedones, papules and pustules (>5). All particulars were endorsed into the study protocol

Drug administration

Each of the selected patients was advised to apply the topical clindamycin (CLINEX LOTION) twice daily by rubbing softly over the acne lesion after washing the skin thoroughly with warm soap-water and patted dry. Patients were instructed to report every four weeks interval for 3 consecutive months to observe the efficacy and adverse effect of the trial medicine topical clindamycin (CLINEX LOTION).

The drug was continued up to 12 weeks in each case. Patients who failed to report after the initial dose or discontinued the drug prematurely were excluded from the study. At the end of 12 weeks treatment with topical clindamycin (CLINEX LOTION) the drug was discontinued in all cases.

Response of the drug

The efficacy of the drug was assessed from the clinical response to treatment, in every 4 weeks interval by counting the comedones, papules, pustules in different grades of acne. The responses were graded as excellent ? 75% clearing, good 50% -75% clearing, fair 25%-50% clearing, poor <less than 25% clearing. Safety of the drug was assessed by noting irritation and burning, pruritus, erythema, dryness, tenderness and oiliness and expressed as present or absent. The responses in each visit were endorsed into the study protocol

Statistical analysis

Chi-square method of statistical analysis was used to study the response.

Observations and Results

Among the 30 cases, 15 were male and 15 were female. The most common age group was 15-20 years (67%). Majority of patients 21 (70%) had duration of acne from 3 to 6 years with average of 3.33 years before receiving topical clindamycin therapy. Among 30 patients 20(67%) were students, 4(13%) were service holders and 6(20%) were in business and other occupations (table-4). Family history was positive in 14(47%) of cases. 80% of the cases in the study population were unmarried. The cases in this study were as follows:Grade III - 60% (18/30) - i,e, comedones,

papules, pustules (>5),Grade II - 20% (6/30) - i,e, comedones, papules, pustules (<5), Grade I - 20% (6/30) - i,e, only comedones. Improvement was observed on the 1st follow up visit at the end of 4 weeks. Marked improvement was observed after 8 weeks and more marked response was found after 12 weeks of therapy with topical clindamycin. In this study the response was excellent in 73.33% of the cases after 12 weeks of treatment and no poor response was observed (Table 6). Excellent response was observed in the highest percentage (100%, 6/6) in the least severe acne (Grade I). Table 7, shows 100% excellent result in Grade I acne. Excellent response was 83.33% and good response was 16.67% in Grade II acne. Excellent response was 61.11%, good response was 27.78%, Fair response was 5.56% and poor response was 5.56% in Grade III acne. In total, the response was excellent in 73.33%, good in 20%, fair in 3.33% and poor in 3.33% of cases. Statistical analysis by chi-square method in the study revealed P-value < 0.01 which is highly significant. 80% of total study populations were seems to be without any clinical side effect Clinical side effects have been shown in table 8. Side effects were minimum. Oiliness was observed in 6.67% of cases, irritation and burning, pruritus, erythema and peeling were comparatively lower in incidence (3.33% each) but overall side effects were statistically insignificant

Table 1: Different grades of acne (Piamphongsant T 1992)

Severity	Comedones	Papules/pustules	Nodules
Mild	Few- several	Few – several	None
Moderate	Several – many	Several – many	Few
Severe	Numerous	Numerous	Many

Table 2: Age and sex distribution

Age in years	Male (n=15)	Female (n=15)	Total (n=30)
15-20	9 (60%)	11 (73%)	20 (67%)
21-25	4 (27%)	3 (20%)	7 (23%)
26-35	2 (13%)	1 (7%)	3 (10%)

Table 3: Duration of Acne of study population (n=30)

Duration in year	Number	Percentage
<3	8	27%
3-6	21	70%
>6-10	1	3%

Table 4: Occupation Distribution (n=30)

Occupation	Number	Percentage
Student	20	67%
Service	4	13%
Business and others	6	20%

Table 5: Frequency of different grades of acne vulgaris (n=30)

Grade	Number	Percentage
I	6	20%
II	6	20%
III	18	60%

Table 6 : Response to therapy after each 4 weeks during the study (n=30)

Response	4 weeks	8 weeks	12 weeks
Excellent	10 (33.33%)	15(50%)	22 (73.33%)
Good	8 (26.67%)	12 (40%)	6 (20%)
Fair	10 (33.33%)	2 (6.67%)	1 (3.33%)
Poor	2 (6.67%)	1 (3.33%)	1 (3.33%)

Table 7 : Response to topical clindamycin after 12 weeks in different grades of acne vulgaris.

Response	Grade I (n=6)	Grade II (n=6)	Grade III (n=18)	Total (n=30)
Excellent	6 (100%)	5 (83.33%)	11 (61.11%)	22 (73.33%)
Good	0	1 (16.67%)	5 (27.78%)	6 (20%)
Fair	0	0	1 (5.56%)	1 (3.33%)
Poor	0	0	1 (5.56%)	1 (3.33%)
Total	6	6	18	30

Table 8 : Distribution of side effects observed during the study (n=30)

Side effects	No of patients with side effects (n=6)	Percentage
Irritation and burning	1 (16.67%)	3.33%
Pruritus	1 (16.67%)	3.33%
Erythema	1 (16.67%)	3.33%
Peeling	1 (16.67%)	3.33%
Oily skin	2 (33.33%)	6.67%

DISCUSSION

In this study overall response to topical clindamycin in the treatment of acne vulgaris has been observed, which shows 100% excellent result in grade I acne. In grade II acne, 83.33% had excellent response and 16.67% had good response. Where as in grade III, 61.11% had excellent result, 27.78% had good response, 5.56% had fair response and 5.56% had poor response. In total, excellent response is seen in 73.33% of the cases and good in 20%. There is fair response in 3.33% and poor response in 3.33% of the cases. Statistical analysis revealed P-Value <0.01 which is highly significant. This 12 week study found clindagel (Clindamycin phosphate 1%) to be effective in the treatment of acne, with reductions in the number of inflammatory and total acne lesions significantly. Clindagel is safe and effective topical therapy for acne vulgaris. Clindamycin phosphatc is widely used to treat acne vulgaris.7 Topical clindamycin and benzoyl peroxide have each demonstrated clinical efficacy in the treatment of acne vulgaris.9 Patients using the 1% clindamycin lotion experienced reductions in number of pustules, papules, open comedones and nodulocystic lesions. Nearly 90% of the evaluable patients at week 12 experienced improvement or marked improvement in their acne. This study demonstrated the efficacy of 1% clindamycin topical lotion in the treatment of moderate to severe acne vulgaris.25 Topical erythromycin and clindamycin are the most commanly used agents and have similar efficacy in patients with acne.3 Results of the present study are comparable to those results. In this study 67% (20/30) patients are in the 2nd decade and all patients are within 35 years of age. This concurs with the observation that acne is sufficiently common that it often has been termed physiologic.5 However, two thirds of affected teenagers wish that they could speak with their physician about acne, but only one third actually do.3 In my study Clinex lotion (topical clindamycin phosphate 1%) was applied twice daily use. In a study conducted by Rizer - R-L et al at USA in 2001, they compared Clindagel, a unique, water based gel formulation of clindamycin phosphate 1% administered once daily and Cleocin T, a slightly different gel formulation indicated for twice daily use, in the treatment of acne vulgaris. Clindagel was safe and effective and equivalent to Cleocin T gel , albeit with a better tolerability profile.7 Leyden J-J et al 2001 administered 1% Clindamycin topically in a twice daily dose.9 In a comparative study of adapalene gel 0.1% plus clindamycin phosphate lotion 1% with clindamycin lotion 1%, Wolf -J -E Jr et al 2003 applied clindamycin lotion twice daily for 12 weeks.8 The dosage schedule used in the current study thus concurs with these references . A study reported by John E. Wolf Jr. MD, et al 2003 showed greater reduction of inflammatory and non inflammatory lesions in mild to moderate acne vulgaris by combination of clindamycin and adapalene than in clindamycin alone.8 Similarly, Warner,-G-T et al 2002 showed that twice daily application of clindamycin 1% / benzoyl peroxide 5% gel for 10 to 16 weeks was more effective in reducing the number of inflammatory lesions than benzoyl peroxide 5%, clindamycin 1% or vehicle in patients with mild to moderately severe acne.11 Whereas in my study it seems that clindamycin alone was significantly effective in mild to moderate acne vulgaris. This variation may be because they have used combination therapy of clindamycin in their study while in my study clindamycin was used as monotherapy. In this study only one patient reported irritation and burning (3.33%). Similarly one patient developed pruritus (3.33%), one patient complained of erythema (3.33%) , and one patient had peeling (3.33%). Oily skin was observed in two patients (6.67%). These side effects are minimum and insignificant. The clinical side effects of topical clindamycin described in the literature includes facial pruritus, irritation and burning, erythema, peeling, dryness, oily skin and diarrhoea rarely. Only 2 cases of pseudomembranous colitis reported.6,8,12 These symptoms were of mild intensity.8 Although diarrhoea was reported by Kuhlman DS et al 1986, no patients discontinued the protocol because of diarrhea.12 Ronald L. Rizer Ph.D. et al 2001 reported no death or serious adverse events in their study and only 3 severe adverse events- sinusitis, contact dermatitis and dental disorder. All other adverse events were mild or moderate. They also reported moderate facial pruritus that resolved without treatment and mild facial pruritus and irritation that cleared without treatment. Adverse events affecting the skin or appendages were infrequent in a study using clindamycin phosphate 1% in acne vulgaris at USA.7 The same study also reported moderate irritation and erythema at baseline that were improved at endpoint. The study also noted moderate or severe peeling rarely at baseline that disappeared at end point. Moderate or severe oily skin evident at baseline showed a decrease

in mean percent incidence at endpoint. In my study there was no diarrhoea or pseudomembranous colitis. No serous adverse events or death occurred in the present study. The symptoms were of mild intensity that concurs with the references. In this study total number of patients having various side effects were 6 (20%) all of which were mild and ell tolerated. No body had to discontinue the therapy for side effects. In my study dermatological side effects were infrequent and mild that disappeared with the continuation of therapy and completely cured after the treatment completed. Results of the present study were comparable to those reported in the literature.

CONCLUSION

This study confirms that clindamycin is safe and effective topical therapy for mild to moderate acne vulgaris with minimum side effects that subside with continuation of the therapy. Proper selection of patients as well as appropriate topical use of the drug for adequate duration will often result in significant clinical improvement with infrequent and mild adverse effects.

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