Oral metronidazole vs. metrogel vaginal for treating bacterial vaginosis: cost-effectiveness evaluation

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of two drug therapies for the treatment of bacterial vaginosis. The two drug therapies were generic oral metronidazole (500 mg twice daily for 7 days) and Metrogel Vaginal (one applicator twice daily for 5 days).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged 18 to 30 years without other medical problems. No other inclusion criteria were reported.

Setting
The setting was an institution. The economic study was carried out at the Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit (MI), USA.

Dates to which data relate
The dates during which the effectiveness and resource use data were gathered were not reported. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not performed to determine the sample size. Sixty consecutive patients with clinical diagnoses of bacterial vaginosis were divided into two groups of 30 patients. One group received metronidazole whilst the other received Metrogel Vaginal. None of the patients were excluded from the initial sample.

Study design
The study was a randomised controlled trial that was carried out in a single centre. The patients were randomised by a nurse, and were blinded to the evaluating physician, unaware of the selected treatment option during the study period. The physician evaluated the patients for bacterial vaginosis through standard wet preparation, whiff test, and pH prior to and after treatment. Patients that proceeded with outpatient therapy were followed for 7 to 10 days, and were then evaluated again. During the follow-up, the patients agreed to refrain from sexual relations, and to avoid alcohol, drugs, and all medication.

Analysis of effectiveness
It was not reported whether the effectiveness analysis was conducted on an intention to treat basis or on treatment completers only. However, all the patients included in the study were accounted for in the analysis. The primary health outcomes were the success rate and the presence of significant complication. The groups were not shown to be comparable in terms of their demographic characteristics or clinical conditions.

Effectiveness results
The treatment for bacterial vaginosis was successful in 27 of the women treated with Metrogel and in 28 of those treated with metronidazole. There were no significant complications in either treatment group. However, three women in the metronidazole group experienced nausea, whilst two women in the Metrogel group reported difficulty in applying the medication vaginally.

Clinical conclusions
The authors concluded that the effectiveness analysis has shown the equivalence of the two drug regimens.

Measure of benefits used in the economic analysis
The two treatments were considered equally effective in terms of the clinical outcomes. A cost-minimisation analysis was therefore conducted.

Direct costs
Discounting was irrelevant due to the short time horizon of the study. The quantities of the resources used and the unit costs were not reported. The cost/resource boundary was not specified. The analysis included only the costs directly related to the actual outpatient treatment. Other cost items that were supposed to be the same in both groups (clinic visits, physician costs, and evaluations) were therefore not included. The costs and the quantities were estimated from actual data. The cost data were obtained from the pharmacist at the institution (clinic’s wholesale costs). The dates during which the resource use data were gathered were not reported. The price year was not reported.

Statistical analysis of costs
No statistical analysis of the costs was reported.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total cost of treatment was $19.72 for Metrogel Vaginal and $1.51 for metronidazole.

Synthesis of costs and benefits
Not applicable.

Authors’ conclusions
Generic metronidazole, rather than Metrogel Vaginal, should be used for the routine treatment of patients suffering from bacterial vaginosis. This is because metronidazole was over 13 times less costly than Metrogel Vaginal, and the effectiveness did not differ statistically between the treatments.

CRD COMMENTARY - Selection of comparators
The authors justified the selection of the comparators. Metronidazole was chosen because it represented a common treatment for bacterial vaginosis, whilst Metrogel Vaginal was selected because it was highly recommended by the manufacturer. You should consider whether these represent commonly used treatments in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the study was enhanced by the randomised and blinded design, which appears to have been appropriate for the study hypothesis. However, statistical analyses were not conducted to show the comparability of the study groups at analysis. In addition, they were not conducted to determine the sample size necessary to ensure a certain probability of detecting a statistically significant difference between the groups. This is of particular relevance because the two treatments were found not to differ.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. As a consequence, the costs and the benefits were not combined. It would have been interesting to have adopted a summary benefit measure based on patients preferences, as it appears that the two interventions could have produced different effects on the life habits of the patients during the study period.

Validity of estimate of costs
The estimation of the costs was somewhat specific to the study setting: the institution was part of a large health system, which could enjoy some cost advantage over small providers due to the high volume of purchasing. The perspective of the study was not explicitly reported. In addition, it was unclear whether the outpatient costs were borne by the institution, the patients, or the health insurers. The only cost item included in the analysis was the actual outpatient treatment. The other costs were considered to be equal, but this assumption was not demonstrated. Finally, the price year was not reported and statistical analyses of the quantities were not conducted.

Other issues
The study results confirmed those from other studies, especially in terms of the equivalent effectiveness. The issue of the external validity of the study was not addressed and sensitivity analyses were not carried out. The generalisability of the results to other settings is, therefore, quite limited.

Implications of the study
The study results were quite important in terms of the resource savings, above all for patients and clinicians who are particularly sensitive to outpatient medications that are not covered by insurance companies. The authors recommended the routine use of metronidazole. The use of Metrogell Vaginal should be restricted to patients experiencing side-effects.

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