Targets and self monitoring in hypertension: randomised controlled trial and cost effectiveness analysis


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
Self-monitoring and targets was compared with usual care in hypertensive patients. The patients in the intervention group were asked to attend their practice every month to measure their own blood pressure (BP) using validated electronic BP machines (Omron M5-I18). They were given about 10 minutes of instruction at baseline on how to use the BP machines. The reception staff were also trained to provide support to patients, as required. The patients received a record card showing the BP target they should aim for: the British Hypertension Society's treatment targets, at that time, were 140/85 mmHg (140/80 mmHg for those with diabetes). If targets were not met, the patients were to attend their general practice.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised hypertensive patients aged 35 to 75 years old receiving treatment for hypertension in primary care and having a BP in the range of 140/85 to 200/100 mmHg.

Setting
The setting was primary care. The study was conducted in eight general practices in south Birmingham, UK.

Dates to which data relate
The sample that provided the effectiveness and resource use data were recruited between 2001 and 2002. 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 carried out prospectively using the same sample of patients as that used in the effectiveness analysis.

Study sample
Representative practices covering different socio-demographic population were included and their patients who satisfied the inclusion criteria were invited to participate. Power calculations were adequately reported. If 434 patients
were followed up, it would be possible to detect a difference of 5 mmHg with a power of 90% and significance level of 5%, assuming a standard deviation of 16 mmHg. Of 3,543 hypertensive patients in the selected age range, 2,057 met the inclusion criteria and were invited to participate. Of these, 1,498 declined the invitation. A total of 441 patients were finally randomised, 227 to the intervention group and 214 to the control group.

Study design
This was a randomised controlled trial that carried out in eight general practices in the UK. The patient was the unit of randomisation. A block-stratified randomisation by practice and diabetes status was undertaken, using opaque envelopes held centrally. The duration of follow-up was one year and it was 91% complete (n=400). Though the study was not blind, the main outcome (BP) was measured in a standardised fashion using a printout from an automated manometer.

Analysis of effectiveness
The primary outcome was change in systolic BP between baseline and follow-up (at 6 and 12 months). The analysis was conducted on an intention to treat basis using the complete case method. A sensitivity analysis explored assumptions for missing values. The groups were broadly comparable at baseline except for gender (52% versus 43% male in the intervention versus control group), which was included in the analytical model as pre-specified in the analysis plan to account for possible confounding. The secondary outcomes were:

- changes in diastolic BP;
- anxiety, as measured using the short form of the Spielberger state anxiety inventory;
- the body mass index, (using electronic scales); and
- the patients’ preferences for BP measurement (i.e. doctor, nurse, self-measurement at the surgery, or self-measurement at home).

Effectiveness results
Systolic BP in the intervention group was significantly reduced after 6 months in comparison with the control group, but not after 1 year. The adjusted mean difference in change was 4.3 mmHg (95% confidence interval, CI: 0.8 - 7.9; p=0.004) at 6 months and 2.7 mmHg (95% CI: -1.2 - 6.6) after 1 year.

No difference was found in diastolic BP, anxiety or health behaviours.

The body mass index reduced significantly more over time in the intervention group than in the control group, (p=0.005).

Reported alcohol intake reduced significantly in the intervention group when compared with the control group in the first 6 months, (p=0.03), but not thereafter, (p=0.56).

The patients in the intervention group ranked home measurement highest, followed by self-measurement in the surgery. Those in the control group ranked measurement by a doctor highest, followed by measurement by a nurse. The difference in ranking was statistically significant, (p<0.001).

Adjustment variables included practice (nested within intervention), diabetes status and gender.

Clinical conclusions
Practice-based self-monitoring resulted in small but significant improvements of BP at 6 months, which were not sustained after 1 year.
Measure of benefits used in the economic analysis
The measure of benefit used was the additional reduction in systolic BP of 1 mmHg.

Direct costs
Prospectively collected trial data from 2001 to 2003 were used to measure consultations for hypertension (with both general practitioners and practice nurses), drug treatment, referrals for hypertension, and intervention costs (for equipment and training). The equipment costs were discounted at 3.5% (per year) over a 5-year life. The unit costs came from standard UK sources. A health service quantity/cost boundary was adopted in the study. The quantities and the costs were not reported separately, and the price year was not stated.

Statistical analysis of costs
The costs were treated stochastically. The data were bootstrapped (1,000 samples) to estimate CIs.

Indirect Costs
The indirect costs were not included.

Currency
UK pounds sterling ( £ ).

Sensitivity analysis
Variability in the cost data was explored through bootstrapping. In addition, a sensitivity analysis was used to explore the effect of missing data on change in BP.

Estimated benefits used in the economic analysis
The mean adjusted effect per patient used in the incremental analysis was 9.9 mmHg (95% CI: 5.8 - 13.9) in the intervention group (self-monitoring) and 7.1 mmHg (95% CI: 3.4 - 10.8) in the control group (usual care).

Cost results
The mean total cost per patient was 251 (95% CI: 233 - 275) for self-monitoring versus 240 (95% CI: 217 - 263) for usual care.

Intervention costs (26.80 per patient) were dominated by the cost of the general practitioners' time in training staff and patients (25.40), with discounted equipment costs being relatively trivial (1.39).

Synthesis of costs and benefits
The mean incremental cost-effectiveness ratio for the intervention group was 5.10 per mmHg (95% CI: -7.2 - 19.1).

The sensitivity analysis indicated that missing values were unlikely to have had an important effect on the outcome results.

Authors' conclusions
Practice-based self-monitoring resulted in small and short-term improvements in blood pressure (BP), which were not sustained after 1 year. The intervention was well received by patients, anxiety did not increase, and there was no appreciable additional cost. Practice-based self monitoring is feasible and results in BP control that is similar to achieved with usual care.
CRD COMMENTARY - Selection of comparators

The authors clearly described and justified the selection of the comparators. Some potentially relevant comparators were omitted (i.e. self-monitoring and targets at home), but the results are relevant for the selected comparators. You should judge whether these comparators are relevant in your own setting.

Validity of estimate of measure of effectiveness

The study design, a randomised controlled trial, is the best design to compare therapeutic strategies. In addition, the trial was adequately conducted. Power calculations were reported. Potential biases and confounding factors were taken into consideration in the protocol phase, and an adjusted analysis was performed in the primary analysis for practice (nested within intervention) and diabetic status, along with baseline differences with potential effects on outcome. The authors noted that the fact that the study was not blind will have had minimal effect on the primary outcome, as BP was recorded in a standardised fashion by a single individual using the printout of an automated sphygmomanometer.

Validity of estimate of measure of benefit

Benefit was measured in natural units (mmHg). However, this measure of benefit does not enable comparisons across health technologies.

Validity of estimate of costs

The costs categories evaluated, as well as the sources used, were adequate for the study perspective (i.e. that of the health service). The authors also cited other papers and broadly estimated the societal perspective, including some patient costs. The resource quantities and the unit costs were partially reported separately, making it difficult for readers to extrapolate the results to other settings. The equipment costs were appropriately discounted over a 5-year life. The fact that the cost year was not reported poses additional difficulties for future reflation exercises.

Other issues

The authors compared their study results with other relevant studies including a systematic review. They stated that their study was the first randomised controlled trial anywhere to evaluate the effect of self-monitoring of hypertension using a community clinic setting for self-measurement. The authors do not appear to have presented their results selectively. The study involved hypertensive patients receiving treatment for hypertension in primary care and this was reflected in the authors’ conclusions. The authors adequately addressed potential limitations of their study. For example, unblinded nature of the study and differential white coat effect. Further limitations were the use of individual instead of cluster randomisation, incomplete follow-up of 9% of the sample, and a relatively low proportion of potentially eligible patients responding to the study invitation. Generalisability issues were not specifically addressed.

Implications of the study

BP can be similarly controlled with either practice-based self-monitoring or usual care, confirming that community-based self-monitoring has the potential to bring the benefits of home monitoring to individuals without the means to purchase their own equipment. The authors suggested that although there is an early and non-sustained improvement of systolic BP at 6 months, how this early improvement might be maintained requires further study. Considering that self-monitoring has low costs, reduces consulting rates, is acceptable to patients and does not increase anxiety, they also suggested that general practitioners should offer this option to their hypertensive patients.

Source of funding

None stated.

Bibliographic details
