

# EVALUATION OF ROXITHROMYCIN IN THE TREATMENT OF UROGENITAL CHLAMYDIAL INFECTIONS

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## ABSTRACT

**Background.** Chlamydia trachomatis infections represent the most frequent sexually transmitted disease in developed countries and probably also worldwide. In women the inflammation may spread to involve the internal reproductive organs, which may lead to extrauterine pregnancy and tubal infertility.

**Methods.** Twenty patients (15 men and five women) with proven chlamydial infection of the lower urogenital tract were treated with the macrolide antibiotic roxithromycin in a single daily dose of 300 mg for 10 days. Before the treatment, the causative organism was detected with a direct immunofluorescent method in swab specimens collected from the urethra and/or cervical canal. The test was repeated after the treatment.

**Results.** Microbiological cure was achieved in 19 patients (95%), and clinical symptoms disappeared in all 20 patients studied (100%).

## KEY WORDS

*Chlamydia trachomatis, urogenital infections, roxithromycin*

## INTRODUCTION

Infections with Chlamydia trachomatis represent the most frequent bacterial sexually transmitted disease in developed countries and probably also in the entire world. Every year about 500 million individuals are infected all over the world, and between five and six million new cases occur in the United States (1). Urogenital infections, predominantly urethritis and epididymitis in men and urethritis and/or cervicitis and salpingitis in women, are caused by C. trachomatis serotypes D to K.

The infection is transmitted mainly by sexual contact (2, 3) and rarely from the genitalia to the

eyes or vice versa. It occurs in young sexually active persons, mostly between 15 and 35 years of age. Up to 70% of women and up to 20% of men have no symptoms (4). The clinical manifestations in men include dysuria with different forms of discharge; complications such as prostatitis, epididymitis and proctitis are uncommon. Symptoms in women are described in extenso in the manuscript by Vrtačnik-Bokal et al.

In our study we tried to evaluate the macrolide antibiotic roxithromycin (Renicin, LEK Pharmaceuticals and Chemicals d.d. Ljubljana) administered on an out-patient basis. We selected roxithromycin because it has the greatest bioavailability among macrolides

and a long elimination half-life, attains high plasma concentrations and shows excellent tissue penetration. The drug achieves high concentrations at the site of the infection (5), yet with no cumulation.

## PATIENTS AND METHODS

We studied patients with a clinical diagnosis of urethritis and/or cervicitis attending the out-patient clinic for sexually transmitted diseases at the Department of Dermatology, University Medical Centre Ljubljana. To establish the aetiology of the inflammation, swab specimens collected from the urethra and/or endocervix were first examined for the presence of gonococci (staining by Gram's method and methylene blue) and trichomonads. A chlamydial aetiology was demonstrated with the use of the *C. trachomatis* Direct Specimen Test (Syva MicroTrak). All specimens were tested directly after collection. According to the manufacturer's instructions, specimens containing at least 10 chlamydial elementary bodies were assessed as positive. Positive and negative control slides were used to verify each result.

Roxithromycin therapy was administered only to patients with a proven chlamydial inflammation. The test results were available within one hour and the treatment was started immediately. Roxithromycin was given in a single daily dose of 300 mg (2 tablets of 150 mg each) for 10 days to a total of 3000 mg.

On follow-up examination at the end of treatment, a control urogenital swab specimen was obtained from each patient and examined by the same methods as prior to treatment.

## RESULTS

On initial evaluation, a chlamydial infection was diagnosed in 15 men and in five women. The average age for the men was 30.7 years, for the women 28 years, and for the group as a whole 30.7 years, corresponding to the period of greatest sexual activity (Tab. 1).

An acute inflammation was established in 16 patients while four had a recurrence. Five patients had been treated previously without success, two with penicillin antibiotics, one with trimoxazole and two with doxycycline, which had been discontinued because of gastrointestinal side effects in one patient and had proved ineffective in the other.

On completion of the treatment, examination of

Tab. 1. Patient characteristics.

Sex		%	Mean age (years)
Males	15	75	30.7
Females	5	25	28.0
Total	20	100	30.1

the urethra and/or cervical canal for *C. trachomatis* was negative in 19 patients and positive in one. All 20 patients were free of symptoms.

## DISCUSSION

Several effective chemotherapeutic agents, among them also macrolides, are available on the market for the treatment of sexually transmitted chlamydial infections. Microbiological and clinical data indicate that erythromycin is not always effective and is often poorly tolerated when given in larger doses. Compared to erythromycin, the newer macrolides, roxithromycin being one of them, are at least as effective in vitro and in vivo for the treatment of chlamydial urethritis and cervicitis, but they have the advantage that they can be given in a single daily dose for a shorter period of time (8,9).

Tab. 2. Clinical and bacteriological cure rate

Clinical cure rate	20	100%
Bacteriological cure rate	19	95%

Since chlamydial infection in women is the leading cause of tubal infertility and extrauterine pregnancy in the developed world (10), correct, timely diagnosis and effective treatment of these infections in women and their partners are extremely important.

The clinical and bacteriologic efficacy of roxithromycin in our patients can be assessed as very good; the pathogen was eradicated in 19 patients and all 20 patients were free of symptoms at the end of treatment. Side effects in the form of diarrhoea and abdominal pain occurred in one patient only and were mild.

Our results agree with the literature reports (11,12) in showing that roxithromycin given in a single daily dose of 300 mg for 10 days is an effective antibiotic with minimal side effects for the treatment of sexually transmitted chlamydial infections of the urogenital tract.

## CONCLUSIONS

The macrolide antibiotic roxithromycin is suitable for the treatment of chlamydial genitourinary

infections. It is equally effective as other antibiotic agents in use.

## REFERENCES

1. Stamm WE. Chlamydia trachomatis genitourinary tract infections. In: Update in STD. Wien. Update Europe, 1994; 24-8.
2. Handsfield HH. Color atlas and synopsis of sexually transmitted diseases. New York, Mc Graw-Hill, 1992; 24-5.
3. Schachter J. Biology of Chlamydia trachomatis. In: Holmes KK, Mardh PA, Sparling PF, Wiesner PJ eds. Sexually transmitted diseases (2nd ed). New York: McGraw-Hill, 1990; 167-180.
4. Luger A. Epidemiology of bacterial STDs. In: Update in STD. Wien: Update Europe, 1994; 8-17.
5. Bergogne-Berezin E. Tissue distribution of roxithromycin. J Antimicrob Chemother 1987; 20: Suppl. B: 113-20.
6. Cates W Jr. Epidemiology and control of sexually transmitted diseases: strategic evaluation. Infect Dis Clin N Am 1987; 1: 1.
7. Stamm WE, Koutsky LA, Benedetti JK et al.: Chlamydia trachomatis urethral infections in men. Prevalence, risk factors and clinical manifestations. Am Intern Med 1984; 100: 47- 51.
8. Bowie WR, Shaw CE, Chan DGW et al. In vitro activity of Ro 15-8074, Ro 19-5247, A-56268 and Roxithromycin (Ru 28965) against Neisseria gonorrhoeae and Chlamydia trachomatis. Antimicrob Agent Chemother 1987; 31: 470-2.
9. Pechere JC. Clinical evaluation of Roxithromycin 300 mg once daily as an alternative to 150 mg twice daily. Diagn Microbiol Infect Dis 1992; 15: 1115-75.
10. Hay PE, Thomas BJ, Horner PJ et al. Chlamydia trachomatis in women: the more you look, the more you find. Genitourin Med 1994; 70: 97-100.
11. Lassus A, Seppala A. Roxithromycin in non-gonococcal urethritis. J Antimicrob Chemother 1987; 20: Suppl B: 157-65.
12. Blanc F et al. An evaluation of tolerance of roxithromycin in adults. J Antimicrob Chemother 1987; 20: Suppl B: 179-83.

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