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CLINICAL ASSESSMENT OF ROXITHROMYCIN IN TREATMENT OF ACNE VULGARIS; DAILY VERSUS ALTERNATE DOSE COMPARISON

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Abstract:

Aim: *Roxithromycin, one of the latest macrolides, has been shown to be effective against acne in some clinical trials. These trials have been done with once or twice daily dosage schedules. In another closely related macrolide, the effectiveness of azithromycin has been demonstrated on alternative days, we conducted this trial to see whether an alternate day regimen of roxithromycin gives comparable results with those of daily regimen or not.*

Place and Duration: *In the Dermatology department of Bahawal Victoria Hospital (BVH) Bahawalpur for six months duration from October 2019 to March 2020.*

Methods: *The study included 140 patients who were randomly divided into two groups. Patients in group I were treated with 300 mg of roxithromycin once daily for eight weeks. Those in Group II used 300 mg of roxithromycin for alternating days for eight weeks.*

Results: *Results could be evaluated in 125 patients, with 15 patients lost to follow up. Out of 60 patients in Group-I, 32% showed good (>50%) improvement, 57% moderate (25-50%) and 10% slight (<25%) improvement. Of the 65 evaluable patients in Group-II, 28% showed good, 55% moderate and 14% slight improvement. Using chi-square tests the difference between the results of the two groups was found to be insignificant (p>0.5). Side effects noted were transient and were nausea, slight gastric upset and diarrhea in 10% patients in Group-I and 4.6% patients in Group-II.*

Conclusion: *As a result, it was found that the alternative day dosing system is almost as effective, but safer and more economical than the day dosing system.*

Keywords *Roxithromycin, acne vulgaris*

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INTRODUCTION:

Acne is a common disease, especially observed in adolescents and occurs due to chronic inflammation of pilosebaceous units. It is a polymorphic disease in which various lesions such as blackhead, pediatrics, pustules, nodules and actively chopped lesions are observed in various lesions, such as secondary or hypertrophic scars. More than one factor plays a role in pathogenesis[1-2]. This oil channel includes the nickname infundibulum, increased production and retention of sebum, propionibacterium acnes and overgrowth of inflammation production[3-4]. The anaerobic P. acnes proliferates in the obstructed lipid rich lumen of pilosebaceous units, where O2 tension is low. It produces biologically active mediators that can lead to the formation of micro foods as well as causing inflammation. Oral antibiotics are the most commonly prescribed oral treatment worldwide, including commonly used antibiotics tetracycline, oxycline, methicillin, minocycline, erythromycin and azithromycin[5-6]. Roxithromycin has been shown to be effective acne in some clinical trials. These studies were conducted once or twice a day with drug programs. Azithromycin, another closely related macrolide, alternative regime of the day has been shown to work well[7-8]. We performed this trial to see whether an alternate day regimen of roxithromycin gives comparable results with those of daily regimen or not.

PATIENTS AND METHODS:

It was an open prospective clinical trial held in the Dermatology department of Bahawal Victoria Hospital (BVH) Bahawalpur for six months duration from October 2019 to March 2020. One hundred and forty patients with acne vulgaris were selected for the study. The patients with a history of diabetes, pregnancy and steroid or antibiotic use were excluded from the study. Each patient has been fully examined and his detailed history has been taken. The necessary data, including the location, size and type of lesion, were recorded in the specified proforma. The changes were evaluated according to the simplified classification proposed by Clark7: 1- mild: comedones present accompanied by a few superficial inflammatory lesions. 2- moderate: Many inflammatory lesions, largely superficial, but more deep-seated pustules evident and tendency of these lesions to scar with time. 3- severe: Nodules and cysts with marked scarring. Patients were randomly divided into two groups. Patients in group I received 300 mg/day of roxithromycin for 8 weeks before meals. Patients in group II received 300 mg of roxithromycin on alternate days for 8 weeks before meals. Patients were called for follow-up every 2 weeks. During each visit, symptomatic and overall improvements were evaluated. Any side effects have been observed. Studies such as routine blood tests, kidney and liver profile were conducted at the initial level, four weeks and at the end of the study. The overall assessment was made 8 weeks after initiation of treatment. Clinical improvement is assessed as follows, 1: good (50%), 2: medium (25-50%), 3: light (&25%), 4: unchanged, 5: deterioration. Side effects are correctly defined when present. The Chi-square test was used for statistical analysis.

RESULTS:

At the end of the study, the results were evaluated in 125 patients (60 in group I and 65 in Group I). Fifteen patients were lost during follow-up. The severity of the disease in this study was as follows: 37% of patients had severe acne, 40% of patients had moderate acne, 23% of patients had mild acne. These patients were separated almost evenly into two groups (Table 1).

Table 1 Patients with various grades of acne.

	Mild	*Moderate*	*Severe*
Group-I (n=60)	15 (25%)	23 (38.3%)	22 (36.7%)
Group-II (n=65)	14 (21.5%)	27 (41.5%)	24 (36.9%)
Total (n=125)	29 (23.2%)	50 (40%)	46 (36.8%)

In Group I, the proportion of women to men was 4:3 and in group II 3:2. The mean age of patients in group I was 19+4 and 20.5 + 5 in Group II. The overall proportion of patients who improved well was 30%; Fifty-six% showed a moderate improvement, while 12% showed a slight improvement. In group I, 32% of patients had a good recovery, 57% had moderate improvements and 10% improved slightly. In Group II, 28% of patients showed good recovery, 55% moderate improvement and 14% slight improvement (Table 2).

Table 2 Results of treatment

	Good improvement	*Moderate improvement*	*Slight improvement*	*No improvement*	*Worsening*
Group-I (n=60)	19 (31.7%)	34 (56.7%)	6 (10%)	1 (1.7%)	0
Group-II (n=65)	18 (27.7%)	36 (55.4%)	9 (13.8%)	1 (1.5%)	1 (1.5%)
Total (n=125)	37 (29.6%)	70 (56%)	15 (12%)	2 (1.6%)	1 (0.8%)

The overall proportion of patients with good or moderate improvement in Group I was 88%, compared to 83% in Group II. Statistically, the difference between the results of the two groups was not significant (p>0.5). Patients suffering from severe and moderate acne have also been shown to be better responding to roxithromycin than patients suffering from mild acne. In regard to side effects of nausea, mild stomach discomfort and diarrhea observed 6 (10%) Group I and 3 (4.6%) patients in group II. These side effects were treated with temporary and symptomatic treatment.

DISCUSSION:

This study showed that roxithromycin is an effective remedy for acne. The efficacy of roxithromycin in acne is due not only to the reduction in number of P. acnes, but also due to inhibitory effects on the production of bacterial lipases, P. acnes associated inflammatory mediators and therefore on the activity of neutrophil chemotaxis[9-10]. In addition, roxithromycin has been reported to accumulate in the pilosebaceous system and has some antiandrogenic effect. Numerous studies have shown the efficacy and safety of acne erythromycin, but unfortunately, associated with a number of defects, including a narrow spectrum of activity, short half-life, intolerance to the gastrointestinal tract and a significant number of drug-drug interactions[11-12]. Since acne treatment includes long-term antibiotic therapy, a long crescent agent can be very useful in improving the patient's compatibility. The latest macrolides are neothramycin, and the pharmacokinetic profile of roxithromycin makes them appropriate factors in this regard[13]. In this study, 88% of patients with roxithromycin 300 mg daily resulted in good or moderate improvement, while 300 mg of 500 mg of roxithromycin on alternative days showed the same degree of improvement in 83% of patients. These results are a little similar to Akamatsu et al.'s. Comparing 150 mg to 150 mg of roxithromycin once daily for 8 weeks, good or moderate improvement was observed in 75% (16/16) and 71.4% (10/14) of patients in two groups, respectively. However, the proportion of patients (27.7%) is much higher in our study showing only good improvement with a less frequent dosage program (300 mg on alternative days) (7.1%) with less frequent dosage observed by Akamatsu et al (once 150 mg per day) showing only good improvements. Kapadia and Talib used 500 mg of azithromycin three times a week for 12 weeks in 35 patients and were observed noticeably (60-80%) 82.9% of patients. Alternately the days we have seen comparable results with 300 mg of 500 mg of paraxithromycin[15]. It is very important to take into account the cost of treatment when treating patients with antibiotics for a long time (especially for poor people in our region), drug tolerance and patient compliance.

CONCLUSION:

The results of this study show that by prescribing 300 mg of roxithromycin on alternate day, rather than every day, we can reduce the total cost of treatment and increase drug tolerance and patient compatibility. However, more research is required to determine long-term efficacy and tolerance.

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