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AUTOMATED CONSTANT CUFF PRESSURE SYSTEM TO MEASURE AVERAGE SYSTOLIC AND DIASTOLIC BLOOD PRESSURE IN MAN[1]

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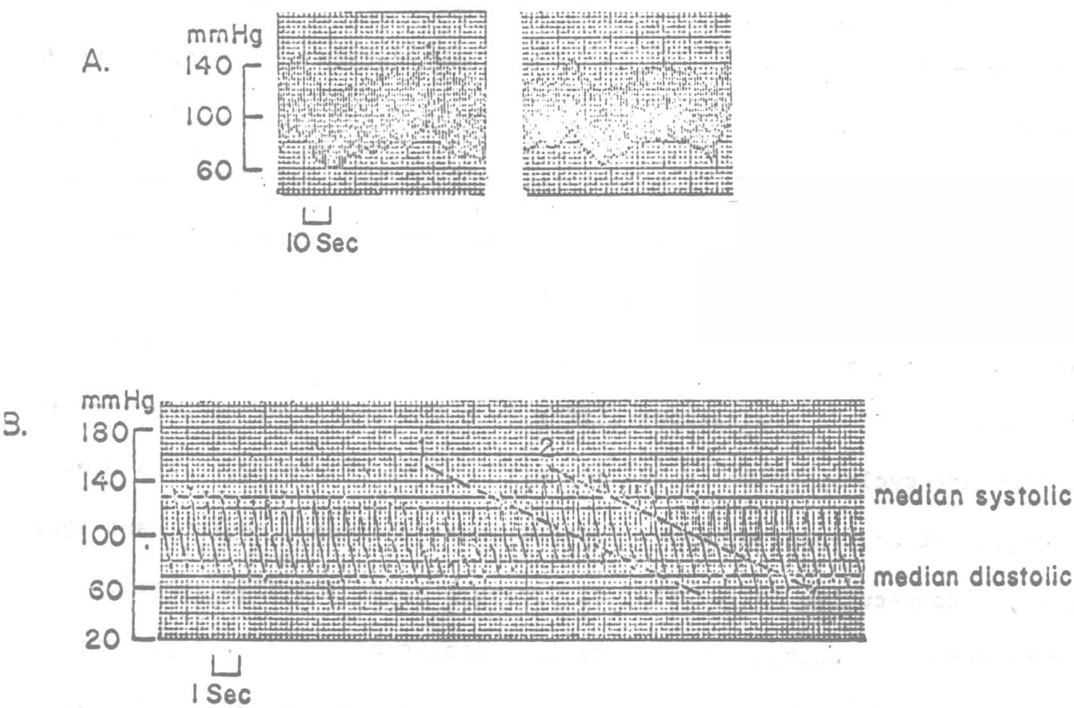

Fig. 1. Sample intra-arterial recordings from one patient.

A. Two samples of intra-arterial pressure waves demonstraing the great variability of beat-to-beat systolic and diastolic blood pressure.

B. Intra-arterial recording from same patient showing in detail the beat-to-beat variability. Diagonal lines 1 and 2 are two imaginary cuff deflations starting a few seconds apart to demonstrate the possible discrepancies between such determinations. Median systolic and diastolic pressure is indicated.

diastolic blood pressures have a range of more than 25 mm Hg. Figure 1B is an intra-arterial recording from the same subject recorded with 10 times the paper speed. It shows in detail 50 pressure waves. The systolic pressure in this instance ranges from a high of 144 mm to a low of 114 mm Hg, while the diastolic pressure ranges from a high of 84 mm to a low of 56 mm Hg. It is apparent that a single sphygmomanometric determination of blood pressure can result in any combination of systolic and diastolic pressure depending on the time of initiation and rate of deflation of the blood pressure cuff. To demonstrate this point, two parallel imaginary cuff deflations have been superimposed on the intra-arterial record starting a few seconds apart. The first results in a reading of 124 mm systolic and 90 diastolic; the second, taken a few seconds later, reads 144 systolic and 60 diastolic. Both determinations differ from the median blood pressure for these 50 heart cycles, which is 128 systolic and 68 diastolic. This demonstration is not an isolated case. Table 1 shows the mean, median, and range based on 50 consecutive intra-arterial pressure waves for five subjects. It can be seen that natural variations in systolic and diastolic pressure range from 10 to 34 mm Hg during of 50 heart cycles, about the time required to take a single manual measure of pressure. Clearly, measures

Insert Table 1 about here

of blood pressure based on a single beat-to-beat interval, no matter what method of recording is used, can result in a false assessment of the subject's typical pressure. The clinical aspects of this problem were experimentally examined by Armitage and Rose [9], who compared single with multiple sphygmomanometric readings and found large variations both

Table 1

Systolic and Diastolic Mean, Median, and Range in mm/Hg of

50 Consecutive Blood Pressure Waves Recorded Intra-arterially*

	Systolic			Diastolic		
Subject	Mean	Median	Range	Mean	Median	Range
1	219.5	219	34	139.4	140	11
2	143.8	143	10	79.7	81	12
3	142.9	142	25	89.9	90	20
4	141.1	142	12	76.2	77	16
5	113.7	113	17	72.4	73	19

*Intra-arterial records from which data were extracted were provided by Dr. Benjamin Murawski of the Cardio-vascular Laboratory at the Peter Bent Brigham Hospital in Boston.

within and between subjects. They concluded that studies based on a single measure of blood pressure would result in frequent misclassification of individuals, exaggeration of the prevalence of hypertension, and a masking of genuine irregularities. In a survey of 722 men, Armitage, Fox, Rose, and Tinker (10) demonstrated large standard deviations for both systolic and diastolic readings taken on different occasions and for duplicate readings taken on the same occasion. These investigators concluded that data from a single blood pressure determination results in as many as 33% false positive and 5% false negative assessments of hypertension when compared to determinations based on the mean of four readings. Studies of the difference in blood pressure between intra-arterial and cuff methods (11), (13) do not assess inter-heart beat variations since comparisons are made of single sphygmomanometric determinations and the systolic or diastolic level of the corresponding pressure wave in the intra-arterial record.

Rationale for Median Blood Pressure

A solution to the problem of beat-to-beat variability in pressure employs a procedure that can yield stable average systolic and diastolic levels for a number of successive pressure waves so that beat-to-beat fluctuations are taken into account. Intra-arterial recordings provide the most accurate measures for this purpose since they can produce a true reading of systolic and diastolic pressure for each heart beat. It is not feasible, however, to use this procedure either in repetitive experiments in the laboratory or in the determination of clinical blood pressure because of obvious medical complications and the need for sterile conditions. Readings made by hand-operated or automated sphygmomanometers can only provide intermittent data, and it would be time consuming and less reliable to compute averages in this fashion.

Shapiro, Tursky, Gershon, and Stern [14], in studying the control of human blood pressure by operant conditioning, developed a method of providing information to subjects about relative changes in blood pressure on each heart cycle. Success in this study was judged by a subject's ability to increase or decrease his median systolic blood pressure as a function of being rewarded on a beat-to-beat basis for changing his pressure in the right direction [15], [16].

Elimination of the feedback and reward capabilities of this system permitted simplification of the logic circuitry needed to track average systolic and diastolic blood pressure. This modification resulted in a new measurement procedure which is based on the idea that when a cuff is inflated and held at constant pressure the Korotkoff sound will be present or absent as a function of the variation in blood pressure in the artery with each heart beat. When the pressure applied to the cuff is greater than the systolic pressure, the brachial artery is occluded and no Korotkoff sound can be detected. When the cuff pressure is lower than systolic but higher than diastolic pressure, a Korotkoff sound will be picked up with every heart cycle. If the constant pressure applied to the cuff is adjusted upward so that a Korotkoff sound is detected on 50% of a given number of heart beats, the cuff pressure defines the median systolic pressure. The same procedure can be implemented at the diastolic level by use of an appropriate method for detecting the muffled (Phase IV) or the absence of the Korotkoff sound (Phase V).

Since the procedure for electronically isolating the muffled Korotkoff sound (Phase IV) is more difficult, the diastolic data in the present paper are based on the last sound (Phase V)[1]. At this level, when the applied cuff pressure is lower than Phase V diastolic, the cuff does not impede blood flow in the artery, and no Korotkoff sound will be detected. If the constant pressure applied to the cuff is adjusted upward so that a sound is detected on 50% of the prescribed number of heart cycles, the cuff pressure defines the (Phase V) median diastolic pressure. This procedure satisfies the two basic requirements for the general measurement of average human systolic and diastolic pressure: (1) The ability to measure variations in systolic or diastolic pressure on each heart cycle, (2) the ability to derive automatically an average measure of systolic or diastolic pressure for a given number of heart cycles.

To evaluate the sensitivity of this method, a test was run on six subjects. For each subject, a standard blood pressure cuff was pumped up to above systolic pressure and reduced in steps of 2 mm Hg to below diastolic pressure. On each determination the cuff pressure was held constant for 50 heart beats, and the percentage of Korotkoff sounds to heart cycles (R-K coincidence) were recorded. Figure 2 is a sample record of two consecutive constant cuff-pressure inflations, 2 mm Hg apart in pressure, recorded at the systolic level. The cuff pressure was reduced by 2 mm Hg in the second trial, resulting in an R-K coincidence increase from 5 (10%) in the first trial to 25 (50%) in the second trial. Figure 3 (solid line) demonstrates the function generated by averaging the (R-K) percentage data of six subjects. On the average, a 2 mm Hg

Insert Figs. 2 and 3 here

increase in cuff pressure at the median systolic level reduced the average percentage of coincident (R-K) sounds from 59% to 29% and a decrease of 2 mm Hg increased it to 76%. Similar changes were observed at the diastolic level. Each individual subject produced approximately the same function. These results demonstrate the sensitivity of the constant cuff pressure system; at median systolic or diastolic pressure a change of 2 mm Hg alters the coincidence (R-K) rate by about ±25%, thus ensuring that median pressure can be accurately measured to within 2 mm Hg.

Description of Constant Cuff-Pressure System

Figure 4 is a simplified block diagram[2] of the constant cuff-pressure system. To determine median systolic pressure, a conventional blood pressure cuff is inflated to above occluding pressure by means of a regulated low pressure compressed air source. The cuff is deflated until the first Korotkoff sound is detected by a crystal microphone mounted over the brachial artery. At this level, pressure is held for a prescribed number of heart cycles. A Statham P23AC pressure transducer monitors the pressure in the cuff, records it on a strip chart, and stores it in memory as a reference for the next inflation. The Korotkoff sound is amplified and fed to an electronic level detector which is set to detect sounds of criterion magnitude. (The criterion

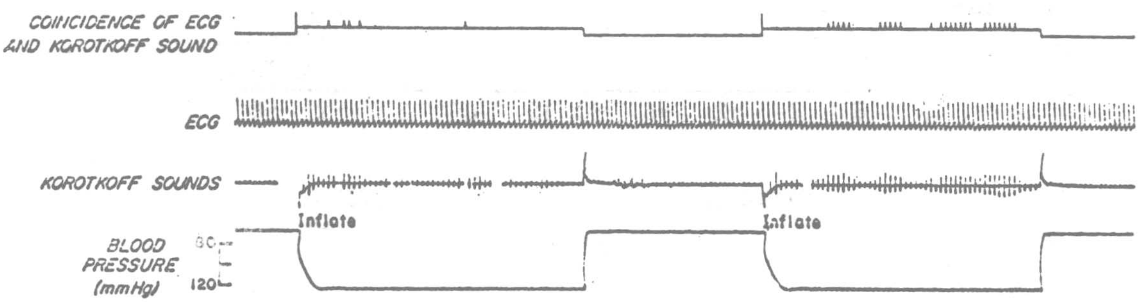

Fig. 2. Typical polygraph record of two consecutive constant cuff pressure trials at the systolic level. Cuff pressure is reduced by 2 mm Hg in the second trial. R-K coincidence increase from 5 (10%) in the first trial to 25 (50%) in the second trial.

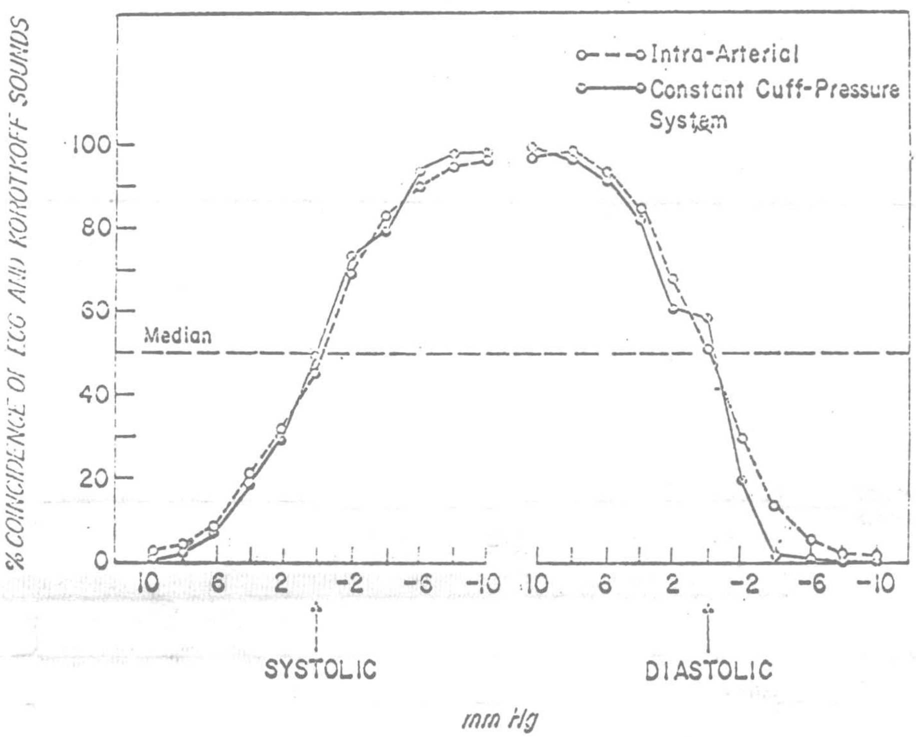

Fig. 3. Percent change in R-K coincidence around systolic and diastolic levels for constant cuff-pressure system (N = 6) as cuff pressure is reduced by 2 mm Hg steps from above systolic to below diastolic pressure. This function is compared to data from intra-arterial records (N = 5) treated in a similar manner.

Korotkoff sound is defined as the equivalent of the first audible sound and greater than any sound produced when the cuff is deflated). The output of this electronic switch is fed to one arm of an electronic logic module that detects coincident events. The patient's ECG is recorded from a pair of electrodes across the body, and the R-wave of each successive QRS complex is detected by a second electronic switch. The output pulse of this switch triggers both a beat counter to regulate the number of beats that will constitute a determination and an adjustable 300 msec flip flop. When the cuff pressure is approximately at the systolic level, this time period represents the propagation time between R wave and the appearance of the Korotkoff sound at the cuff [17], [18]. The gate signal from this flip flop is fed to a second input of the "AND" gate coincidence circuit. The use of this 300 msec gate reduces the possibility of artifact from gross body movements and insures a decision about the presence or absence of a Korotkoff sound on each heart cycle. The occurrence of R-wave and Korotkoff sound (R-K) produces an output from the coincidence circuit that triggers a counter. At the end of a prescribed number of heart cycles, this counter retains the number of beats that produced a Korotkoff sound, and this number divided by the total number of beats constitutes the percentage of Korotkoff sounds during that determination. The cuff pressure is by definition at the median systolic pressure when Korotkoff sounds are detected on 50% of the monitored heart cycles. The data shown in Fig. 3 (solid line) indicate that when there is a 25 - 75% R-K coincidence, the cuff pressure is within 2 mm Hg of the median pressure, and no change is necessary on the next inflation. One to twenty-four per cent R-K coincidence indicates that cuff pressure is greater than median arterial pressure, and cuff pressure is automatically lowered by 2 mm on the next inflation. If 76 - 99% coincidence is detected, the cuff pressure is lower than median arterial pressure, and on the next inflation it is automatically raised by 2 mm Hg. If R-K coincidence is 0 or 100%, the system assumes a greater than 2 mm Hg discrepancy, and a ±4 mm Hg step is automatically taken to rapidly return the system to median level. When median systolic pressure is determined, the pressure is stored in systolic memory, and the cuff is deflated.

Cuff deflation is maintained for 30 seconds to insure restoration of free blood flow in the venous return. This reduces the possibility of measurement errors due to blood accumulation in the veins and the resultant discomfort to the subject. There has been no report of subject discomfort from the use of the constant cuff-pressure system in three years of use in our laboratory in experiments involving more than 200 subjects.

At the end of this rest period a similar procedure is used to determine median diastolic pressure. The cuff is again pumped up to the recorded systolic pressure and slowly deflated until a criterion last sound is detected. The pressure is held at this level for the prescribed number of heart cycles at each determination. When the criterion diastolic sound is detected on 50% of the monitored heart cycles, the cuff pressure represents the true median diastolic pressure. The system is as sensitive to small changes in cuff pressure at this level as it is at systolic pressure. A $\pm$ 2 mm Hg change in cuff pressure alters the R-K coincidence percentage by approximately 25%. At the diastolic level, cuff pressure is increased by 2 mm Hg when R-K coincidences drop below 25% and decreased by 2 mm Hg when R-K coincidences rise above 75%.

Assessment of Accuracy

An assessment of the accuracy of the constant cuff-pressure system was made by comparing the data generated in the laboratory (Fig. 3, solid line) to a similar treatment of the previously described intra-arterial recordings. Systolic pressure in these patients ranged from a high of 225 mm Hg to a low of 110 mm Hg, and diastolic pressure ranged from a high of 135 mm Hg to a low of 65 mm Hg. Systolic and diastolic levels for 50 consecutive blood pressure waves were measured, and the median, mean, and range for each subject determined (Table 1). Mean and median systolic and diastolic pressure are less than 1 mm Hg apart in each patient and are thus interchangeable as indices of average blood pressure. The wide variation in the range from patient to patient again demonstrates the strong possibility of error in any determination of blood pressure based on a single beat.

These intra arterial data were treated in the following manner. Starting at the highest pressure level recorded for each subject, an imaginary cuff pressure was reduced in steps of 2 mm Hg. At each step the number of waves were counted that would have produced a Korotkoff sound at that constant pressure level and a percentage of these waves to total calculated. These percentages were plotted (Fig. 3, broken line) and compared to the original data. In this case a 2 mm Hg increase from the median systolic pressure reduces the percentage of Korotkoff sounds from 56% to 28% and a decrease of 2 mm in cuff pressure increases the percentage to 70. The striking similarity between the two sets of curves in Fig. 3 demonstrates that median pressures measured by this system can be as accurate as median pressure arrived at by averaging intra-arterial readings.

The accuracy of the constant cuff-pressure method can best be demonstrated by simultaneously recording intra-arterial pressure from one arm and recording median pressure by use of the constant-pressure method from the other arm. The patient was a 50-year old male who was admitted for a right heart catheterization to diagnose a possible pulmonary artery aneurysm. Arterial pressure was recorded directly from the brachial artery of the left arm, and median systolic pressures were obtained from the right arm using the constant cuff-pressure method. Five sets of 32 consecutive pressure waves were recorded several minutes apart. The intra-arterial data were treated as previously described to obtain the mean, median, and range for each determination. Table 2 shows the comparison between the median intra-arterial systolic blood pressure measure for each set of 32 beats and the median systolic pressure as determined by the constant cuff-pressure method. All comparisons are less than 2 mm Hg apart, demonstrating

Insert Table 2 about here

that this method of obtaining median systolic pressure is as accurate as averaging a similar number of intra-arterial readings.

Table 2

Comparison of Simultaneously Recorded Intra-arterial and Constant Pressure Cuff Systolic Blood Pressure in mm/Hg on One Patient, 5 Trials of 32 Heart Cycles*

	Intra-arterial Pressure		Constant Pressure Cuff System
Trials	Median	Range	Median
1	114	14	112
2	112	16	114
3	114	20	114
4	113	20	114
5	112	14	112

*Dr. Herbert Benson of the Combined Cardio-vascular Unit at Boston City Hospital provided the patient and the facilities to generate these data.