Can improved software facilitate the wider use of ambulatory blood pressure measurement in clinical practice?

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Background 24-h ambulatory blood pressure measurement (ABPM) is now recognized as being indispensable in the diagnosis and management of hypertension. The technique must, therefore, be made available in primary care, but in doing so it must be recognized that unfamiliarity with the technique may lead to misinterpretation of data.

Objective To facilitate the wider application of ABPM, especially in primary care, we examined the features that would facilitate the development of a standardized user-friendly software program for the presentation, analysis and interpretation of data.

Methods and Results The following features were considered essential to any software program for ABPM: standardized plots of 24-h profiles; computer interpretation of ABPM data and patterns; a user-friendly one-page report, flexible statistical analysis, and the facility to group data and to export data for audit and research analysis. The dabl[®] ABPM program incorporating these features was introduced into the Blood Pressure Unit, Beaumont Hospital in 2000 and has been used in over 15 000 ABPM recordings. The program is now being used widely in general practice and specialized centres.

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Introduction

The evidence that ambulatory blood pressure measurement (ABPM) gives information over and above conventional blood pressure measurement has been growing steadily over the past 25 years, [1] and longitudinal studies have shown that ABPM is a stronger predictor of cardiovascular morbidity and mortality than conventional measurement [2–6]. A number of national societies have published recommendations for the use and interpretation of ABPM in clinical practice [7-11]. In the United States lack of payment to physicians for ABPM had effectively restricted its clinical use. Recently, however, the Centres for Medicare and Medicaid Services, has approved the technique for reimbursement, thus opening the way for widespread use of the technique [12]. Until recently, ABPM has tended to be available in specialist hospital centres, but with international acceptance that ABPM should be available to patients with established and suspected hypertension, clearly it must also be available in general practice. There is, however, concern that the large amount of data from ABPM may be misinterpreted due to unfamiliarity with the technique.

Conclusions It is feasible to design a software program to provide a standardized plotting format for ABPM, a basic analysis of data for day-to-day clinical work, or elaborate analyses for research, and an interpretative report to assist diagnosis and to provide an educational process for doctors and nurses not familiar with the technique.
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Background

When the Blood Pressure Unit was founded in 1979, ABPM recordings were performed with the Remler ambulatory device, and these had to be plotted manually, greatly impeding its more widespread use. However, it soon became apparent that computerized methods would have to be designed to handle the large data from ABPM efficiently [13]. Over the years we have used many ABPM devices [14,15] each with its own software presenting plots in different formats with a wide variety of statistical analyses, many of which were not relevant to clinical practice. To facilitate research by having all results available for analyses in a single database, we developed a specialized program, which became known as dabl [16]. Over two decades this program went through seven versions as technology and research into ABPM advanced, with the latest version being based on our experience derived from ABPM in over 25 000 hypertensive patients [17] and normal subjects [18].

A number of results from research influenced the development of $dabl^{\mathbb{R}}$ ABPM. Firstly, the controversy as

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to the normal reference values for ABPM had to be reconciled. In 1990, we conducted the first study on normality in ABPM, which allowed us to plot the normal bands for the Irish population [18]. Further evidence from research showing the importance of nocturnal hypertension [19] and the presence of white-coat hypertension during the first hour of ABPM recording allowed daytime, night-time and white-coat windows to be introduced. White-coat hypertension is explicitly addressed by providing a dedicated white-coat window, which is indicated on the plot by a vertical bar and statistics are provided for this period, and may be excluded from or included in other statistical calculations [20]. Statistics were developed for each of these windows as well as the full 24-h period and new measures, such as blood pressure load and a variety of measures of variability, were also incorporated for research purposes. The program also introduced time weighting of blood pressure measurements—an important factor omitted in most existing software. If ABPM is to be widely used in clinical practice there is a need to ensure that the data is interpreted correctly. Educational seminars and workshops have had limited success and are expensive. To address this issue, interpretative reports were incorporated, which assist diagnosis of the varying patterns of ABPM, and greatly reduce the time taken by physicians to report on the recording. Consideration was given to how best to present results in a user-friendly report. Whereas earlier versions of dabl, used pre-printed two-page reports designed for dot matrix printers, later versions took advantage of the quality of laser printouts to fit an informative and relevant report on a single page. Finally, it became apparent that the use of a variety of devices with storage of data in different computer repositories, some of which might become inaccessible with changing technologies, was a serious disadvantage for research. The effective and efficient management of a disease will be dependent ultimately on the ability of management technology not alone to collect and present information on individual patients, but also to have the capability of collecting, sorting and analysing data for specified groups. An important development, therefore, was the storage of all data on a single database regardless of the ABPM device used, with an export facility to allow for the export of both entered and calculated data for use in research studies.

When it became evident that there was going to be demand for ABPM in primary care we realized that the difficulties we had experienced were going to be an impediment to the broader application of the technique. However, *dabl* had been developed as an in-house research facility, which was not in a format suitable for widespread distribution. To achieve this objective, we formed a collaborative partnership with a company that specialized in software management systems and restructured the research software to produce a production version of $dabl^{\mathbb{R}}$ ABPM suitable for both clinical use in

clinical practice in hospitals and general practice, and for research use in specialized centres.

Software requirements to facilitate wider application of ABPM

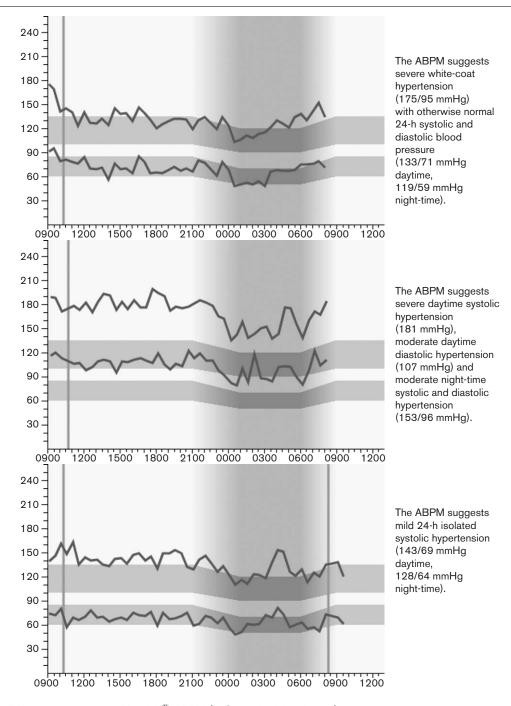
In reality, re-structuring the *dabl* software was more complex than initially envisaged, and the program was completely re-designed to incorporate the features we had identified as being desirable in performing ABPM; these were:

- General applicability and ease of use: *dabl* [®] ABPM uses a series of icons to facilitate the user to initialize the monitor at the commencement of the procedure and to download the recorded data at the end of the 24-h period in a fast and user-friendly manner irrespective of the monitor used.
- Standardized plots of 24-h profiles: a standardized graphic presentation of ABPM for use with all ABPM devices was designed to provide consistency and to remove the need to be familiar with a variety of plotting schemes (Fig. 1). The normal bands for 24-h ABPM and the windows of the 24-h profile were also included in the plotting schema.
- Computer interpretation of ABPM data and patterns: the provision of interpretative reports of ABPM thereby assists the diagnostic process while also giving the novice user support during a period of familiarization with the diagnostic options of the technique.
- Flexible statistical analysis: the program is suited to the requirements of the user. For example, in a busy general practice, basic data giving average day and night-time values (Table 1) and a visual plot are all that may be required, whereas for research purposes more statistical detail will be needed (Table 2).
- A user-friendly one-page report: the program provides (i) a brief or detailed statistical summary of the white-coat, daytime, night-time and 24-h periods; (ii) a standardized plot showing the normal bands for ABPM pressures, the white-coat and night-time windows and the patient's 24-h plot; (iii) an interpretative report based on the data providing the user with a suggested diagnosis. The user is able to input the name, address and institutional details into a design format to suit personal needs, which serves as a default template for future reports.
- Export of data for audit and research analysis: the program provides a facility for analysing research data, auditing performance and collating and exporting data to analytical programs.

Experience with dabl® ABPM

The development of the program was a collaborative venture between the software developers and a clinician in charge of a department in which ABPM was extensively used, and the final program was the result of many months of trial and modification until the program was deemed

Fig. 1



Some common ABPM patterns interpreted by dabl® ABPM. (© Copyright dabl ltd 2004)

satisfactory for clinical use. The system was introduced to the Blood Pressure Unit in 2000 and it has been used in over 15 000 ABPM recordings. The following benefits have resulted in considerable advantage both in the service and research functions of the Unit:

- Reporting time: the Blood Pressure Unit, which carries out 20 ABPMs daily, previously had to rely on a
- registrar reporting on each ABPM, which averaged 2–3 h per working day. The registrar now spends less than 15 min checking and initialling the computer-generated report.
- Training staff: previously it was necessary to organize a training session at every change of registrar (6-12 months), which was a time-consuming endeavour that is no longer required.

Table 1 dabl® ABPM statistics for clinical analysis

	Unit	White-coat window			Daytime			Night-time			24-h		
		SBP	DBP	HR	SBP	DBP	HR	SBP	DBP	HR	SBP	DBP	HR
Readings		3	3	3	21	21	21	10	10	10	43	43	43
Mean	mmHg (bpm)	161	88	47	133	71	44	118	59	40	129	68	42
Load	%	63	30	0	14	0	0	18	0	0	20	2	0
Dip %	%										11	17	8

SBP, systolic blood pressure (mmHg); DBP, diastolic blood pressure (mmHg); HR, heart rate (bpm).

Table 2 dabl® ABPM statistics for research analysis

	Unit	White-coat window			Daytime			Night-time			24-h		
		SBP	DBP	HR	SBP	DBP	HR	SBP	DBP	HR	SBP	DBP	HR
Readings		3	3	3	21	21	21	10	10	10	43	43	43
Mean	mmHg (bpm)	161	88	47	133	71	44	118	59	40	129	68	42
SD	mmHg (bpm)	15	7	2	8	7	3	9	8	2	11	9	3
Load	%	63	30	0	14	0	0	18	0	0	20	2	0
High readings	%	100	67	0	38	0	0	50	0	0	47	12	0
Area under curve	mmHg (bpm)	26	5	0	2	0	0	3	0	0	4	0	0
Leese	%	0	0	47	0	1	52	0	2	57	0	2	54
Maximum	mmHg (bpm)	175	95	50	146	85	49	134	68	45	152	85	49
Minimum	mmHg (bpm)	141	79	44	120	56	40	106	48	39	103	48	39
CoV	%	9	8	5	6	10	6	8	14	4	8	14	7
RMSSD	mmHg (bpm)	20	12	3	10	9	3	7	7	3			
Median	mmHg (bpm)	169	91	47	132	70	43	118	60	40			
Load events		1	1	0	4	0	0	1	0	0	7	2	0
Leese events		0	0	1	0	1	1	0	1	1	0	3	1
Max load duration	min	83	53	0	89	0	0	150	0	0	300	120	0
Max leese duration	min	0	0	83	0	31	630	0	30	300	0	31	1320
Dip %	%										11	17	8
Dip	mmHg (bpm)										14	12	4

SBP, systolic blood pressure (mmHg); DBP, diastolic blood pressure (mmHg); HR, heart rate (bpm).

- Electronic transmission of ABPM reports: the one-page report can be transmitted electronically by e-mail to referring doctors, thereby saving postage of reports.
- Research and audit: the program has allowed for the standardization of ABPM in the many research studies conducted in the Blood Pressure Unit [21] and for the provision of monthly statistics on referral patterns, drugs used and levels of blood pressure achieved in the Cardiovascular Clinics.
- Standardization: increasing international use of the system has resulted in greater standardization of reporting and managing hypertensive patients thereby increasing the opportunities for collaboration on clinical research.
- Accreditation by the Department of Health and Children: The National General Practice Information Group of the Department of Health and Children (Ireland) has accredited the *dabl* program for certification according to the requirements for certification (RFC02), which are in accordance with European Union standards for medical software.

Discussion

The development of the dabl[®] ABPM program has been informative and instructive to us in the emerging

discipline of eHealth. In the first instance, we realized that we had the clinical experience and the scientific evidence to develop a computerized system for improving the clinical use of ABPM, but we lacked the skills necessary to develop the software to contemporary standards. To achieve this, it was necessary to form a business partnership and to be prepared to invest in the future development of our system. The likelihood of recouping the financial investment may be remote but the alternative was to let the idea perish and to await the introduction of a computerized solution by manufacturers of ABPM devices. Experience to-date in this area has demonstrated that without the expert influence of clinicians familiar with the subject, a satisfactory outcome is unlikely. We suspect that this argument is applicable to most innovative software solutions in eHealth. One way of dealing with the financial demands of software development is for academic institutions to be prepared to give financial support to innovative solutions in information technology for health care management.

In practice, the *dabl*[®] *ABPM* program has found generally favourable acceptance, especially in primary care. In this regard, it is fulfilling its primary role of giving doctors and nurses, who are unfamiliar with ABPM, the confidence to use the technique and to become familiar with the data

and plotted patterns. In addition, general practitioners have found that the program has simplified the performance of ABPM saving physician and nurse time and ultimately reducing the cost of performing the technique. Our experience using the program in the Beaumont Hospital Blood Pressure Unit, has also demonstrated this feature. The National General Practice Information Group of the Department of Health and Children (Ireland) has accredited the dabl programs for certification according to the requirements for certification (RFC02), which are in accordance with European Union standards for medical software.

Finally, software systems must never be regarded as 'finished'; clinical practice changes, the evidence that dictates the output of a program must in time become redundant, and new innovations will be brought to information technology, factors which make it necessary to encourage partnerships between software developers and clinicians, so that each can avail of the others expertise in the exciting and promising discipline of eHealth.

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