Efficacy of Azithromycin Pulse Therapy in Acne Vulgaris Treatment: A Hospital Based Study

Sanjeev Sharma, Priyank Kumar¹, Sanjay Banjare², S K Jain³ Professor and Head, Department of Pharmacology, Teerthankar Mahaveer Medical College and Research Centre, Moradabad, India, ¹Assistant Professor, Department of Dermatology, Teerthankar Mahaveer Medical College and Research Centre, Moradabad, India, ²Post Graduate Student, Department of Pharmacology, Teerthankar Mahaveer Medical College and Research Centre, Moradabad, India, ³Professor, Department of Anatomy, Teerthankar Mahaveer Medical College and Research Centre, Moradabad, India

Corresponding Author: Dr. S K Jain, Professor, Department of Anatomy, Teerthankar Mahaveer Medical College and Research Centre, Moradabad, India. Phone - +91-9997168754. E-mail: drskjain2005@rediffmail.com

Abstract

Background: Acne vulgaris or simply (acne) is a common dermatological problem. Acne most commonly seen in adolescence age, caused by increased androgens in both sexes. It is caused due to *Propionibacterium acnes*. In spite of many range of antibiotics available Azithromycin is one of the antibiotics that has been recently prescribe for treatment of acne which is as effective as doxycycline and minocycline. This study is undertaken to see the efficacy of Azithromycin in treatment of acne vulgaris.

Methods: This study is performed on 200 patients (100 male & 100 females) in Teerthankar Mahaveer Medical College and Hospital Moradabad, using special grading system GAGS. The exclusion criteria for the study were pregnancy, a history of macrolide sensitization and retinoid therapy.

Results: Grade I patient showed effect of 80%. Grade II 90% recovery. Grade III is also effective as a 90% recovery, but Grade 4 were not much effective only 40% recovered.

Conclusion: This study showed that azithromycin has greatest advantage over other systemic antibacterials in acne because it is long acting drug and can be used in single dose three times weekly.

Keywords: Acne vulgaris, GAGS & Propionibacterium acnes

INTRODUCTION

Acne vulgaris is a common inflammatory disorder of the Pilo-sebaceous follicles. It is a multi-factorial disease and its patho-physiology centers on the interplay of follicular hyper-keratinization, colonization with *Propionibacterium acnes* (PA), increased sebum production, and inflammation.

This disease has a high prevalence, occurring mainly in adolescence. Although the peak of prevalence is around the 17th year of life, acne lesions can appear earlier and are not uncommonly observed in the age group ranging from 12 to 14 years, in which the condition is under reported.¹

Antibiotic therapy has long been found useful in the management of moderate-to-severe acne vulgaris. Mechanisms of action include suppressing growth of PA, reducing the production of inflammatory mediators, and acting in immune modulation.

Commonly prescribed antibiotics include tetracyclines, doxycycline, minocycline, limecycline and erythromycin. Azithromycin is one of the antibiotics that has been recently prescribe for treatment of acne which is at least as effective as doxycycline and minocycline.²⁻⁵

Aziythromycin is a nitrogen-containing macrolide antibacterial agent and a methyl derivative of erythromycin with actions and uses similar to those of erythromycin.^{6,7} Its extensive distribution in the tissues allows pulse-dose regimen recommendation for increased compliance.⁸

MATERIAL & METHOD

The primary focus of this open-label non-comparative therapeutic study was to assess the efficacy of 500 mg of azithromycin thrice weekly (once on every other day) for 8 weeks in the treatment of Acne vulgaris in TMU patients. This study enrolled 200 patients from the outpatient dermatology clinic at Teerthankar Mahaveer hospital during the period from December 2012 to December 2013. Patients were examined by dermatologists and an assessment was made, including a full count of acne lesions, we used special grading system of GAGS. The lesions were counted at the beginning of the treatment and at weeks. The difference between the number of lesions observed at baseline and the number seen in subsequent examinations was used to evaluate the efficacy of therapy. At every check-up we assessed the clinical response to azithromycin, any adverse events, and patient tolerance. The exclusion criteria were pregnancy, a history of macrolide sensitization and retinoid therapy. Patients with relapsing acne previously treated with antimicrobials such as doxycycline, minocycline, and erythromycin were eligible to be enrolled in the study after a six-month wash-out period. No topical therapy was associated. Patients were advised not to undergo any beauty procedures, such as chemical peels, bleaches during the study period. All patients were also evaluated at 2 months, post-treatment follow-up visit. 200 hundred patients 100 male and 100 female 17-25 yrs of age and with mild to severe acne (score of acne 19-38), in the Global Acne Grading System (GAGS), were included in the study.9 Every patient was being exact physical examination and graded by GAGS. In GAGS: Acne patients were assigned into 4 grades.

- Mild = 1-18 Score,
- Moderate = 19-30 Score
- Severe = 31-38 Score
- Very Severe >39 Score⁹

In this study patients were excluded if: Global acne score was greater than 39 or lower than 19. Concomitant use of anti-androgenic drugs Isotretinoin use in the last six months Participants were awarded and investigators got written informed consent from them. After that, they were allocated to four groups as a grading system. We prescribed Azithromycin in these groups as follow:

Grade I: 500 mg Azithromycin as initial dose followed by 500 mg weekly pulse doses for 8 week.

Grade II: 500 mg Azithromycin as initial dose followed by 500 mg weekly pulse doses for 8 week.

Grade III: 500 mg Azithromycin as initial dose followed by 500 mg weekly pulse doses for 8 week.

Grade IV: 500 mg Azithromycin as initial dose followed by 500 mg weekly pulse doses for 8 week.

We followed patients over a 08-week period and visited them monthly. At each visit, acne lesions were assessed by blinded dermatologist to treatment protocols and GAGS was used to evaluate the response of patients to treatment. The patient visits were done at the end of first, second and third month.

Table 1: Grading of acne vulgaris using visual analogue scale

Grade	Score	Observation
Grade 1 (Mild)	1-18	Microcomedone
Grade 2 (Moderate)	19-30	Comedone
Grade 3 (Severe)	31-38	Inflammatory Papule/Pustule
Grade 4 (Very-severe)	>38	Nodule Nodulo-Cystic

RESULTS

At this open therapeutic trial 200 patients were enrolled (100 males, 100 females) all of them were teenagers and adolescents (ages 17-50 years) with moderate-sever papulo-pustular acne. Grade I patient were achieved good excellence effect 80%. Grade II is also effective as 90% recovery. Grade III is also effective as a 90% recovery. But Grade 4 were not much effective only 40% recovered. And around over all total efficacy of the Azithromycin was 75% for treatment of acne vulgaris.

Table 2: Evaluation of efficacy of therapy

Grade of Response	% of Reduction of Acne	
Grade I	Up to 80%	
Grade II	Up to 90%	
Grade III	Up to 90%	
Grade IV	Up to 40%	

Table 3: Over all distribution of all acne patients (%)

Grade	Male	Female	Recovered Patient	Total % of Recovered Patient
Grade 1	15	35	40	80%
Grade 2	35	15	45	90%
Grade 3	20	30	45	90%
Grade 4	30	20	20	40%
Total	100	100	150	75%

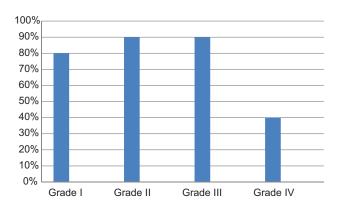


Figure 1: The efficacy of Azithromycin pulse therapy in acne vulgaris treatment

DISCUSSION

Acne is multifactorial disease primarily of teenagers with follicular plugging and inflammation. It is the most common skin disease; affecting almost every individual during puberty.^{10,11}

Despite the initially high default (expected in our community and circumstances, and this could be partially explained by the delayed response of acne lesions), the response rate and compliance of our patients was encouraging. But the compliance was much improved in those who continued treatment and noticed a desirable response. Also the easy dosing schedule and the higher tolerability of the drug contributed to this compliance. The use of mobile phone for communication had helped us greatly in follow up and to encourage patients continue treatment. The side effects reported were few (gastric upset, abdominal pain, diarrhea and headache) and fortunately, no serious reaction reported. Our patients achieved over all response (75%). Federico who reported a good-excellent response of 90.4% after 4 weeks of therapy⁸ and slightly higher than Singhi¹² who reported a response of 70.25 %. Gruber et al¹³ compared azithromycin with minocycline and observed a satisfactory clinical response (70-75%) with both the drugs. These findings suggest that azithromycin is a better alternative in patients with moderate to severe acne and has no serious side effects. This study showed that azithromycin has greatest advantage over other systemic antibacterials in acne because it is long acting drug and can be used in single dose three times weekly, no other acne drug has this property. Another advantage is the relatively long disease-free period after discontinuation of therapy which may be explained by the fact that azithromycin persists in tissues for long period. 11,12 The drawback of this study is that it is open-labeled non comparative, but it threw alight to the tolerability, efficacy and safety of this drug in acne, since till now it is not so widely used in India and we expect the chance of Propionibacterium acnes resistance to be much lower than to other systemic antibacterials used for acne. The stability of azithromycin in gastric acid may be responsible for the low incidence of gastrointestinal disturbances which is very troublesome in the tetracyclines. Photosensitivity not reported in any patient, though we used the drug during summer season. This is another advantage of azithromycin over other

antibacterials used in acne. Proper patient selection is mandatory as patients with inflammatory acne responded better than those with comedonal acne because the mode of action of azithromycin is mainly antibacterial and anti-inflammatory, but not keratolytic. Further studies are required to identify the optimum dose and duration of therapy and to compare the efficacy of the drug with other systemic antibacterials.

CONCLUSION

This study showed that azithromycin has greatest advantage over other systemic anti bacterials in acne vulgaris because it is long acting drug and can be used in single dose three times weekly, no other acne drug has this property and its persistence in tissues is more as compared to other antibiotics.

REFERENCES

- Herane MI, Ando I. Acne in infancy and acne genetics. Dermatology 2003; 206:24-28.
- Fernandez-Obregon AC. Azithromycin for the treatment of acne. Int J Dermatol. 1997;36:239-40.
- Fernandez-Obregon AC. Azithromycin for the treatment of acne. Int J Dermatol 2000; 39:45-50.
- Kus S, Yucelten D, Aytug A. Comparison of efficacy of azithromycin vs. doxycycline in the treatment of acne vulgaris. Clin Exp Dermatol 2005; 30:215-20.
- Gruber F, Grubisic-Greblo H, Kastelan M, Brajac I, Lenkovic M, Zamolo G. Azithromycin compared with minocycline in the treatment of acne comedonica and papulo-pustulosa. J Chemother 1998; 10:469-73.
- Peters DH, Friedel HA, McTavish D. Azithromycin. A review of its antimicrobial activity, pharmacokinetic properties and clinical efficacy. Drug 1992; 44:750-99.
- Alvrez-Elroco S, Enzler MJ. The macrolides. Erythromycin, clarithromycin and azithromycin. Mayo Clin Proc 1999; 74:613-34.
- Lalak NJ, Morris DL. Azithromycin clinical pharmacokinetics. Clin Pharmacokinet 1993;25:370-4.
- Hardy DJ, Henesey DM, Beyer JM, et al. Comparative in vitro activities of new 14-, 15-, and 16-membered macrolides. Antimicrob Agents Chemotherapy 1988; 32: 1710-1719.
- Neu HC. Clinical microbiology of azithromycin. Am J Med 1991; 91 (Suppl. 3A): 12S-18S. 8. Federico B, Francesco S, Gianluca P. et al. Azithromycin: A new therapeutical strategy for acne in adolescents. Dermatology Online Journal 13 (4): Volume 14 Number 3.
- Wolfram S, Paus R, Burgdorf W. Thiem clinical companion Dermstology. Diseases of sebaceous glands. George Thiem Verlag, Germany 2006;ch 34.530.
- Singhi MK, Ghiya BC, Dhabhai RK. Comparison of oral azithromycin pulse with daily doxycycline in the treatment of acne vulgaris. Indian J Dermatol Venereol Leprol 2003;69:274-6.
- Gruber F, Grbisic-Greblo H, Kastelen M, et al. Azithromycin compared with minocycline in the treatment of acne comedonica and papulo pustulosa. J Chemotherapy 1998;10: 269.

How to cite this article: Sanjeev Sharma, Priyank Kumar, Sanjay Banjare, S K Jain. "Efficacy of Azithromycin Pulse Therapy in Acne Vulgaris Treatment: A Hospital Based Study". International Journal of Scientific Study. 2014;1(4):21-23.

Source of Support: Nil, Conflict of Interest: None declared.