Cost-effectiveness and cost-benefit of sumatriptan in patients with migraine

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
Sumatriptan therapy was compared with nontriptan medications in the treatment of acute migraine.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
To be included in the study, the patients had to meet three criteria. First, to have a doctor's diagnosis of migraine. Second, to have received their first sumatriptan prescription between October 1994 and August 1996. Finally, to be continuously enrolled in the managed care organisation (MCO) for 6 months before and after their first sumatriptan prescription.

Setting
The setting was primary care. The economic study was carried out in Western Pennsylvania, USA.

Dates to which data relate
The effectiveness data were collected from July 1994 to February 1997. The resource use data were collected from April 1994 to February 1997. It was unclear whether a common price year was used for the costing.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

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

Study sample
No power calculations were described. In all, 206 eligible patients consented to participate in the study and to change from their usual migraine medication to sumatriptan. There was no control group.

Study design
The authors described the design as a "prospective, pre-test, post-test, observational, outcomes study". This can also be described as a within-group comparison study. The authors did not justify their choice of experimental design. The
study was conducted in one MCO, but it was not stated whether this was at a single site or multiple sites.

The effectiveness data for the 3 months preceding the initial sumatriptan prescription were collected through a self-reported questionnaire. The data collected were then doubled to represent a 6-month period, with the assumption that the effectiveness was consistent for the additional 3 months. The patients were followed up by postal questionnaire at 3 and 6 months following the change in their medication.

Twenty-eight patients (13.5%) did not complete the study. The reasons for this were failure to return the surveys (9%), disenrolled by the MCO (2.5%), migraine medication changed by the physician (1%), pregnancy (0.5%), and lost to follow-up (0.5%). Participants who completed the study were paid $40. The patients were followed up for 6 months from the initiation of sumatriptan therapy.

**Analysis of effectiveness**
The analysis was based on the 178 participants who completed the study. Their average age was 39 years, 90% were female and 82% were in paid employment.

The chosen outcome measure was the total disability time (time lost from work and other usual activities) that the patients experienced due to migraine. Time lost from work was the sum of the number of complete days missed and the number of days worked while symptomatic, adjusted by the subjective effectiveness at the time. Time lost from usual non-work activities was calculated by the same method.

**Effectiveness results**
During the 6-month study, a total of 1,898 migraine-disability-days were averted with sumatriptan therapy (662 for work and 1,236 for non-work activities). On average, the patients experienced 1.8 fewer migraine-disability-days with sumatriptan than with their prior nontriptan drug therapy.

**Clinical conclusions**
The authors concluded that sumatriptan reduced the patients’ disability and improved their ability to function at work and non-work activities.

**Measure of benefits used in the economic analysis**
The measure used in the economic analysis was the total migraine disability time.

**Direct costs**
The quantities and the costs were reported separately. Both health service reimbursement costs and the patients’ out-of-pocket co-payments were included in the analysis. These were obtained from the MCO for each patient. Migraine-related claims included prescriptions for medication, physician visits, specialist-consultant visits, emergency department visits, and claims for migraine-related tests and procedures. The study reported the average costs. The resource use data were collected from April 1994 to February 1997, but it was unclear if there was a common price year for the costing. Discounting was not relevant since the cost data covered less than one year.

**Statistical analysis of costs**
The resource use and cost data were treated deterministically.

**Indirect Costs**
A rationale for including the productivity costs was given. The total disability time (i.e. time lost from work and from other non-work leisure activities), as reported by the patients, was measured. Time lost from work was the sum of the number of complete days missed and the number of days worked while symptomatic, adjusted by the subjective
effectiveness at the time. Time lost from usual non-work activities was calculated by the same method. The 1996 national average wage rates, by job category, were used to assign individual costs. The use of wage rates to value non-work leisure time was justified by the human capital approach to quantify patients' disability time in economic terms. The costs incurred by relatives and friends were not included. Disability data were collected from April 1994 to February 1997. Discounting was not relevant since the cost data covered less than one year.

Currency
US dollars ($).

Sensitivity analysis
Three one-way sensitivity analyses of the costs were undertaken. The parameters examined were medical reimbursement costs, patients' wage rates, and the exclusion of costs for non-work disability time. From these, the generalisability of the results was assessed and an employers' perspective investigated. The range for medical costs was taken from published regional medical fees. Labour statistics were used to form the range in wages. A threshold analysis was performed on the number of disability days extrapolated for the 3 to 6 months before the initiation of sumatriptan.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total health costs for 6 months' sumatriptan therapy were $108,829. These comprised $18,351 for medical costs, $74,861 for pharmacy costs and $15,617 for patient co-payments. The corresponding costs for 6 months' usual medication were $61,228, of which $26,192 was for medical costs, $22,209 for pharmacy costs and $12,827 for patient co-payments. With a decrease in disability costs, offset by an increase in health care costs, the overall net savings with sumatriptan relative to usual medications was $222,332 (or $1,249 per patient) for the 6-month period.

Synthesis of costs and benefits
An incremental cost-effectiveness ratio (ICER) of $25 for each migraine-disability-day averted was obtained by dividing the difference in total health care costs ($47,601) by the number of migraine-disability-days averted in the subsequent 6-month period.

The sensitivity analysis showed that the results were relatively robust to changes in medical costs and differences in the wage rates of the patients. However, the ICER increased to $59 if an employer rather than a societal perspective was taken. The threshold sensitivity analysis showed sumatriptan ceased to be cost-beneficial if the number of migraine-disability-days was overestimated by 10 or more days in the 3 to 6 months before the commencement of sumatriptan therapy.

Authors' conclusions
The initiation of sumatriptan for migraines was cost-effective and patients, employers and society all benefited economically.

CRD COMMENTARY - Selection of comparators
No explicit justification was given for the comparator used, but it appears to have represented current practice. The authors did not specify which nontriptan drugs the patients used. As different medications have varying effectiveness in the treatment of migraine, the choice of the comparator has a direct impact on the effectiveness results.
Validity of estimate of measure of effectiveness
The basis of the analysis was a within-group comparison study design, which was inappropriate for the study question. The authors commented that, by analysing the patients' medical claims data for all health conditions, the patients acted as their "own controls". However, this type of study is associated with problems of confounding. A different type of design, which incorporates a control group or crossover between the groups, would give more robust results. The lack of a control group makes it difficult to establish how much of the effect seen in the patients was due to the intervention and how much was simply caused by participating in the study. The patients received a cash payment of $40 for completing the study. The effectiveness results relied on patient recall of the preceding 3 months. The study sample was not shown to be representative of the study population. A threshold sensitivity analysis was used to investigate an assumption about migraine frequency in the 3 to 6 months before the initiation of sumatriptan.

Validity of estimate of measure of benefit
The estimation of benefits was obtained directly from the effectiveness analysis. This choice of estimate was justified.

Validity of estimate of costs
All the categories of cost relevant to the perspective adopted were included in the analysis. The authors chose only to consider the indirect costs of the patients, and not their friends or relatives. However, this would not have affected the conclusion. The costs and the quantities were reported separately, but no common price year was reported. No statistical analysis of the quantities was performed. A statistical analysis of the prices was not performed, but some cost parameters were explored in a sensitivity analysis. Discounting was not relevant since the cost data covered less than one year.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. They also addressed the issue of generalisability to other settings. The study enrolled predominately female patients who were employed, but it generalised conclusions across male and females. The authors reported that, at the time of the study, sumatriptan was the only serotonin receptor agonist available. The analysis does not extend to other drugs of this class.

Implications of the study
The authors strongly supported the use of sumatriptan for treating migraines. However, the short follow-up time, in combination with a weak study design, suggests that further analysis is warranted.

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