Evaluation of a therapeutic conversion from amlodipine to felodipine

Manzo B A, Matalka M S, Ravnan S L

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 study examined the effectiveness of felodipine compared with amlodipine in elderly hypertensive patients, after switching treatment with amlodipine (10 mg) to felodipine (10 mg). The patients were converted from amlodipine on an identical milligram dose of felodipine. Dosage adjustments after the conversion were left to the discretion of primary care providers.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all hypertensive patients receiving amlodipine, regardless of co-morbid conditions.

Setting
The setting was primary care. The study was conducted in the USA.

Dates to which data relate
The dates to which the effectiveness and resource data related were not reported. The price year was also not reported.

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

Link between effectiveness and cost data
The costing was carried out retrospectively on a sub-set of the patients used in the effectiveness analysis.

Study sample
Power calculations, to assess the number of patients needed to detect significant differences, were not performed in advance. All 283 patients identified were sent a survey by mail. The survey consisted of a validated, self-administered symptom assessment profile (SSAP) and five questions specific to the change programme. A letter explaining the intention of the study was added to the survey. Nine mails appeared to be undeliverable and 147 patients returned the survey. Of this group, 102 (69%) continued taking felodipine. The remaining 45 patients had other co-morbid conditions that necessitated switching to a more appropriate antihypertensive drug. Patients continuing felodipine were included for the analysis if they had visited the primary caregiver at least once within the 6 months before and after the conversion. Finally, 68 (67%) patients were eligible for the evaluation. This group consisted of elderly men with a mean...
age of 69.9 years (standard deviation 10.81). Thirty-two (47%) patients had uncomplicated hypertension and 36 (53%) had at least one additional cardiovascular risk factor (heart failure, angina, stroke, myocardial infarction, diabetes mellitus).

Study design
A within-group analysis was carried out, in which effectiveness data relating to the 6 months before and 6 months after the conversion were evaluated. The study was performed at a local pharmacy in the USA (specific information was not reported).

Analysis of effectiveness
Patient satisfaction and tolerability of felodipine were based on the results of the returned surveys (n=102). The analysis of clinical outcomes was limited to 68 patients (67%) who visited a primary caregiver within the 6 months before and after the conversion. The primary health outcomes were systolic and diastolic blood pressure and heart rate. These were measured by qualified medical staff during the patients’ visits and retrieved retrospectively by electronic chart review. Measurements performed during hospital admissions or emergency care visits were omitted.

Effectiveness results
A total of 95% (n=102) of the respondents were satisfied with the conversion. One patient (1%) did not tolerate felodipine and had aggravated ankle oedema.

The mean systolic pressure was 143.9 (+/- 22.8) mmHg before the conversion and 139.5 (+/- 18.5) mmHg after the conversion. The mean change was -4.38 mmHg, (p non significant). The mean diastolic blood pressure was 72.9 (+/-11) mmHg before conversion and 70.3 (+/- 12.9) mmHg after conversion. The mean change was -2.60 mmHg, (p non significant).

The mean heart rate was significant lower after the conversion, 72.1 (+/- 13.7) beats/minute versus 67.9 (+/- 12.9) beats/minute. The mean change was -4.20 beats/minute, (p=0.008).

Concomitant cardiovascular drugs prescribed before and after the conversion were comparable.

Clinical conclusions
The clinical conclusions were not explicitly reported. In general, felodipine appears to have been well tolerated. No negative results in blood pressure were shown. The mean heart rate was significantly lower 6 months after the conversion.

Measure of benefits used in the economic analysis
The clinical outcomes were left disaggregated. In effect, a cost-consequences analysis was performed.

Direct costs
The annual acquisition costs of amlodipine and felodipine were included. The costs during one year were calculated. No discounting was performed. The resource quantities for 68 patients were taken from computerised data and were used to calculate the annual costs for the entire group. Differences in the doses (mg) of the alternative drugs were considered. The costs and the quantities were not reported separately, and no price year was reported.

Statistical analysis of costs
The costs were presented as point estimates. No statistical analyses were performed.
Indirect Costs
Not applicable.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not performed.

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

Cost results
The costs presented were limited to the annual cost of amlodipine and the cost-savings arising from the conversion to felodipine.

The calculated annual acquisition cost of amlodipine for the entire group was $26,809.

The conversion to felodipine, taking account of the higher mean doses of this drug, resulted in annual cost-savings of $15,888.

Synthesis of costs and benefits
Not applicable since, in effect, a cost-consequences approach was undertaken.

Authors' conclusions
Felodipine was well tolerated and was not associated with increased side effects. Despite the need of higher doses of felodipine compared with amlodipine, conversion to felodipine resulted in cost-savings.

CRD COMMENTARY - Selection of comparators
The authors justified the selection of the comparator. The use of amlodipine appears to have been the current practice in the authors' setting. You should decide if this is valid in your setting.

Validity of estimate of measure of effectiveness
The basis of the analysis was a naturalistic study design, which may enhance the generalisability of the results to daily practice. However, the population studied may not be representative of a more general population of hypertensive patients, as the sample consisted only of elderly men. Moreover, the analysis of the clinical outcomes was limited to a sub-group of 68 patients and, as the authors acknowledged, the study was not powered to determine a true difference. The data were gathered retrospectively, thus it was unclear whether the differences presented were solely related to the conversion. The results presented should be interpreted with caution.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. In effect, a cost-consequences analysis was conducted.

Validity of estimate of costs
The perspective adopted was not explicitly stated, although it was likely to have been that of the health care payer.
However, not all the costs relevant to this perspective were included. There was no information on the possibility that resources might have been used outside of the primary care setting (e.g. secondary care). The cost and the quantities were not reported separately, which limits the possibility of generalising the results to other settings. Moreover, the prices used seem to have been based on negotiated price levels, and the price year was not reported. Resource use was derived using actual data from a restricted (relative small) sample of patients converted to felodipine. These results were then extrapolated to the entire population that had switched from amlopidine to felodipine. Statistical analyses on the prices and the quantities were not performed. Overall, the level of reporting of the cost analysis was insufficient.

Other issues
The authors compared the results appropriately with findings from other studies. In addition, they acknowledged that both the small sample size and the retrospective design of the study limit the generalisability of the results to other settings. The authors also acknowledged some other limitations of their study. The results reflected the scope of the analysis.

Implications of the study
The authors stated that the (cost) results were less desirable than those predicted in advance, although extrapolation of the results to all patients in the database may generate more savings.

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