CORRELATION STUDY OF ARTERIAL BLOOD PRESSURE LEVEL TO THE AMPLITUDE OF THE PRESSURE PULSE WAVEFORM

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ABSTRACT

Automated blood pressure measurements are usually characterized by poor operational reliability and a considerable degree of complexity in performing the measurement. This paper introduces a new technique for the indirect measurement of the systolic and diastolic blood pressure of an individual. The technique is based upon a statistically consistent relationship between the amplitude of the pulsative pressure waveform at the systolic and diastolic points, and the amplitude of pulse signals detected when the artery is fully occluded. Clinical testing and statistical analysis techniques are used to derive appropriate numerical values for these relationships. The proposed procedure thus incorporates an adaptive measurement philosophy achieving minimum observer involvement and consequently high instrument accuracy. Overall measurement errors are maintained well within proposed standards for automated sphygmomanometers.

Keywords: Blood pressure, measurement, clinical data, statistical analysis, error.

INTRODUCTION

Accurate clinical blood pressure readings have been a concern ever since the indirect method was developed at the turn of the century (Hill and Flack[1], Geddes[2]). Conventional non-invasive methods for blood pressure measurement rely on the use of an inflatable occlusive cuff followed by analysis of the Korotkoff sounds by either stethoscopic or electronic auscultation of the sounds (Collins and Magoda[3], McGough and McDonald[4], Schulze *et al.*[5]). Other available techniques are based upon the oscillometric method (Walker[6]) or measure mean arterial pressure (Ramsey[7]) or long term variations of blood pressure by peak and trough detection of the pressure waveform (Mitchell, Ruff and Murnaghan[8]).

The basic design concepts of available instrumentation require human intervention in recording the appropriate pressure levels. They are usually characterized by the need for medical supervision during measurement and a lack of performance reliability. The measurement complexity and lack of reliability have prevented the widespread non-professional use of these devices, despite a growing awareness of hypertension as a serious health hazard and an increasing recognition of the importance of early detection and treatment of the disease.

This paper describes a new technique for the measurement of systolic and diastolic blood pressure in humans. More specifically it is concerned with the clinical testing of a prototype device, and the statistical analysis and evaluation of clinical data, aimed at validating the basic hypothesis of the proposed method.

Clinical tests clearly indicate that the onset of the systolic and diastolic modes is a function of the pressure characteristics of the individual. Thus, clinical evidence indicates a specific and statistically consistent relationship between various pressure signal amplitudes and corresponding Korotkoff sounds. When the artery is completely occluded at some maximum pressure level, a highly sensitive pressure transducer detects small-amplitude pulse signals that are due to the pumping action of the heart. These signals are called background pulses. A consistent and proportional relationship exists between the amplitude of the artery-occluded pressure pulses (background amplitude) and those resulting during deflating of the cuff, corresponding to the onset and termination of the Korotkoff sounds. The amplitude of the pressure pulses at these two particular points of the heart pressure is called systolic and diastolic amplitude, respectively. The above mentioned relationship is exploited in the design of an electronic sphygmomanometer which, in addition to the pressure transducing device, contains suitable electronic instrumentation for processing and displaying the electrical signals. The tests, conducted in a hospital environment, were designed to record the amplitude of the 'background' pulses obtained with the artery fully occluded as well as the pulses corresponding to the individual's systolic and diastolic blood pressure levels.

The proposed instrument may be used eventually by any individual. The main unit is battery powered containing the electronic and display components as well as the pressure transducer. The latter is in fluid communication with an inflatable cuff. The instrument is turned on and a range selection

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switch (160, 200 or 240 mmHg maximum cuff pressure) is positioned to the desired range. The cuff is then inflated and a warning light indicates when maximum pressure has been reached. From that point on, a specially designed relief valve allows for a uniform cuff deflation. The instrument operation is automatic, storing initially the amplitude of the background pulse (B), from which it calculates the amplitude for systolic pressure (B x SR) and for diastolic pressure (B x DR). As these amplitudes occur with cuff deflating, the corresponding systolic and diastolic pressures are displayed on an LED (SR and DR are constants for all patients).

The design features of the proposed sphygmomanometer allow for minimum observer errors and maximum simplicity in taking accurate measurements.

EXPERIMENTAL PROCEDURE

Equipment

Figure 1 shows in block diagrammatic form, the basic elements of the instrument used for the collection of the clinical data. The cuff pressure is transferred through a suitable tube to the pressure transducer which converts pressure levels to corresponding electrical signals. The latter are processed electronically and monitored continuously with a strip chart recorder. The instrument incorporates a warning light which flashes when a desired maximum pressure level is reached in the cuff area. Initially, three such settings for maximum pressure were made available, corresponding to pressure levels of 160, 200 and 240 mmHg, respectively. A suitable setting could then be selected depending upon the age, sex and physical characteristics of the individual monitored so that he would be subjected to minimum discomfort while maintaining the accuracy of the measurement within acceptable limits. Additionally, a conventional sphygmomanometer was used in parallel with the prototype while a stethoscope monitored the onset and termination of the Korotkoff sounds.

The procedure

The testing procedure is aimed at collecting an appropriate sample of data in order to confirm the hypothesis that the ratio of the systolic pulse amplitude to the amplitude of the background pulses remains approximately constant, independently of the individual tested. A similar relationship must also exist for the ratio of the diastolic amplitude to that of the background pulse amplitude.

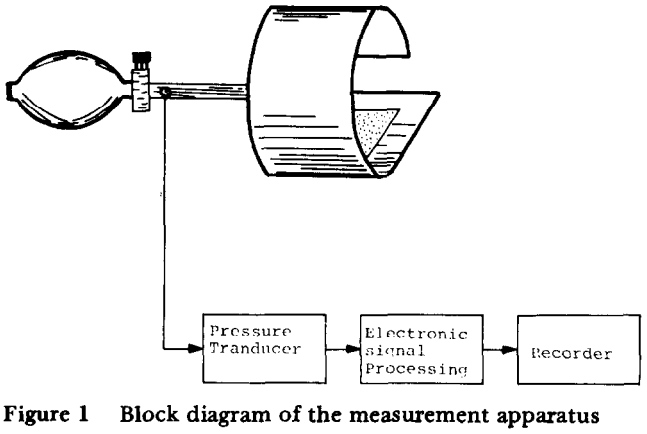

Figure 1 Block diagram of the measurement apparatus

One or two observers perform the required testing on a randomly selected population of patients in a hospital environment. The procedure involves the following steps:

(a) The systolic and diastolic arterial pressure of each subject is measured using conventional means and recorded, together with other pertinent information such as age, sex and physical condition of the individual.

(b) The prototype is set into operation with the maximum pressure setting determined from the results of step (a). Maximum cuff pressure is set so that during deflation a number of cardiac cycles precede the onset of the Korotkoff sounds and giving, therefore, background pulses for a sufficiently long time interval.

(c) Cuff pressure is increased until the warning light comes on; at that point, the recorder is set into operation and the cuff is deflated from then on at a constant rate through an appropriately designed valve. This procedure continues until the diastolic level is reached.

(d) During the course of the procedure the Korotkoff sounds are being monitored continuously. The first detected sound, as the cuff pressure is reduced from its maximum value, is used to mark off: (1) the systolic pressure level and (2) the corresponding pulse on the recording. Similarly, the final sound which is detected when the cuff pressure is further reduced is used to indicate the diastolic pressure level of the individual and the corresponding diastolic pulse.

Steps (a) through (d) are repeated in succession for the whole sample population considered. Each measurement is a continuous recording of the pulsed arterial pressure variations, starting with the background pulses, proceeding through the systolic level and ending after the diastolic level has been reached. Direct measurement of the peak-to-peak magnitudes of the pulse waveforms leads to an evaluation of the systolic to background and diastolic to background ratios (*Figure 2*).

The chart recordings provide additional information as to the modulated nature of the pulse-shaped pressure waveform caused by the breathing cycle of the subject, the individual's heart rate, the absolute strength of the pressure signals and the effect of the pulse shape on the value of the ratios estimated. The procedure, as outlined above, is in accordance with the AAMI proposed standard[9] for electronic or automated sphygmomanometers.

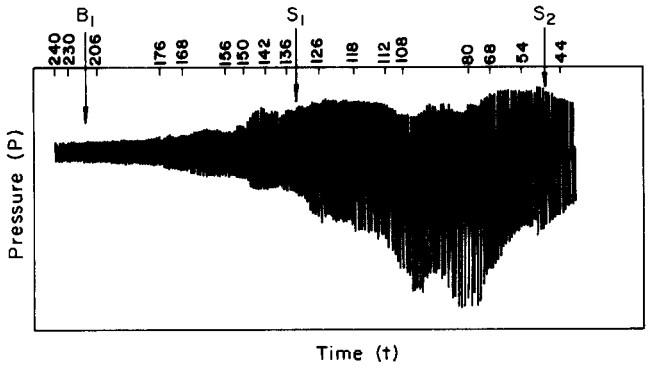

Figure 2 A typical arterial pressure pulse waveform. Sex F; Age 27; Background pulse amplitude, $B_1 = 1$; systolic pulse amplitude $S_1 = 4$; diastolic pulse amplitude $S_2 = 5.5$; $SR_1 = 4$; $DR_2 = 5.5$; $\Delta SR_1 = 3$; $\Delta DR_2 = 4.3$

THE CLINICAL TESTING PROGRAMME

Testing methodology

The clinical testing programme was divided into two phases: the first phase (phase I) involved 54 individuals. Two observers performed the blood pressure measurements independently, resulting in a total sample population of 108. For 86 of these, pressure in the cuff area at the beginning of the testing procedure was set at 160 mmHg, while for the remaining 22 samples the initial cuff pressure was set at a maximum level of 200 mmHg.

At the conclusion of this first phase an initial pressure setting of 160 mmHg did not always allow for the amplitude of the background pulses to remain fairly constant for the duration of a number of cardiac cycles. Moreover, the data collected during this programme phase were not sufficient for a determination of the absolute measurement error, and consequently of the accuracy of the instrument.

The second testing phase (phase II) was designed and executed, therefore, in order to alleviate the shortcomings of its predecessor. Cuff deflation starts at a maximum pressure level of 200 or 240 mmHg. A continuous recording of the absolute pressure, via independent means, is taken for comparison purposes. With an initial cuff pressure of 200 or 240 mmHg, the amplitude of the background pulses remains nearly constant for a sufficient time interval. *Figure 2* shows a typical pressure waveform. The background pulse region (with the brachial artery fully occluded) is clearly distinguishable. As the cuff pressure decreases further, and blood flow through the artery is initiated, the pulse amplitude increases continuously until it reaches a maximum point. From then on, the amplitude of the pressure waveform decreases to zero as blood flows unobstructed through the artery. Additional information included in the figure pertains to the age and sex of the individual tested.

Statistical results

The statistical analysis aims to: determine the most probable values for the'systolic to background' and 'diastolic to background' ratios; evaluate the consistency of these results over the whole subject population; estimate the error the proposed arterial pressure measurement technique introduces when compared to conventional auscultatory methods.

The amplitude of the pulse waveform at the systolic level is read directly from the recording and compared with the amplitude of the background pulses. A similar procedure is followed for the diastolic pressure level. The analysis refers to the statistical distributions of the 'systolic to background' (SR) and 'diastolic to background' (DR) ratios as well as the distributions of the absolute measurement errors.

For phase I data, it is shown, using a Mann and Whitney test, that the two samples (from the first and second observer) belong to the same population. *Table 1* shows a summary of the statistical characteristics for the first phase sample data.

Analysis of the available second phase data leads to the following distributions:

(1) Distribution of the 'systolic to background' ratio (SR). *Table 2* summarizes the statistical characteristics of this distribution. The histogram of the SR distribution is shown in *Figure 3a.*

(2) Distribution of the 'diastolic background' ratio (DR). The characteristics of this distribution are again summarized in *Table 2* while its histogram is shown in *Figure 3b.*

(3) Distribution of the absolute error of the measured values of the 'systolic to background' ratio (DSR). The absolute error for a specific measurement is defined as follows. It is assumed that the measuring instrument is operating at a fixed 'systolic to background' ratio value equal to the statistical mean. i.c, SR = 4.275. In a given measurement, the background pulse amplitude is multiplied by SR and the result is the systolic pulse amplitude. This amplitude corresponds to a pressure level $P_{s,meas}$ on the pressure scale of the recording (shown in *Figure 2*). An independent (but parallel) measurement of the systolic pressure using conventional means gives a value equal to

Table 1 Statistical characteristics for phase I sample data

Phase I statistical characteristics	SR initial pressure		DR initial pressure	
	160 mmHg	200 mmHg	160 mmHg	200 mmHg
Mean value	3.561	4.42	3.3745	3.781
Standard deviation	0.6803	1.082	0.26	0.707
Summation of data	306.3099	380.130	74.24	83.19
Minimum value	2.25	2.85	1.74	2.59
Maximum value	6.8	3.780	7.470	4.96
Number of samples	86	86	22	22

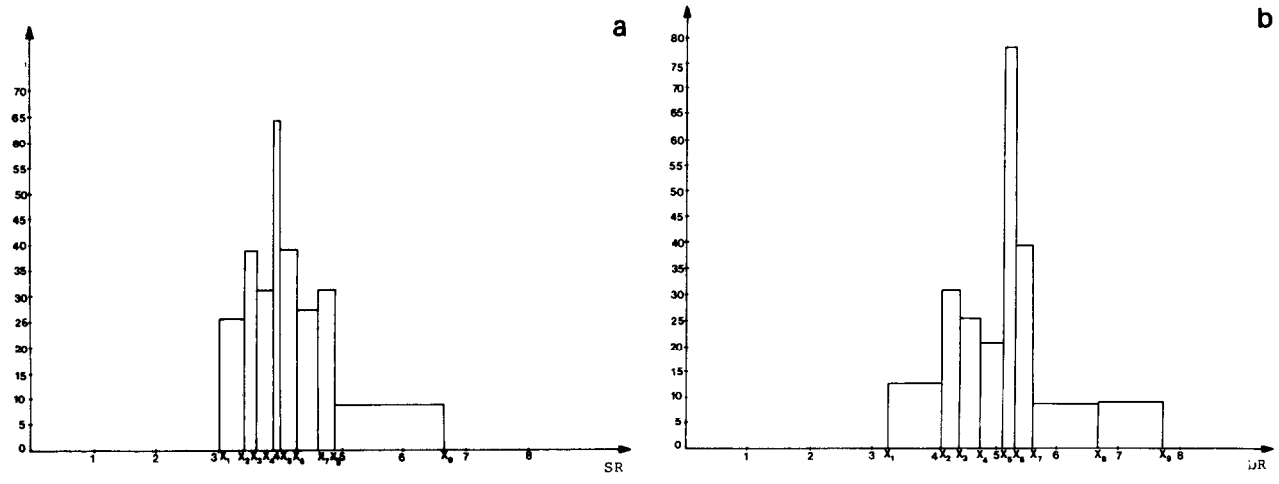

Figure 3 Histogram of frequency distribution for (a) SR and (b) DR

Table 2 Statistical characteristics for phase II sample data

Phase II statistical characteristics	SR	DR	ΔSR	ΔDR
Mean value	4.275	5.198	3.488	3.482
Standard deviation	0.732	0.951	3.255	4.179
Summation of data	324.89	395.05	265.1	264.6
Minimum value	3.056	3.261	0	0
Maximum value	6.667	7.733	13	16.5
Number of samples	76	76	76	76

$P_{s,st}$. The absolute error is defined by the relation $|P_{s,st} - P_{s,meas}|$ and is expressed in *Table 2* while *Figure 4a* shows the histogram of this distribution.

Application of the χ^2-test leads to the conclusion that ΔSR does not follow a normal distribution. For this reason, a polynomial approximation, $P_1(x)$, to the distribution statistics is chosen to functionally represent ΔSR. Specifically, a fourth order polynomial of the form:

$$P_1(x) = a_4x^4 + a_3x^3 + a_2x^2 + a_1x + a_0 \quad (1)$$

is specified and the coefficients $a_0 \ldots a_4$ are determined using a least squares method. A computer code simulating the least square algorithm gives the following results:

$a_0 = 0.0825077$ $\quad a_1 = 0.78789783$

$a_2 = -0.0104133$ $\quad a_3 = -0.0002427$

$a_4 = 0.000027$

It is understood that the function $P_1(x)$ is defined

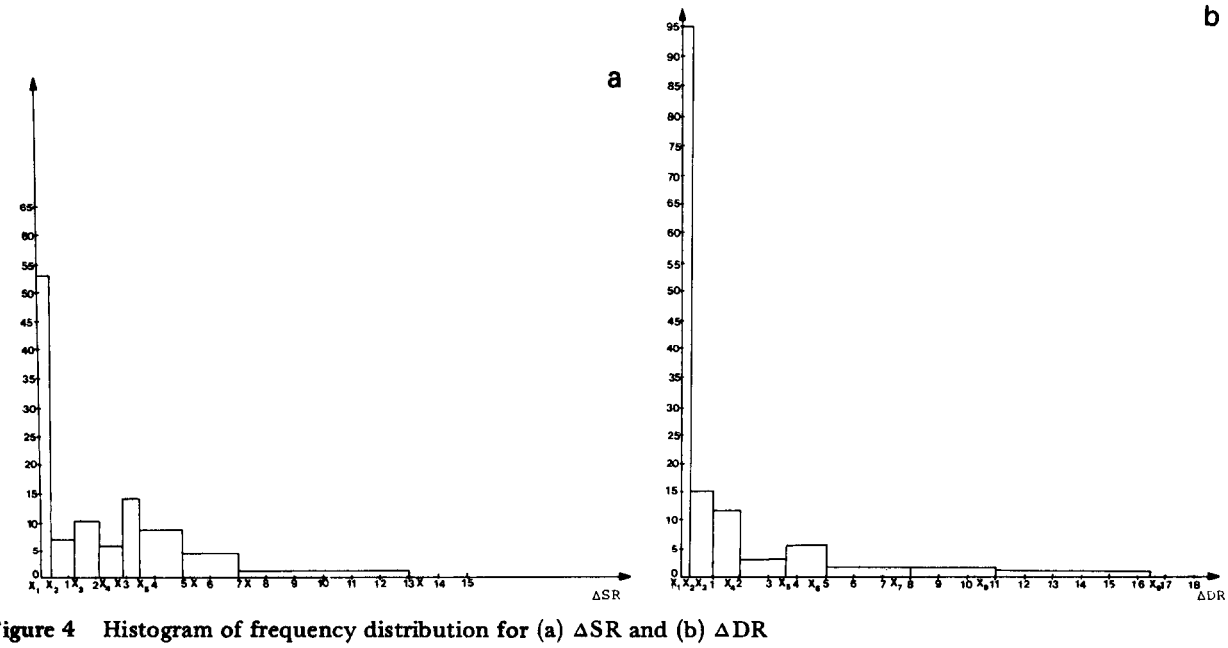

Figure 4 Histogram of frequency distribution for (a) ΔSR and (b) ΔDR

by the expression:

$$\text{Prob}(x > x_k) = 1 - P(x_k) \quad (2)$$

that is, the probability that the variable x is greater than some value x_k is equal to $1 - P_1(x_k)$. *Figure 5* shows both $P_1(x)$ and the density distribution function $\Phi_1(x)$. The latter gives the probability of the variable x (i.e. the value of ΔSR) to be equal to a value x_k, i.e:

$$\text{Prob}(x = x_k) = \Phi_1(x_k) \quad (3)$$

From the $P_1(x)$ distribution data, it follows that, with a 90% probability, the absolute error, ΔSR, is in the range:

$$0 \leqslant \Delta SR \leqslant 7.825 \text{ mmHg} \quad (4)$$

whereas the mean or probable error (i.e. the error for a 50% probability) is equal to 2.618 mmHg, or

$$0 \leqslant \Delta SR \leqslant 2.618 \text{ mmHg} \quad (5)$$

It is worth illustrating the meaning of the confidence interval. Let us assume that 100 measurements are available and for 90 of these the absolute error ΔSR is in the range of the confidence interval, i.e. between 0 and 7.825 mmHg. It is stated then that $0 \leqslant \Delta SR \leqslant 7.825$ with a probability of 90%.

(4) Distribution of the absolute error of the measured values of the 'diastolic to background' ratio, ΔDR. The absolute error ΔDR is expressed in similar terms as ΔSR; the ratio DR is now set equal to the mean value of the DR distribution, i.e. DR = 5.198. *Table 2* summarizes the characteristics of this distribution whereas *Figure 4b* shows its histogram. The coefficients of $P_2(x)$ defined in a similar manner as $P_1(x)$ are found to be:

$a_0 = 0.27927348$ $\quad a_1 = 0.16054979$

$a_2 = -0.01799949$ $\quad a_3 = 0.001068$

$a_4 = -0.00002472$

The $P(x)$ and $\Phi(x)$ diagrams are shown in *Figure 6*.

The 90% confidence interval is found to be equal to:

$$0 \leqslant \Delta DR \leqslant 9.75 \text{ mmHg} \quad (6)$$

and the probable error is estimated to be given by:

$$0 \leqslant \Delta DR \leqslant 1.66 \text{ mmHg} \quad (7)$$

As was pointed out above, second phase testing begins with a maximum cuff pressure of either 200 or 240 mmHg. On the basis of the initial pressure value (200 or 240 mmHg), the sample population may be finally divided into two separate classes, (i) the population sample of 62 individuals for which the initial pressure value is 200 mmHg, and (ii) the remaining 14 samples with an initial pressure setting of 240 mmHg. The characteristics of both the 'systolic amplitude to background' and 'diastolic amplitude to background' ratios for these two classes are listed in *Table 3*.

The functional dependence of the SR and DR ratios upon the initial pressure setting is strong when this initial value is below 200 mmHg. In the 200–240 mmHg range though, this dependence diminishes substantially, resulting in almost constant amplitude background pulses for at least an interval of five to six cardiac cycles for all individuals tested.

Realization of an electronic sphygmomanometer, on the basis of the statistical results presented above, involves the implementation of three pairs of 'systolic to background' and 'diastolic to background' ratios, according to the value of the initial pressure level selected. Thus, if the initial pressure level is 160 mmHg, then SR = 3.561 and DR = 4.42; for an initial pressure of 200 mmHg, SR = 4.286 and DR = 5.092 and for an initial pressure of 240 mmHg, SR = 4.234 and DR = 5.668.

ERROR ANALYSIS

The statistical analysis of the previous paragraph leads to a direct estimation of the probable measurement error. The probable error (i.e. the absolute error for a confidence level of 50%) is found from *Figures 5* and *6* to be 2.1618 mmHg and 1.66 mmHg for the systolic and diastolic pressure levels, respectively. Under these conditions the instrument performs accurately, since the measurement error is well within the proposed ± 5.0 mmHg accuracy standard (AAMI[9]). Possible error sources may be due to:

- the observer
- the equipment
- the subject tested
- the environmental conditions

Table 3 Statistics according to initial pressure level

Phase II statistical characteristics	SR initial pressure		DR initial pressure	
	200 mmHg	240 mmHg	200 mmHg	240 mmHg
Mean value	4.286	4.234	5.092	5.668
Standard deviation	0.770	0.5289	0.994	0.708
Summation of data	265.7625	59.2751	315.701	79.349
Minimum value	3.056	3.619	3.261	5.167
Maximum value	6.667	5.375	7.733	7.5
Number of samples	62	14	62	14

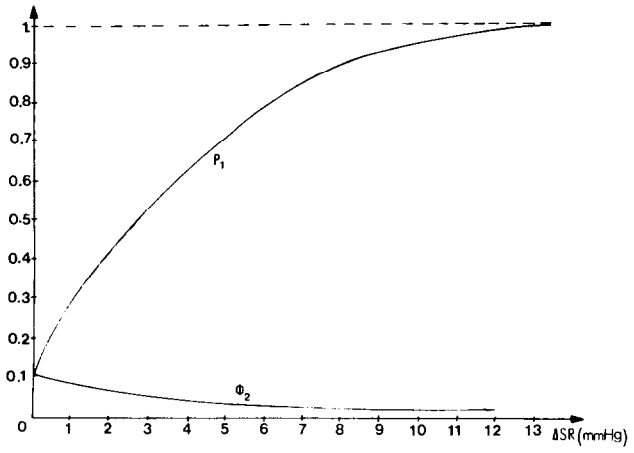

Figure 5 Graphical representation of $P_1(x)$ and $\Phi_1(x)$

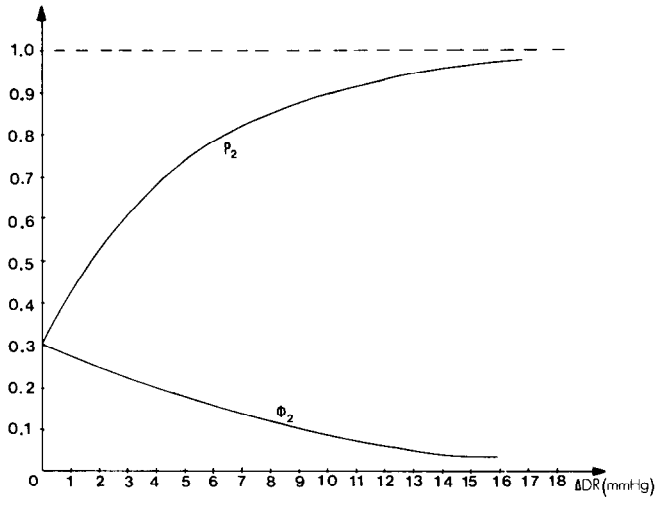

Figure 6 Graphical representation of $P_2(x)$ and $\Phi_2(x)$

The proposed instrument is designed to operate with a minimum observer involvement, thus minimizing the error contribution from this category. Errors due to equipment arise primarily from the non-linear characteristics of the electronic pressure transducer (of the order of 1%) and the other components (amounting to about 0.5% of full scale). The subject tested may contribute a substantial part of the experimental error by allowing motion of the arm during measurement, abnormal breathing, etc. Finally, environmental conditions, such as vibrations, noise, etc., may affect the accuracy of the measurement.

DISCUSSION

The instrument operation, incorporating three separate range values (160, 200 and 240 mmHg) for the initial pressure at which cuff deflation begins, results in acceptable accuracy levels. Error estimates for both the systolic and diastolic readings are statistically maintained within recommended standards. Minimizing observer errors has increased the overall operational reliability of the proposed scheme, particularly when typical systolic/diastolic discrepancies with a standard can be up to 10.2/7.5 mmHg, as reported in recent clinical studies (Scherwitz, Evans, Hennrikus and Vallbona[10]).

A prototype sphygmomanometer was constructed and tested with a conventional mercury manometer taken as the standard. A test population of 40 subjects was considered and the initial 'artery occluded' pressure was set at 200 mmHg. The statistics of the resulting measurement error for both the systolic and diastolic pressure levels were found to fit the error distributions $P_1(x)$ and $P_2(x)$, respectively, with a confidence level of 10%. Thus, clinical testing and the associated statistical analysis have shown the validity of the basic hypothesis upon which the proposed sphygmomanometer is constructed.

Further improvement in performance may be achieved by selecting for each measurement, an optimum SR and DR value. The available test data are used in conjunction with a least squares algorithm in order to derive a functional relationship between the 'systolic to background' and 'diastolic to background' ratios, and the amplitude of the background pulses. Programming these relationships into the memory unit of an appropriately designed instrument and utilizing the optimum ratio values for each testing situation will minimize the absolute measurement error resulting in increased instrument accuracy.

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