Costs and outcomes of risperidone treatment in schizophrenia in the Czech Republic
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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 risperidone versus standard neuroleptics in the treatment of schizophrenia. Standard neuroleptics comprised a combination of chlorpromazine, chlorprothixene, haloperidol, levomepromazine, oxyprolepine, perphenazine and thioridazine.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged between 18 and 65 years who were suffering from schizophrenia or schizoaffective disorders. The inclusion criteria specified patients who had been treated with risperidone or standard neuroleptics between 1 January 1995 and 31 December 1998. In addition, the patients had to have an ICD-10 diagnosis of schizophrenia or schizoaffective psychosis, and have been treated with a standard neuroleptic drug for at least 12 months prior to risperidone initiation or the switch from one standard neuroleptic drug to another. Patients on standard neuroleptics were excluded if they had ever received risperidone or clozapine.

Setting
The setting was primary care. The economic analysis was conducted in Prague, Czech Republic (CR).

Dates to which data relate
The effectiveness and resource use data were collected retrospectively between 1 January 1995 and 31 December 1998. The price year was 1998.

Source of effectiveness data
The effectiveness data were derived from a single retrospective study.

Link between effectiveness and cost data
The costing was carried out retrospectively using the same sample of patients as that used in the effectiveness study.

Study sample
The power analysis of repeated measures ANOVA indicated a sufficient number of patients in the two groups (n=60 in each group). First, 67 patients treated with risperidone were included in the analysis (risperidone group). Then, 67 patients treated with standard neuroleptics (comparison group) were matched with the risperidone group in terms of
age, gender, marital status and diagnosis. A total of 134 patients were included in the analysis.

**Study design**
The study design was a within-group comparison alongside a case-control study, which was conducted in 18 public outpatient psychiatric clinics. The duration of follow-up was 2 years: 12 months before (pre-risperidone period or pre-switch period) and 12 months after (risperidone period or post-switch period) the risperidone initiation or the switch from one standard neuroleptic drug to another.

**Analysis of effectiveness**
All of the patients included in the study were accounted for in the analysis. The primary health outcome used in the analysis was the monthly global assessment of functioning (GAF) scores. The first author obtained all the GAF ratings, and the "interrater reliability" with oneself was checked in the course of time. The average yearly GAF score was calculated for every patient. The sociodemographic and clinical characteristics were shown to be similar between the groups at baseline.

**Effectiveness results**
There was no difference in outcomes between the two study groups in the first and second years of the assessment.

The mean GAF was 41.2 (+/- 8.7) in the pre-risperidone period and 43.6 (+/- 6.7) in the pre-switch period, (p=0.0841).

The mean GAF was 44.6 (+/- 10.6) in the risperidone period and 43.9 (+/- 7.5) in the post-switch period, (p=0.6667).

**Clinical conclusions**
The study showed that risperidone had equivalent efficacy to standard neuroleptic drugs.

**Measure of benefits used in the economic analysis**
Since the effectiveness analysis showed no difference in effectiveness between the intervention and comparator, the economic analysis was consequently based on the difference in costs only. Thus, it has been classified as a cost-minimisation analysis.

**Direct costs**
The perspective of a health insurance company (more specifically, the General Health Insurance Company of the CR) was adopted. The direct costs included psychiatric hospitalisations, visits to outpatient clinics, outpatient neuroleptic drugs, outpatient treatment of adverse effects of neuroleptics, and outpatient psychopharmacotherapy other than neuroleptics. The resource quantities were obtained from a review of the outpatient psychiatric charts. The medication costs were calculated according to the Drug Price List of the General Health Insurance Company of the CR. The psychiatric hospitalisation costs were calculated according to the Department of Medical Information and Statistics of a university hospital in the CR. All the costs were considered in 1998 values. The costs and the quantities were reported separately. Discounting was unnecessary since all the costs occurred over two successive periods of one year.

**Statistical analysis of costs**
A two-sample t-test was used for the statistical analysis of costs.

**Indirect Costs**
The indirect costs were not included in the analysis.
Currency
US dollars ($) and Czech crowns (Kc) were used. The conversion rate was Kc30.2 = $1 (1998 values).

Sensitivity analysis
A one-way sensitivity analysis was conducted on the cost variables (the costs were divided by a coefficient of 2). All of the analyses were repeated after excluding 8 risperidone drop-outs and their 8 matched control patients. The analyses were further repeated, considering outpatient psychiatric examination and psychiatric hospitalisation costs fixed in the European Community (Italy).

Estimated benefits used in the economic analysis
Not applicable since the economic analysis was classified as a cost-minimisation study.

Cost results
There was no significant difference in the individual or total annual costs between the two groups in the first year of the assessment.

In the second followed period, the cost of risperidone was significantly higher ($915.1) than that of standard neuroleptic drugs ($96.9), (p<0.0000). The other costs were not significantly different between the study groups. The total annual cost in the risperidone group ($1,418.3) was significantly higher than that in the comparison group ($696.7), (p<0.0000).

The cost of treating adverse effects was less than 1.5% of the total cost in each group.

Synthesis of costs and benefits
No synthesis of the costs and benefits took place. However, the sensitivity analysis showed that the results were not influenced by the reduction in treatment cases. The one-way sensitivity analysis revealed that none of the cost variables was sensitive. In addition, when the costs fixed in Italy were considered, no significant differences in the total costs were found between the risperidone and the comparison groups in either the first year ($8,784 versus $7,337), (p=0.4686), or the second year ($6,502 versus $6,780), (p=0.8483).

Authors’ conclusions
The treatment of schizophrenia with risperidone was not cost-saving from the perspective of the General Health Insurance Company of the Czech Republic (CR).

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear. The comparator was chosen because it represented the standard treatment for patients suffering from schizophrenia or schizoaffective disorders in the author’s setting. You should consider whether this is a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a within-group comparison, alongside a case-control study. However, selection bias was likely to have been low due to the matching of control patients. The patients were shown to be comparable at analysis, so confounding should be minimised. The GAF material and scores (dimensions, items, type of scoring) were not described, and the validity of the measure of effectiveness unclear. The authors acknowledged that the effectiveness outcomes might have been different if other methods, such as rating scales or quality of life scales, had been used. Due to the observational nature of the study, the overall internal validity is likely to be quite low.
Validity of estimate of measure of benefit
The analysis of benefits was based upon the therapeutic equivalence of treatment alternatives. The economic analysis therefore included only the costs and, consequently, was classified as a cost-minimisation study.

Validity of estimate of costs
The authors adopted the perspective of a health insurance company and, as such, all the relevant costs appear to have been included. The indirect costs were not relevant to the perspective chosen. However, the authors noted that schizophrenia has been shown to be associated with high indirect costs and that risperidone might decrease these costs. Consequently, the exclusion of the indirect costs might have biased the results in favour of the standard treatment. Both the price year and conversion rate were reported. In addition, the costs and the quantities were reported separately. These factors improve the reproducibility of the results in other settings.

Other issues
The generalisability of the results was not discussed. Adequate comparisons were made with studies dealing with the same topic. The study enrolled patients suffering from schizophrenia or schizoaffective disorders and this was reflected in the authors’ conclusions. The authors highlighted limitations of their study and do not appear to have reported the results selectively. The authors did not consider other antipsychotics such as amisulpride or clozapine, even though these have been shown to be cost-effective treatment options in patients suffering from schizophrenia (see ‘Other Publications of Related Interest’).

Implications of the study
The authors suggested that the difference in the direct costs between the two treatments will probably become insignificant in the future when the country's economy has developed.

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Other publications of related interest

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MeSH
Adolescent; Adult; Aged; Antipsychotic Agents /economics /therapeutic use; Cost-Benefit Analysis; Czech Republic; Female; Hospitalization /economics; Humans; Length of Stay /economics; Male; Mental Health Services /economics /utilization; Retrospective Studies; Risperidone /economics /therapeutic use; Schizophrenia /drug therapy /economics /rehabilitation; Treatment Outcome