

Home blood pressure monitoring in diabetes

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Abstract

Forty three children with diabetes were recruited to evaluate home blood pressure monitoring using an electronic oscillometric sphygmomanometer (Philips HP5330). This device was found to be simple to use and reliable. It fulfilled the accuracy criteria of the American Association for the Advancement of Medical Instrumentation for both systolic and diastolic blood pressure and those of the British Hypertension Society for systolic blood pressure. Thirty eight children successfully measured their own blood pressure at home and taught other family members to do the same. The results indicate that home blood pressure monitoring is of value in the management of diabetic children.

Diabetic nephropathy is the major life threatening complication of juvenile onset diabetes.¹ Preceding the nephropathy by as much as 10 years there may be a small but significant rise in blood pressure, usually together with micro-albuminuria.² Antihypertensive therapy at this normotensive stage (according to the criteria of the World Health Organisation (WHO)³) can prevent the progressive decline in renal function and associated rise in blood pressure.⁴ Blood pressure then, should be measured as accurately as possible in young diabetic patients.

When measured in outpatient clinics, blood pressure is often raised.⁵ In adults, a series of pressure measurements at home is helpful in distinguishing patients with sustained hypertension from those with 'office hypertension'.⁶ Home recordings using an electronic sphygmomanometer correlate closely with ambulatory measurements,⁷ which have been shown to be of greater predictive value than office measurements.⁸ The accurate assessment of blood pressure in young diabetics should therefore probably include a representative home series before appropriate diagnostic and therapeutic decisions can be made.

As familial hypertension may be a risk factor for nephropathy,⁹ the blood pressure of parents and siblings should also be assessed; home monitoring would provide a practical means of doing this.

To our knowledge, home blood pressure monitoring in diabetic children and their families has not previously been evaluated. As the usefulness of such a technique depends primarily on the reliability and accuracy of the equipment when used in the population under review and on the abilities of those performing the home monitoring, this study was designed to examine

these factors and to assess the potential value of home blood pressure monitoring.

Patients and methods

Forty three (26 male, 17 female) children and teenagers with insulin dependent diabetes were recruited randomly from the clinic over a six month period. Their mean age was 15.0 years (range 8.8-19.3 years) and mean duration of diabetes 6.7 years (range 0.2-17.3 years). The home monitor used was the Philips HP5330 which measures systolic and phase V diastolic blood pressure by the oscillometric method and displays the results digitally. The study initially validated the home monitor, and then examined the results of home blood pressure monitoring in these patients and some of their families.

VALIDATION OF THE HOME MONITOR

The validation procedure included the criteria of the American Association for the Advancement of Medical Instrumentation (AAMI)¹⁰ and the British Hypertension Society (BHS) protocol.¹¹

Pressure indicator accuracy and interdevice variability

Calibration was checked by connecting the monitor to a standard mercury column with a Y connector. The pressure recorded on the monitor was then compared with that indicated on the mercury column. This was done for pressures of 0, 50, 100, and 150 mm Hg before use and on return from each family for all of the eight monitors purchased for the study. The AAMI protocol requires 95% of measurements to be within 3 mm Hg of the reference standard. Interdevice variability was assessed by analysis of variance.

Device validation

The subjects rested in a sitting position for at least five minutes before their blood pressure was measured on the right arm using an adult cuff (bladder size 12×22 cm). No child was admitted to the study in whom this cuff size would have been inappropriate.¹² The blood pressure was measured simultaneously with the monitor and a random zero sphygmomanometer by using a Y connector. Two or three pairs of readings were recorded at two minute intervals. Systolic and diastolic (phase V) pressures were recorded by auscultation to the nearest 2 mm Hg.

The AAMI protocol requires the mean difference to be <5 mm Hg and the standard

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deviation (SD) to be ≤ 8 mm Hg for both systolic and diastolic pressures. The BHS protocol grades the monitor on the cumulative percentage of measurements differing from the reference sphygmomanometer by 5, 10, and 15 mm Hg.

Acceptability for home use

The patients were taught to use the home monitor and were asked to record their own blood pressure at home three times between 1730 and 2100 hours for three days. They were asked to rest in a sitting position for at least five minutes before starting and to leave at least two minutes between readings. The importance of correct positioning of the cuff around the right arm, correct inflation procedure,¹³ a steady deflation rate of 2–3 mm Hg/second, and keeping the arm and tubing still during the measurements (as oscillometric devices can give inaccurate results with excessive movement) were all explained and reiterated in an instruction leaflet given out with the monitor. A chart was provided for recording the results with space for comments on the monitor. The patients were asked to teach the rest of the family how to use the device and record the results at home in a similar manner.

The monitor was collected from the home a week later. The participating family members were weighed and measured, asked details of illnesses, medication, and whether they had encountered any problems in using the monitor.

The mean value for systolic and diastolic pressures was calculated for each diabetic child and their natural mother, father, and eldest sibling (aged >10 years). Any measurement where either the systolic or the diastolic pressure was >30 mm Hg from the mean was rejected as invalid and the mean computed again from the remaining measurements. Any occasions on which it had been recorded that the monitor had failed to function were also noted as were any other comments written or verbal about the monitor. Unless at least three valid measurements were available the blood pressure series was not used for further analysis.

EVALUATION OF HOME BLOOD PRESSURE MONITORING

The mean of each diabetic child's blood pressure measurements that had been recorded using the home monitor in the clinic (when validating it against the random zero sphygmomanometer) was calculated and compared with the mean home blood pressure obtained with the same home monitor. The mean home blood pressure of the diabetic children and siblings was compared with the blood pressure centiles for height based on the data of Andre *et al*¹⁴ as suggested by the BHS.¹² The mean home blood pressure of each parent was graded according to WHO criteria: normal (<140/90), borderline (between 140/90 and 160/85), and high (>160/85).³

Results

VALIDATION OF THE HOME MONITOR

Pressure indicator accuracy and interdevice variability

At all pressures compared (0, 50, 100, and 150

mm Hg), 100% monitor measurements were within 3 mm Hg of those indicated on the mercury column. Each monitor was used by between four and eight families and there was no deterioration in accuracy over the course of the study. Analysis of variance revealed no significant interdevice variability.

Device validation

A total of 124 paired measurements were recorded in 43 patients (three pairs of readings in 38 patients and two pairs in five patients). The range of systolic pressures in the 43 diabetic children was 75–157 mm Hg and the range of diastolic pressures was 43–98 mm Hg. The home monitor's systolic pressures fulfil the AAMI standard for accuracy (mean (SD) difference 1.7 (5.1) mm Hg) and achieve BHS grade B. The monitor's diastolic pressures fulfil the AAMI criteria (mean (SD) difference 4.9 (5.8) mm Hg), and achieve a BHS grade D. There was no statistical evidence of terminal digit preference in the random zero sphygmomanometer readings.

Acceptability for home use

None of the 43 patients invited to participate declined at the start of the study and 38 completed the home monitoring satisfactorily. Five failed to complete the home blood pressure series, but when asked to demonstrate whether they could use the monitor correctly, all were able to do so. A total of 69 natural parents (33 fathers, 36 mothers) and 27 eldest siblings (15 male, 12 female) also participated.

Rejected readings occurred in <2% of over 1100 home blood pressure measurements. These were usually very high systolic readings which tended to occur as a result of excessive movement during the procedure. Five participants noted when the monitor either failed to record (usually when the cuff deflation was too slow) or recorded 'error' (usually when cuff deflation was too fast). A total of 61% of participants produced nine measurements each, while the others produced between three and eight. Although most of these stated that they had not had sufficient time to do all three readings for three evenings as requested, some of these missing readings may have resulted from machine failures or faulty technique.

A few subjects complained that the cuff was uncomfortable. There were otherwise no reports of any significant problems and the majority of diabetic children and their families said that they had enjoyed participating in the study.

EVALUATION OF HOME BLOOD PRESSURE MONITORING

Only the results for systolic pressure were used in reviewing the blood pressure of the diabetics and their families.

Of the 38 diabetic children who completed the study, 66% had a mean home systolic pressure within 10 mm Hg of their mean clinic systolic pressure (fig 1). Three children had a clinic blood pressure more than 10 mm Hg

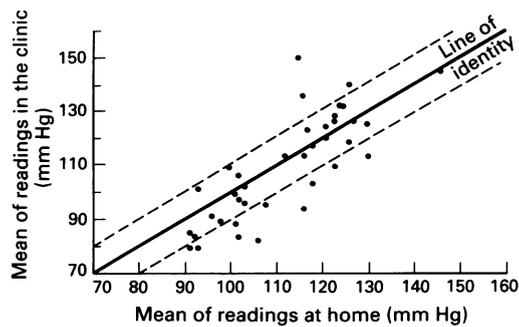


Figure 1 Comparison between the mean systolic blood pressure measured by the home monitor in the clinic and the mean systolic blood pressure at home.

above their mean home blood pressure, one differing by 35 mm Hg. Ten children had a home blood pressure more than 10 mm Hg higher than their clinic pressure.

One 17 year old diabetic boy had a mean systolic pressure of 145 mm Hg both in the clinic and at home; this was above the 90th centile for his height. His mother is a diabetic and her mean home systolic blood pressure was 134 mm Hg on antihypertensive treatment. One diabetic girl whose home blood pressure was on the 90th centile has a brother whose blood pressure was on the 97th centile and a father, aged 56 and non-obese, whose home systolic pressure was 168 mm Hg. The blood pressure of all the other diabetic children and their siblings was unremarkable (figs 2A and 2B).

Three fathers had a borderline raised systolic pressure (between 140 and 160 mm Hg) but the other members of their families were normotensive.

Discussion

This study successfully validated the use of the Philips HP5330 home sphygmomanometer in diabetic children and demonstrated the feasi-

bility of home blood pressure monitoring in this group and their families.

Electronic sphygmomanometers designed for use in adults may not be sufficiently simple to use, reliable and accurate for use in children and teenagers. Some devices designed for self measurement of blood pressure fall far short of basic standards and some of the validation tests to which they have been subjected are also questionable.^{10 11} The detailed protocols of the AAMI and BHS address these problems and it is hoped that, in the future, home sphygmomanometers will be subjected to more rigorous validation procedures by the manufacturers before being put on the market. Meanwhile, by adapting a combination of those stringent tests to a paediatric setting, we have provided a model for further studies and have validated one home monitor for more regular use by the diabetics attending our clinic.

The home monitor was shown to be reliable in that all eight monitors maintained a high degree of pressure indicator accuracy throughout the study and did not significantly vary from each other. It passed the validation criteria for the AAMI protocol and achieved a BHS grade B for systolic pressure (grade A has proved unobtainable by any device so far⁹), but performed less well for diastolic pressures. However, this does not invalidate its use, as measurement of diastolic pressure in children is notoriously difficult, inaccurate, and inconsistent.^{14 15} The random zero sphygmomanometer was used as the reference standard in preference to a standard mercury sphygmomanometer, although it was known that it slightly underestimates both systolic and diastolic pressures.¹⁶ This was done to minimise observer bias and prevent digit preference since there was by necessity a single observer (CG).

Important features of the home monitor were that it was simple to use and seldom malfunctioned. Even those who failed to complete

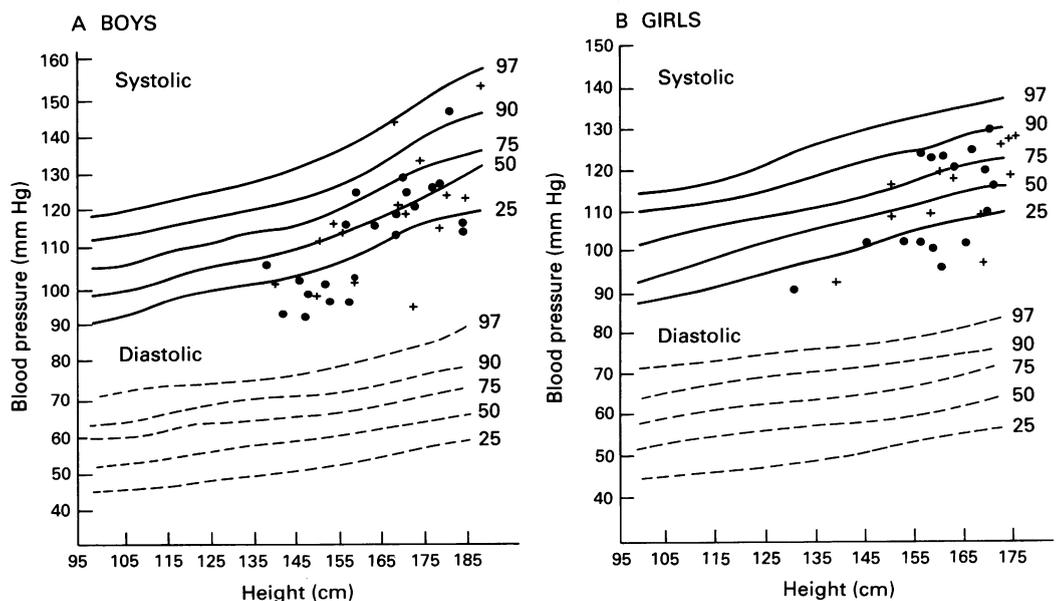


Figure 2 (A) Systolic blood pressure of diabetic boys (●) and their male siblings (+) plotted on centile charts for height.¹⁴ (B) Systolic blood pressure of diabetic girls (●) and their female siblings (+) plotted on centile charts for height.¹⁴

the home blood pressure monitoring had understood after one demonstration how to use it correctly but were not sufficiently motivated to continue with the study. The majority of the diabetic children participated enthusiastically and also enlisted their families into the study with excellent results. The participants were asked to measure their blood pressure in the evenings rather than throughout the day to improve the acceptability of the study. As this is a time of day when blood pressure is relatively stable,¹⁷ the home series was still felt to be representative of their day to day blood pressure.

The numbers of diabetic children, parents, and siblings involved in this study were small as it was a validation and feasibility exercise. However, the results clearly demonstrate the potential value of home blood pressure monitoring. It appears to distinguish office hypertension from sustained hypertension: the boy with a persistent systolic pressure of 145 mm Hg has since been further investigated and treated, whereas the girl with a clinic pressure of 150 mm Hg and a home pressure of 115 mm Hg has avoided unnecessary intervention.

The home monitor provides a profile of the family's blood pressure, so that diabetic children who are possibly at risk of hypertension can be followed more closely. Whether familial hypertension is an important risk factor in diabetic nephropathy requires further research. As many diabetic teenagers attend clinics unaccompanied, home monitoring is a practical method of assessing the blood pressure of their families and probably of more relevance than an occasional clinic measurement. It may also provide useful information for the general practitioner in the surveillance of families with a tendency to hypertension (the father with hypertension is now being treated). In fact, such family blood pressure studies should perhaps be done in conjunction with general practitioners, possibly using the diabetic liaison health visitor to teach and supervise the home monitoring.

It was surprising that 10 children had a home blood pressure higher than their clinic pressure. Although none of these was above the 90th centile, these home readings may be of greater prognostic significance than their clinic blood pressure, as has been demonstrated in adults.⁸ Large prospective studies would be needed to answer this question.

We did not use a control group of non-diabetic families in this study but instead compared the blood pressure of the diabetic children and their siblings with centile charts

which relate pressure to height. These are particularly useful in diabetic children in whom blood pressure and height are measured regularly. In any child whose blood pressure is in the upper centiles or whose pressure appears to be crossing centiles, a home series and family blood pressure profile may be appropriate.

In summary, the management of diabetic children includes the prevention of complications. Careful assessment of blood pressure is part of that surveillance and this study demonstrates that home monitoring is feasible and accurate. We believe it has great potential value in the management of diabetic children, particularly in distinguishing sustained from office hypertension, and in providing a blood pressure profile of a diabetic child's family.

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