

EFFICACY OF ROXITHROMYCIN 300MG TWICE DAILY IN TREATMENT OF CHRONIC INFECTIONS

C. DEEPA LATHA*, G. NAGAVENI, G. VIJAYALAKSHMI

Associate Professor, Bhaskar Medical College, Yenkapally (V), Moinabad (M), Email: cdeepalatha@gmail.com

Received: 21 August 2011, Revised and Accepted: 30 September 2011

ABSTRACT

Aim: To evaluate safety and efficacy of Roxithromycin 300mg twice daily in treatment of chronic infections.

Methods: This is an open label, noncomparative, post marketing surveillance study conducted at various clinics across the Hyderabad city. Where 60 patients of various chronic infection were enrolled. All patients were administered Roxithromycin 300mg twice daily for a period of 3 to 14 days. Response to therapy was assessed at end by four point scale of excellent, good, satisfactory and poor.

Result: The overall clinical response was rated as excellent and good for chronic respiratory infections and moderate to good for gastrointestinal infections when compared to other infections.

Conclusion: Roxithromycin 300mg BD is effective and well tolerated in treatment of chronic respiratory infections.

Key words: AECB: Acute exacerbation of chronic bronchitis, BD: Twice daily.

INTRODUCTION

Infections are most common cause of hospital admission and antibiotics play a major role in treatment of various infections like chronic respiratory infections, ear infections, nose, throat, genitourinary infections and skin and soft tissue infections.

Roxithromycin is good option when selecting antibacterial therapy for respiratory tract infections,¹ as it is well tolerated and has low propensity to produce clinically significant drug-drug interactions. Advantage of Roxithromycin lies in that it is acid stable Macrolide characterized by excellent absorption and penetration in respiratory tissues and fluids. It attains high tissue concentrations that are maintained for prolonged period.

Apart from having good antibacterial action it also has additional anti-inflammatory action.² Roxithromycin therapy decreases production of pro-inflammatory cytokines and decreases sputum production. These anti-inflammatory actions are beneficial for patients suffering from chronic respiratory infections such as chronic sinusitis & chronic bronchitis. Clinical efficacy has been confirmed in treatment of community acquired pneumonia, atypical pneumonia, ear, nose, and throat infections, skin & soft tissue infections

MATERIALS AND METHODS

Study design

The study was a prospective, non-comparative, post-marketing surveillance study to evaluate the efficacy and safety of Roxithromycin. This study was conducted at various clinics across Hyderabad city, Andhra Pradesh.

Study subjects

Patients of either sex and above 12 years of age with clinical or radiological diagnosis of various chronic infections were screened for enrollment. Patients who had received any form of antimicrobial therapy during the previous 12 hours were excluded from the study. Also patients with known hepatic or renal insufficiency and critically ill patients were excluded.

Interventions

All enrolled patients received Roxithromycin 300mg tablets and administered two times daily for a period of three days to 14 days, based on the severity of infection and clinical response to treatment. Patients were followed up on days 3, 5, 7, and 14 after baseline.³

Assessments

Assessments for efficacy was made based on the response to therapy which was assessed by the investigator at the end of therapy based on a four-point scale of excellent, good, satisfactory & poor.

Statistical analysis

Data from all the patients irrespective of non-completion was analyzed for efficacy and safety. Data is expressed as numbers and percentages for the category. Efficacy outcomes are expressed as numbers and percentages.

P value significant with positive correlation < 0.05.

RESULTS

Out of total 60 patients

Patients of respiratory tract infection are 33 and clinical symptoms assessed are Cough, breathlessness, wheeze and fever, with excellent to good results covering average of 26% and 57%.

10 patients of Gastroenteritis with pain abdomen, loose stools and vomitings were administered and response seen were good to satisfactory covering 12% & 40%.

Satisfactory response was seen in 60% patients with uncomplicated urinary tract infections with symptoms of burning micturition, pain during voiding of urine and dysuria.

Out of 7 patients with acute suppurative otitis media with pain, discharge. 1 patient had excellent response and 2 were showing good response with 4 patients showed satisfactory results.

ADVERSE EVENTS

No adverse events were reported which were related to the Roxithromycin therapy during the study period. None of the patients discontinued the treatment due to drug related adverse effects.

DISCUSSION

Roxithromycin has proven efficacy in the treatment of respiratory tract infections with 55% improvement in good & 20% in excellent category when compared to other infections⁴. In a study on 60 patients, the efficacy and tolerability of Roxithromycin was compared with cefexime in treatment of chronic respiratory infections. At the end of the study treatment period, clinical cure rates were 100% for Roxithromycin and 94% for cefexime.

Table 1:

| Infections | Excellent (No of patients) | Good (No of patients) | Satisfactory (No of patients) | Poor (No of patients) |
|--|-------------------------------|--------------------------|----------------------------------|--------------------------|
| RESPIRATORY INFECTIONS (33) | | | | |
| AECB(11) | 26%(3) | 56.5% (6) | 17.3% (2) | nil |
| Asthmatic bronchitis (12) | 22.2% (2) | 57.0% (6) | 20.9% (2) | 2%(2) |
| Community acquired pneumonia (10) | 20.7% (2) | 57.1% (6) | 22.3%(2) | nil |
| Gastroenteritis (10) | 5%(1) | 12%(2) | 40% (4) | 30% (3) |
| Urinary tract infections (10) | nil | 10% (1) | 60%(6) | 30% (3) |
| Ear infections (7) | 11% (1) | 30% (3) | 40% (3) | nil |

Roxithromycin at a daily dose of 300mg twice daily is effective and well tolerated in treatment for Respiratory tract infections when compared to other infections.

CONCLUSION

Roxithromycin 300mg twice daily is effective and well tolerated in treatment of chronic respiratory infections

REFERENCES

1. Dr. A. O Parikh M.D FCPS, Indian Medical Gazette. May 2010, Vol. CXLIV, Pages 181-185.
2. Drugs. 37(1):8-41, Jan 1989.
3. American Journal of Medicine. Volume 117, Issue 9, Supplement 1, 26-29 (8 November 2004).
4. Yonsei Medical Journal Volume 41, 3, pp 340-344, 2000.