Left ventricular hypertrophy and cardiovascular risk stratification: impact and cost-effectiveness of echocardiography in recently diagnosed essential hypertensives

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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 echocardiography in the assessment of cardiac target organ damage related to hypertension. The M-mode echocardiographic study of the left ventricle was performed under two-dimensional control. Left ventricular mass was estimated from end-diastolic left ventricular internal diameter (LVIDd), interventricular septum and posterior wall thickness using the formula of Devereux and Reiekek, and normalised to body surface area. Relative wall thickness was calculated as twice the posterior wall thickness divided by the LVIDd. A more detailed description of the technology is given in an earlier study (Cuspidi et al. 2004, see ‘Other Publications of Related Interest’ below for bibliographic details).

Type of intervention
Screening and diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised consecutive, never treated, hypertensive patients referred to an outpatient clinic. Inclusion criteria were Grade-1 and Grade-2 hypertension (clinical blood pressure values between 90 and 190 mmHg diastolic or 140 and 179 mmHg systolic), diagnosed in the previous 12 months and confirmed during the first visit to the clinic. Patients were excluded if they showed evidence of target organ damage at routine investigations, congestive heart failure, myocardial infarction, cardiac valve disease, history of coronary bypass or coronary angioplasty, diabetes mellitus, renal insufficiency, and any condition preventing technically adequate ambulatory blood pressure monitoring. Patients with suspected secondary hypertension were also excluded.

Setting
The setting was secondary care. The economic study was carried out in an outpatient hospital clinic in Italy.

Dates to which data relate
The effectiveness and resource data were collected between 1999 and 2005. The cost data were obtained from the Italian National Health System but the price year was not stated.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used for the effectiveness study.
Study sample
The authors did not report the use of power calculations to determine the sample size. The screening process involved 670 consecutive untreated patients with Grade-1 and Grade-2 hypertension. Of these, 21 were excluded because of secondary hypertension, 33 for Type-2 diabetes mellitus or evidence of target organ damage according to routine investigations, 15 for valvular disease, and 11 for unwillingness to participate or miscellaneous reasons. A total of 590 hypertensive individuals finally met the inclusion criteria, of which 580 completed the study, having ambulatory blood pressure monitoring and ultrasonographic examinations of good technical quality. Demographic and clinical characteristics were presented for 579 patients (223 men and 113 women under 50 years of age; 132 men and 111 women over 50 years of age). (This info is likely to contain a typographical error as the number should add to 580.)

Study design
This was a prospective cohort study that was based in a single centre. No details of follow-up were provided.

Analysis of effectiveness
The basis of the analysis of effectiveness was treatment completers only. The primary outcomes considered were the prevalence of LVH and the prevalence rates of patients' reclassification in the high-risk class. Clinical and demographic characteristics of patients according to age and gender showed that, in groups of older hypertensive patients, clinic and 24-hour systolic blood pressure was higher, body mass index was similar, prevalence of current smokers was lower than that of younger patients, and prevalence of isolated clinic hypertension was similar to their younger counterparts. A logistic regression model was used to evaluate the independent contributions of age, gender, clinic and ambulatory systolic and diastolic blood pressure, and overweight on LVH.

Effectiveness results
The logistic regression showed that both age older than 50 years and 24-hour systolic blood pressure of 140 mmHg or more were independently associated with LVH.

As a result of the routine electrocardiography evaluation of cardiovascular risk, 93 out of 580 patients (16.3%) had no cardiovascular risk factors (other than high blood pressure). These were classified in the low added risk stratum. A total of 487 (83.7%) patients were classified in the medium risk added stratum.

Echocardiography resulted in a change in the initial risk stratification distribution. In the whole population, 14.4% and 70.8% of patients remained in the low and medium strata, respectively, whereas 14.8% were reclassified in the high stratum, (p<0.01).

The prevalence rates of patients' reclassification in the high-risk class according to age and gender were 8.9% in men younger than 50 years of age, 12.3% in women younger than 50 years of age, 26.7% in men aged 50 years and older, and 15.3% in women aged 50 years and older.

Clinical conclusions
The study showed that the detection of LVH by echocardiography induced a significant change in the initial risk assessment of the study population.

Measure of benefits used in the economic analysis
The authors used the number-needed-to-detect (NND) a case of LVH as the measure of benefits for the economic analysis. The NND was computed as the number of patients examined divided by the number of LVH cases diagnosed.

Direct costs
The cost/quantity boundary adopted for the study was not explicitly stated. However, it appears to have been that of the
hospital. It was unclear from the paper whether all the relevant cost categories were included, as the authors only reported a total cost per echocardiography examination. Price data were obtained from the Italian National Health Service. The price year was not stated.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
No indirect costs were included.

**Currency**
Euros (EUR).

**Sensitivity analysis**
No areas of uncertainty were identified or investigated.

**Estimated benefits used in the economic analysis**
The NND for one case of LVH was 6.7 in the overall population (9.6 in younger patients and 4.5 in older patients).

**Cost results**
The authors reported an approximate cost of EUR 62 per echocardiographic examination.

**Synthesis of costs and benefits**
The authors reported an overall total cost of EUR 418 per detected case of LVH.

The estimate performed in the sub-group of patients over 50 years of age was EUR 234 for men and EUR 405 for women.

The cost per case in the sub-group of patients younger than 50 years was EUR 595.

**Authors’ conclusions**
The probability that echocardiography may reclassify patients under 50 years of age from low or medium risk to high risk was very limited. In addition, the cost per detected case of left ventricular hypertrophy (LVH) was particularly high. The authors suggested that their data do not support systematic echocardiograph assessment in all uncomplicated hypertensive individuals.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. It represented standard practice and reflected general practice in Italy. You should decide whether this represents standard practice in your own setting.

**Validity of estimate of measure of effectiveness**
The study used a prospective cohort design. There was no adjustment for potential confounding factors and it was unclear from the paper whether the effectiveness analysis was handled credibly. Moreover, it is difficult to know whether the sample size was large enough to obtain robust results. The prevalence of LVH and the prevalence rates of patients' reclassification in the high-risk class appear to have been valid measures of effectiveness. However, the
observational nature of the study represents a limitation to its internal validity.

**Validity of estimate of measure of benefit**
The summary measure of benefit used in the economic analysis appears to have been appropriate compared with those of similar studies. However, given that it was an intervention-specific health benefit measure, it does not enable comparisons with different health care interventions.

**Validity of estimate of costs**
The perspective was unclear, but it appears to have been that of the hospital. The authors limited their analysis to the total cost per echocardiography, as stated by the Italian National Health System, and the expenditure areas included in this estimation were unclear. This limits the transferability of the results. Further, the cost estimates are likely to be specific to Italian Outpatient Clinics. Uncertainties around the cost estimate were not investigated, nor were the cost data adequately reported. Overall, the costing reporting was limited.

**Other issues**
The authors made extensive and detailed comparisons of their findings with those of published studies. They stated that the prevalence of LVH was similar, but acknowledged variability in the results of previous research due to differences in the demographic and clinical characteristics of study populations. The authors also pointed out that prevalence of LVH is dependant on the criteria used for diagnosis, and a partition index to body height would have increased the prevalence of LVH, therefore enhancing the impact of cardiac ultrasound on risk reclassification. A more detailed costing exercise would have been more informative to the decision-maker, while a detailed description of resource use would have enhanced transferability to other settings.

**Implications of the study**
The results of the study support the contention that cardiovascular risk stratification based on routine evaluation, as recommended by current guidelines, could underestimate the effective total risk. The systematic use of echocardiography should be mostly directed at hypertensive men aged 50 years or older, owing to its unfavourable cost-effectiveness ratio in younger patients. These findings should be considered in light of the limitations outlined.

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**Other publications of related interest**


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