

ABSTRACT

Objective: To assess the relative cost effectiveness of moxifloxacin once-daily empirical monotherapy and ofloxacin/ metronidazole twice daily combination therapy for the treatment of uncomplicated pelvic inflammatory disease in adult female patients.

Design: This is a retrospective cost analysis using data from a clinical trial in order to perform the economic analysis from a funder perspective. The cost analysis is based on the clinical results of the MAIDEN study which is a prospective, randomized, double-blind, multicentre, multinational Phase III study comparing the efficacy and safety of moxifloxacin 400 mg po od for 14 days with ofloxacin 400mg po bid plus metronidazole 400mg po bid for 14 days in patients with uncomplicated pelvic inflammatory disease. Decision analysis is used to characterise the economic outcomes between groups and provide a structure upon which to base the sensitivity analyses. Published 2004 cost values are used throughout. Cost values for moxifloxacin are based on the retail price of Avelon tablets in South Africa as appears on the Orderwise Retail Pharmacy Ordering System (September 2004). Cost values for the comparator, ofloxacin and metronidazole, are based on the cheapest available generics on the South African market i.e. Zanocin 400 and Metazol 400mg respectively.

Method: The cost analysis is based on the clinical results obtained from the MAIDEN study. Patients were enrolled in either the moxifloxacin treatment group (Group A) or the ofloxacin / metronidazole comparator group (Group B). Resource utilization included:

- cost for study antimicrobials (total number of doses for the study period)
- treatment for adverse events occurring up to 7 days after stopping the study medication
- treatment for failures (includes patients continued on antimicrobial therapy after the 14 day course of therapy)
- cost of additional physician visits to treat adverse events and treatment failures

The primary end-point is the overall cost of treatment per patient as determined by:

Clinical response 7 to 14 days after the last dose of study medication (Test-of-Cure visit)

Since the clinical findings from the MAIDEN study showed that moxifloxacin treatment was at least as efficacious as ofloxacin/metronidazole treatment, a cost-minimization analysis was performed and the results were analysed according to decision analysis. Decision analysis was used to characterise the economic outcomes between the groups and provided a structure upon which to base the sensitivity analyses. The outcomes were depicted on a decision tree which proportionately determined the cost of treatment per patient in the two treatment groups.

Results:

No significant differences in clinical success rates were detected. Differences were mainly due to the cost of treating adverse events in the two groups. Costs per patient in the monotherapy vs combination therapy comparisons were R10 847.00 for moxifloxacin and R16 630.00 for ofloxacin/metronidazole treatment. Sensitivity analyses revealed that moxifloxacin monotherapy can be cost effective compared with ofloxacin/metronidazole combination therapy in different situations.

Conclusion:

Per patient, the cost of drug treatment and treatment of adverse events and clinical relapses was R10 847.00 for treatment with moxifloxacin therapy and R16 630.00 for ofloxacin/metronidazole therapy . In comparison to ofloxacin/metronidazole combination therapy, moxifloxacin monotherapy was therefore cost saving.