# Clinical efficacy of moxifloxacin in the treatment of exacerbations of chronic bronchitis: a systematic review and meta-analysis

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## CRD summary

This review aimed to compare the clinical efficacy of moxifloxacin to that of antibiotic regimens routinely used to treat exacerbations of chronic bronchitis. The authors concluded that the clinical success rate tends to be higher for moxifloxacin than for standard antibiotic treatments. However, methodological concerns, especially about the validity of the pooled estimate, suggest that the reliability of the authors
conclusions is unclear.

## Authors' objectives

To compare the clinical efficacy of moxifloxacin to that of antibiotic regimens routinely used to treat exacerbations of chronic bronchitis.

## Searching

PubMed was searched for reports published between January 1997 and July 2005; the keywords were stated. In addition, the reference lists of identified studies were screened and the manufacturer of moxifloxacin was asked for the results of relevant unpublished trials.

## Study selection

### Study designs of evaluations included in the review

Studies using random allocation of patients to treatments were eligible for inclusion. All of the included studies were designed as equivalence trials.

### Specific interventions included in the review

Trials comparing moxifloxacin with another antibiotic were eligible for inclusion. The comparator drugs in the included studies were clarithromycin, azithromycin, amoxicillin-clavulanic acid, levofloxacin, ceftriaxone and cefuroxime. Moxifloxacin was given at a dose of 400 mg/day over 5 days.

### Participants included in the review

Studies of patients with exacerbations of chronic bronchitis were eligible for inclusion. In all included studies a consistent and internationally accepted definition of chronic bronchitis was employed (presence of productive cough for at least 3 months in 2 consecutive years). However, various definitions of exacerbations were used and inclusion criteria differed with regard to the severity of the exacerbation. The mean age of patients in the included studies ranged from 52 to 69 years.

### Outcomes assessed in the review

Studies that assessed results in terms of clinical cure or improvement were eligible for inclusion. In the included studies, clinical success and bacteriological success were generally measured between 7 and 10 days after completion of treatment and in some trials between 10 and 14 days after start of treatment.

### How were decisions on the relevance of primary studies made?

The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

## Assessment of study quality

The authors did not state that they assessed validity, although loss to follow-up was reported.

## Data extraction

Data on clinical efficacy, loss to follow-up and several study characteristics were extracted.

## Methods of synthesis

**How were the studies combined?**

The studies were combined in a meta-analysis using both fixed-effect and random-effects models.

**How were differences between studies investigated?**

Differences between the studies were apparent from inspection of the tables and were discussed in the text. Statistical heterogeneity was assessed using the chi-squared statistic. Subgroup analyses were undertaken for patients with various risk factors: older than 60 years of age, more than 3 exacerbations
in the preceding year, cardiopulmonary co-morbidity, concomitant use or oral corticosteroids and forced expiratory volume lower than 50%.

## Results of the review

Nine studies (n=4,951) were included in the review: 5 randomised double-blind trials (n=3,344) and 4 randomised open trials (n=1,607).

In all included studies, moxifloxacin was found to be at least equally effective as the comparator treatment. In one trial moxifloxacin was superior to the standard antibiotic treatment and the results reached statistical significance: 69.7% versus 62.1 % improvement (95% confidence interval: 0.3, 15.6).

A meta-analysis based on data from 9 trials (3,905 patients) showed a non statistically significant increase of 1.5% in the clinical success rate associated with moxifloxacin. Differences between risk subgroups could not be observed.

## Cost information

The authors reported estimated treatment costs for exacerbations of chronic bronchitis in primary and secondary care.

## Authors' conclusions

The clinical success rate tends to be higher with moxifloxacin in comparison with standard antibiotic treatments.

## CRD commentary

The review addressed a clearly defined research question. Relevant sources were searched; however, an additional search of other sources (e.g. databases that focus on drug-related subjects) would have been desirable. Attempts were made to retrieve unpublished studies, thus limiting the potential of publication bias. It was unclear whether attempts were also made to prevent further error or bias in the review process. The authors presented some details of the included studies but more detailed information about the outcome measurement (clinical and bacteriological success) would have been desirable. It appears
that the validity of the included studied was not assessed and taken into account in the evidence synthesis. The authors' conclusions reflect the evidence presented. However, given the potential methodological limitations identified, the extent to which these are reliable is unclear.

## Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that clinical trials are needed to demonstrate superiority of the new antibiotics used in the treatment of exacerbated chronic bronchitis and chronic obstructive pulmonary disease, and to prevent the recurrence of exacerbations.

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