Fluconazole compared with endoscopy for human immunodeficiency virus-infected patients with esophageal symptoms

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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
Fluconazole compared with endoscopy for Human Immunodeficiency Virus (HIV)-infected patients.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
HIV-infected patients with esophageal symptoms. No further details were given.

Setting
Hospital. The economic study was carried out in Atlanta, Georgia, USA.

Dates to which data relate
The main effectiveness data were taken from a clinical trial conducted in the period 1990-94. Resource and cost data were mainly derived from data collection forms. The price year was not stated.

Source of effectiveness data
Estimates of fluconazole efficacy, and endoscopic findings responding to empirical antifungal therapy, were derived from a single randomized trial.

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

Study sample
A cohort of 134 HIV-infected patients with esophageal symptoms. The patients were randomized prospectively to groups receiving either standard doses of fluconazole or endoscopy. The patients in the fluconazole group (68) had a mean age of 34.0 (+/- 5.7) years (P=0.095), 85.3% were male (P=0.444), 48.5 were homosexual or bisexual (P=0.287), 27.9% were intravenous drug users (P=0.776) and 44.1% were AIDS carriers (P=0.463). The patients in the endoscopy group (66) had a mean age of 35.9 (+/- 7.7) years (P=0.095), 80.3% were male (P=0.444), 39.4% were homosexual or bisexual (P=0.287), 25.8% were intravenous drug users (P=0.776) and 37.9% were AIDS carriers (P=0.463). Power calculations to determine the sample size were not given.
Study design
The study was a randomized controlled trial. The duration of the follow-up was 53 months. The loss to follow-up was one patient from the endoscopy group (the patient failed to return for the final procedure and could not be contacted).

Analysis of effectiveness
The analysis of the clinical study was based on treatment completers only. The primary health outcomes used in the analysis were estimates of fluconazole efficacy and endoscopic findings responding to empirical antifungal therapy.

Effectiveness results
Of 68 patients in the fluconazole group, 82% were estimated to have a complete resolution within the first week of therapy and 12 patients were estimated to have no response. Of the patients with no response, 10 were estimated to have esophageal ulcers. Of 65 patients in the endoscopy group, 65% were estimated to have Candida esophagitis, 15% esophageal ulcer and 14% both Candida esophagitis and esophageal ulcer. Patients responding to empirical antifungal therapy, or who had Candida esophagitis alone at endoscopy, were less likely to have severe symptoms ($P=0.027$) or odynophagia as the only symptom ($P<0.001$), but more frequently had odynophagia and dysphagia ($P=0.007$) and thrush ($P=0.002$).

Clinical conclusions
Empirical oral antifungal therapy with fluconazole is highly efficacious and safe for HIV-infected patients with new-onset esophageal symptoms.

Measure of benefits used in the economic analysis
The authors did not derive a summary benefit measure and as such the benefits are assumed to be equal to the effectiveness measures.

Direct costs
The costs of fluconazole therapy and endoscopy were included in the analysis. Quantities were analysed separately from costs. Discounting was not applied. The quantity/cost boundary adopted was the hospital. The price date was not stated.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
Of 68 patients in the fluconazole group, 82% were estimated to have a complete resolution within the first week of therapy and 12 patients were estimated to have no response. Of the patients with no response, 10 were estimated to have esophageal ulcer. Of 65 patients in the endoscopy group, 65% were estimated to have Candida esophagitis, 15% esophageal ulcer and 14% both Candida esophagitis and esophageal ulcer. Patients responding to empirical antifungal therapy, or who had Candida esophagitis alone at endoscopy, were less likely to have severe symptoms ($P=0.027$) or odynophagia as the only symptom ($P<0.001$), but more frequently had odynophagia and dysphagia ($P=0.007$) and thrush ($P=0.002$).

Cost results
The fluconazole therapy was estimated to have an average saving of $738.16 per patient. The average cost per patient in
the endoscopy group was estimated to be $977.77 compared with $239.61 in the fluconazole group (P<0.0001).

**Synthesis of costs and benefits**
A synthesis of the estimated benefits and costs was not given. No incremental analysis was performed.

**Authors' conclusions**
Empirical oral antifungal therapy with fluconazole is highly efficacious, safe and cost-effective for HIV-infected patients with new-onset esophageal symptoms.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparator is clear. Empirical antifungal treatment has been recommended for HIV-infected patients with new-onset esophageal symptoms, reserving endoscopy for those in whom empirical therapy fails. You, as a user of this database, should consider whether these are widely used health technologies in your own setting.

**Validity of estimate of measure of benefit**
The estimate of measure of benefit used in the economic analysis is likely to be internally valid. The data have not been used selectively to assess the safety and cost/effectiveness of fluconazole.

**Validity of estimate of costs**
Adequate details of methods of quantity/cost estimation were not given. Important cost items do not appear to have been omitted.

**Other issues**
The authors' conclusions were justified, given the uncertainties in the data. The issue of generalisability to other settings or countries was not addressed although appropriate comparisons were made with other studies. The results do not appear to have been presented selectively.

**Implications of the study**
Further research is needed to include in the study population patients who had previously been using oral-systemic agents on a long-term basis, and patients with a prior history of esophageal disease and being unable to eat.

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None stated.

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