

Efficacy and safety of Oral Azithromycin in the Treatment of Mild to Moderate Acne Vulgaris

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Abstract

Background: Acne is a very common skin disorder in our society. Azithromycin, an oral macrolide, has been found to be a new treatment for this disease.

Objective: To assess the efficacy and safety of alternate day oral azithromycin 500 mg in the treatment of mild to moderate acne vulgaris.

Design: A quasi – experimental study.

Place and Duration of Study: The study was conducted at the Department of Dermatology, Unit – I, KEMU / Mayo Hospital, Lahore, during the six months period from 11th April to 10th October, 2009.

Subjects and Methods: One hundred and twenty patients of acne vulgaris were enrolled and baseline lesions were recorded. All patients were advised to

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take azithromycin 500 mg thrice a week orally for a period of 8 weeks after which they were followed up for the next 8 weeks at 2 weeks interval. The mean facial lesion count at baseline and after 8 weeks therapy was performed in all the cases. The treatment was considered excellent if there was clearance of >80% of lesions, good at 50 – 80% clearance and poor if there was clearance of < 50% of lesions. The safety of treatment administered was assessed on the basis of local or systemic side effects of the drug.

Results: Out of 120 evaluable patients, there were 53 males and 67 females. Mean age of the patients was 21.2 ± 4.1 years. The mean facial lesion count after 8 weeks therapy was much reduced. The treatment revealed an excellent response in 79 (66%) patients, good in 31 (26%) and poor in 10 (8%) cases. Azithromycin was well tolerated by all the patients.

Conclusion: Azithromycin 500mg thrice weekly for 8 weeks is found to be an effective and safe treatment for acne vulgaris.

Key Words: Acne, vulgaris, azithromycin, macrolide.

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Introduction

Acne is primarily seen in adolescents and occurs due to chronic inflammation of pilosebaceous units.^{1,2} It is characterized by a variety of lesions such as comedones, papules, pustules and nodules followed by pitted or hypertrophic scars.^{2,3} Multiple factors are involved in the pathogenesis including increased production and retention of sebum due to plugging of infundi-

bulum of the sebaceous ducts, overgrowth of *Propionibacterium acnes* (*P. acnes*) and induction creation of inflammation.³⁻⁵ The anaerobic *P. acnes* is believed to play a major role in the induction of inflammation by producing lipases, proteases, hyaluronidases and chemotactic factors.^{3,5}

The choice of treatment depends upon clinical severity of disease.¹ Mild acne needs topical therapy while in moderate to severe acne, systemic treatment is also required in the form of antibiotics, hormonal therapy and oral retinoids.^{1,4} Tetracycline, doxycycline, minocycline and erythromycin are the most widely used oral antibiotics worldwide.^{1,4,6} Adverse effects with oral antibiotics are common, since they are taken for prolonged periods, and compliance is sometimes also a problem.¹

Recently, azithromycin has been used in acne patients.^{1,4,5} It has a long tissue half – life and requires less frequent dosage, which is useful in increasing the compliance and tolerability of the patient.^{1,4,5,7} The present study was planned to assess the efficacy of oral azithromycin 500mg thrice a week in acne vulgaris in our patients because no study of this kind has previously been done in our community.

Patients and Methods

This was an open clinical trial (interventional quasi-experimental study). The study was conducted in the Outpatient Department of Dermatology Unit – I, King Edward Medical University / Mayo Hospital, Lahore, from 11th April to 10th October, 2009 after approval from the Hospital Ethical Committee and informed consent from the patient. A complete medical history and clinical assessment was recorded. One hundred and twenty patients of either sex, more than 13 years of age, with mild to moderate acne (comedones, papulopustules and few nodules with no scarring) of 03 months duration, were enrolled.

Patients who had been on any topical medication for acne during the last 02 weeks or oral medication during the last 04 weeks were excluded from the study. The pregnant and lactating females were also excluded. Patients with concomitant skin disease such as rosacea, melasma, hidradenitis suppurativa etc. and having co-morbidity on history and previous investigations such as diabetes mellitus, chronic liver disease and chronic renal failure, were also excluded.

Those patients who fulfilled the inclusion and exclusion criteria were enrolled and baseline lesions

were recorded. All patients were advised to take azithromycin 500 mg thrice a week orally for a period of 8 weeks. They were asked not to use anything topical for acne vulgaris other than prescribed treatment and use non-medicated, hypoallergenic soaps during the study period. All patients were followed at 2 week intervals during the treatment period of 8 weeks. The number of lesions was calculated at the beginning of the treatment (baseline) and at two weekly intervals for subsequent visits. The difference between the number of lesions observed was noted to evaluate the efficacy of therapy. The efficacy was assessed according to the protocol i.e. excellent if there was clearance of > 80% of lesions, good at 50 – 80% clearance of the lesions and poor if there was clearance of < 50% of lesions. Patients were further followed up for a period of 8 weeks after the end of treatment.

All the data was entered into SPSS version 11 and analyzed accordingly. The quantitative variables like age and number of acne lesions were presented by calculating mean and standard deviation. The qualitative variables like gender, marital status, occupation and efficacy of drug after 8 weeks of treatment were also presented by calculating frequency and percentages. A *p* value equal to or less than 0.05 was considered statistically significant.

Results

A total of 125 patients were enrolled in the study, out of which 120 patients completed the study. There was 1 delayed exclusion while 4 patients were lost to follow-up. The age range noted was 14 – 30 years with (mean age, 21.2 ± 4.1 years). Out of 120 evaluable patients, there were 68 (56.7%) patients in the age range of 14-20 years, 32 (26.7%) between 21 – 25 years and 20 (16.6%) patients in the age range of 26 – 30 years. There were 53 (44.2%) males and 67 (55.8%) females with a male to female ratio of 1:1.8. Regarding the marital status, 28 were married and 92 unmarried. Majority of patients had their disease for the last 3 weeks to 1 month (40%), 1 to 2 months (35%) and 2 to 3 months (25%). Most of the patients were students (50.8%), followed by housewives (18.2%), businessmen (9.2%), teachers (6.7%), office workers (6.7%), laborers (6.7%) and doctors (1.7%).

The mean facial lesion count at each 2 week interval and after 8 week therapy was much reduced (Fig. 1 and 2). The difference between the number of lesions observed at baseline and after 8 week treatment was

noted. A clearance of 90% was observed in 79 patients followed by 56% clearance in 31 patients and 40% clearance in 10 patients. So, the drug showed excellent response in (66%) patients, good response in (26%) and poor in (8%) cases (Fig. 3). The beneficial effects were maintained for further 8 weeks in post treatment follow-up period.

In our study, adverse events noted were nausea in 3 (2.5%) patients, heartburn in 2 (1.6%) and diarrhea in 2 (1.6%) cases. All the adverse events were mild in intensity and these alleviated after taking symptomatic

treatment, successfully. Azithromycin was well tolerated by all other patients.

Discussion

Acne vulgaris is a common disorder affecting nearly 80% of individuals between the ages of 12-24 years.¹ While acne does not affect health overall, its impact on emotional well – being can be critical and is associated



Fig. 1a: Papulopustular lesions before treatment



Fig. 1b: Lesions reduced after treatment



Fig. 2a: Papulopustular lesions before treatment

Fig. 2b: Lesions reduced after treatment

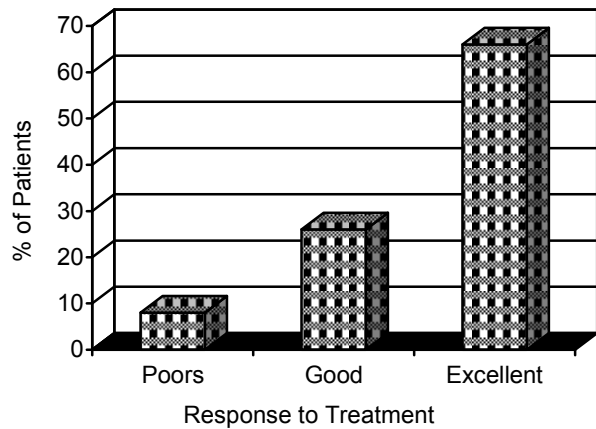


Fig. 3: Efficacy of Azithromycin.

with depression, anxiety, and higher than average unemployment rates.^{1,2} The present study was designed to evaluate the efficacy and safety of a new drug azithromycin which belongs to the azalide group of antibiotics and is closely related structurally to macrolides like erythromycin.^{1,5} It is more tissue stable, penetrates deeply into tissues and has a higher terminal half-life than erythromycin.^{1,5} A weekly pulse dose schedule of azithromycin has recently been introduced to treat acne for a period of 3 months and it significantly increase patients' compliance because of the reduced total number of administered drugs.^{1,5-7}

Most of the patients in our study were in the 14-20 years age group, similar to the trend seen worldwide.^{1,5} This is probably due to the fact that hormones at adolescence are at their peak in this age group.^{1,3,5} In the present study, a greater preponderance of females was observed as compared to males. This is in contrast to other international studies¹⁻⁵ and can be attributed to the fact that females are more conscious of their cosmetic disfigurement and tend to present earlier than males in our society.¹

In our study, 90% clearance was observed in 79 patients followed by 56% in 31 patients and 40% clearance in 10 patients. In comparison of the efficacy profile during each follow-up visit, the drug was found to be effective in the reduction of lesions which is statistically significant ($p < 0.05$). This also correlates with other international studies.^{1,5,8,9}

The improvement in clearance of acne lesions in present study was seen in 92% patients with (> 56 – 80% clearance) which is in accordance with the study by Bardazzi *et al.* who found remarkable improvement with maximum clearance (> 50%) in 90.4% patients.¹ The studies by Wahab *et al.* and Kapadia *et al.* found

azithromycin to be efficacious in 80% and 82.9% patients respectively while Rafiei and Yaghoobi found azithromycin to be efficacious in 84.7% patients.^{5,9,10} The discrepancy in efficacy of azithromycin among different above mentioned studies is because of different treatment regimens and grades of acne selected in various studies.⁸⁻¹³ The poor response seen in few patients (8%) is probably due to the fact that these cases have more non-inflammatory lesions and the drug has been found less effective in non-inflammatory lesions which is in accordance with other studies.^{1,9,11}

The drug was well tolerated in our study. However, adverse events were reported in 5.7% patients but were of mild intensity and reversible in nature. The side effects noted with azithromycin in other studies were similar and the incidence and severity was also lower which is in accordance with our study.^{8,10}

Conclusion

The present study concluded that oral azithromycin 500 mg thrice weekly for 8 weeks, appears to be an effective and safe treatment for mild to moderate acne in adolescents.

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