Cost-effectiveness of ambulatory blood pressure monitoring in the follow-up of hypertension

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 two strategies for arterial hypertension (AH) follow-up in primary care:
follow-up of conventional clinical blood pressure (CBP) every 3 months during 1 year; and
initially CBP and 24-hour ambulatory blood pressure monitoring (ABPM), and follow-up of CBP every 3 months during 1 year.

Type of intervention
Other (treatment monitoring).

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised hypertensive patients from a rural Spanish setting. The inclusion criteria for the study were:

a previous diagnosis of AH by repeated measurements of CBG,
age over 17 and under 91 years in both sexes;
an absence of antihypertensive agents (AHTA), or AHTA prescribed more than 3 months before and not modified during the 3 months prior to inclusion; and
the patient's consent to participate in the study.

The exclusion criteria were extensive and were reported in full in the paper.

Setting
The setting was primary care. The economic study was carried out in Spain.

Dates to which data relate
The effectiveness data were obtained between 15 November 1999 and 28 April 2003. The dates for the resource use data were not explicitly reported. A precise cost year was not reported, although pre 2002 costs were expressed in 2002 euros.

Source of effectiveness data
The effectiveness data were derived from a single study.
Link between effectiveness and cost data
It was unclear whether the costs were obtained using the same patient sample as that used in the effectiveness study. The authors did not report whether the costing was undertaken prospectively or retrospectively.

Study sample
The authors reported that a minimum of 266 patients were required to detect a difference in costs of EUR 0.4 or more per patient per month, with an alpha risk of 0.05 and a beta risk of 0.20 in a one-sided contrast, assuming a standard deviation of EUR 6.59 per month and a reinstatement rate of 16%. Since the first 266 hypertensive patients attending the clinic were recruited, this was a convenience sample. The authors reported that the diagnosis of AH and control of blood pressure were based on repeated measurements of CBP, following the criteria of the sixth report of the Joint National Committee (see ‘Other Publications of Related Interest’ below for bibliographic details). Of the patients recruited, 11 did not want to participate and 14 fulfilled one of the exclusion criteria or did not achieve adequate 24-hour ABPM readings. Therefore, 241 patients participated and completed the study.

Study design
This cross-sectional study was carried out in a single centre. Since both methods were used to measure the blood pressure of the same patients in the study, there was no intervention or placebo group. A total of 241 patients completed the study and no loss to follow-up was reported.

Analysis of effectiveness
The effectiveness of the treatments was defined as good control of AH with a CBP reading lower than 140/90 mmHg (< 130/85 mmHg in patients with diabetes mellitus, damage of target organs or cardiovascular disease) or a daytime average 24-hour ABPM lower than 135/85 mmHg, according to guidelines by Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure. The analyses of the clinical study were conducted on the basis of treatment completers. The authors reported that the study design involved the same patients for both strategies. Therefore, the absolute number of well-controlled cases for each strategy was sufficient for comparing the effectiveness since both strategies had the same patients and, consequently, the same total number of analysed individuals.

Effectiveness results
The authors reported a 2x2 table for good-controlled and poor-controlled blood pressure by CBP and ABPM. The effectiveness of ABPM was 55.60%, compared with 8.29% for CBP. The authors also reported 32 cases of false positives with CBP. They did not report any 95% confidence intervals or p-values.

Clinical conclusions
The effectiveness of ABPM was much higher than that of CBP. Monitoring blood pressure by CBP resulted in false positives.

Measure of benefits used in the economic analysis
The authors used the number of well-controlled cases as the measure of benefit in the economic analyses. They also reported the number of false positives for each strategy, to estimate the unnecessary lifetime pharmacological cost.

Direct costs
Unit costs per patient per year were estimated for each strategy, using the values reported in previous studies and values provided by the equipment supplier. These included an examination by mercury sphygmomanometer with a muff, an examination by monitor for ABPM, nursing consultation and medical consultation (Mata et al. 2002, see 'Other Publications of Related Interest' below for bibliographic details). A unit of follow-up cost of the CBP per patient per
year consisted of the cost of 4 examinations by mercury sphygmomanometer with a muff, 4 nursing consultations and 2 medical consultations. A unit of follow-up cost of the ABPM per patient per year consisted of the cost of 1 examination by monitor, 6 nursing consultations and 4 medical consultations. The authors reported the total cost of measurements made in a year for each strategy and these estimates were used in the economic analyses. To evaluate the impact of false positives in the economic analyses, the authors also reported the average annual drug treatment cost per patient.

Statistical analysis of costs
No cost and resource data were collected from the same sample alongside this cross-sectional study. The costs were treated deterministically.

Indirect Costs
Given the perspective used, indirect costs were not considered.

Currency
Euros (EUR) and Spanish pesetas (PES). PES were converted to EUR at a rate of PES 166.386 = EUR 1.00.

Sensitivity analysis
Sensitivity analyses were carried out to investigate the impact of the discount rate (2, 5, 8 and 10%) on the total lifetime drug treatment cost of AH per patient, for men and women, in the net saving analyses generated by ABPM.

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

Cost results
The authors reported the total cost of measurements made for each strategy, EUR 18,793 for CBP and EUR 31,942 for ABPM. Therefore, the incremental total cost was EUR 13,148. The authors also reported the average total drug treatment cost for men and women at different discount rates.

At a discount rate of 2%, the cost of lifelong drug treatment was EUR 3,686 for a female patient and EUR 3,212 for a male patient. The figures for other discount rates were presented in the paper.

Synthesis of costs and benefits
The cost-effectiveness analyses showed that the cost of a well-controlled case was EUR 940 for CBP and EUR 238 for ABPM. The incremental cost-effectiveness ratio of a well-controlled case of ABPM against CBP was EUR 115. The authors also reported the incremental cost of implementing ABPM in all the false-positive cases to be EUR 13,149. When removing this incremental cost from the potential saving in the cost of drug treatment in these cases, the authors reported the estimated net saving of implementing ABPM was EUR 98,646 at a discount rate of 2%. Estimates at other discount rates were presented in the paper.

Authors' conclusions
Ambulatory blood pressure monitoring (ABPM) is significantly cheaper and more cost-effective than conventional measurement of blood pressure, reduces the cost of arterial hypertension (AH) follow-up, and improves patients' quality of life.

CRD COMMENTARY - Selection of comparators
A justification was provided for the strategies compared. CBP, measured using a mercury sphygmomanometer, is the
conventional parameter with which to diagnose AH and to monitor blood pressure in the authors' setting. The readers should decide if this represents a valid comparator in their own setting.

Validity of estimate of measure of effectiveness
The evidence came from a cross-sectional study, which was appropriate given the objective and design of the study. The authors reported clear inclusion and exclusion criteria for the study, and also a clear definition of the measure of effectiveness following national guidelines. With these criteria, readers could assess whether this study sample reflects the population in their setting. Power calculations were conducted to ascertain the appropriate sample size, thus the results obtained are likely to be statistically significant. As the same patients were involved in comparing the two strategies, comparability issues (e.g. potential biases and confounding factors between the patient groups) are not an issue. However, the observational nature of the study design may limit the internal validity of the estimates obtained.

Validity of estimate of measure of benefit
The authors used the number of well-controlled blood pressure cases as the measure of benefit in the cost-effectiveness analyses. In addition, the number of false positives was used in estimating the potential net saving from unnecessary drug treatment for AH.

Validity of estimate of costs
The analysis of the costs was consistent with the perspective of the public payer. It included all the relevant categories of costs The cost estimates were specific to the study setting, although information on the unit costs and quantities of resources was provided for each included item, which will aid transferability. However, the costs of adverse effects, which were relevant in false-positive cases with drug treatment, were not considered in the costing. Therefore, the reported cost-effectiveness ratio of the CBP strategy with false-positive cases receiving drug treatment and the potential net savings are likely to have been underestimated, whilst the incremental cost-effectiveness ratio of the ABPM strategy against the CBP strategy is likely to have been overestimated. The authors used the total cost of measurements made for each strategy in the analyses. However, they did not report how the total cost of each strategy was estimated. With the exception of the price year for equipment for CBP and for the antihypertensive agents, the authors did not report the price year for other values used in their estimations.

Other issues
The authors made appropriate comparisons with those from other studies, which in general showed variation between the results of other studies. The authors do not appear to have presented their results selectively and their conclusions appear to have reflected the study findings. The authors acknowledged that the results should be interpreted with caution before generalising them to a different population.

Implications of the study
The authors recommend that, given study results showing ABPM to be significantly cheaper and more cost-effective than conventional measurement of blood pressure and to reduce the cost of AH follow-up and to improves patients' quality of life, together with the future application of European rules banning mercury-containing sanitary apparatus in Spain, the healthcare administrations must implement an alternative diagnostic method such as ABPM in primary care as soon as possible.

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**Other publications of related interest**
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**Indexing Status**
Subject indexing assigned by NLM

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