Clinical Studies

A New Compact 24-Hour Indirect Blood-Pressure Recorder and Its Clinical Application

Osamu TOCHIKUBO, M.D., Kohsuke MINAMISAWA, M.D.,
Eiji MIYAJIMA, M.D., Masao ISHII, M.D.,
Akihiko YANAGA,* and Youji YUKINARI*

SUMMARY

A new portable noninvasive recorder ($4 \times 6.5 \times 14$ cm in size, 390 g in weight) was developed for monitoring 24-hour blood pressure and its clinical applicability was investigated. Employing an ordinary-size cuff, this is the lightest and the most compact apparatus of its kind ever developed. It is powered by a rechargeable battery. The cuff is pressurized by a miniature, low-noise, rotary micropump. To eliminate noises resulting from body motion, two microphones are used to distinguish Korotkoff sounds. Systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) are measured automatically at intervals of 1 to 60 min throughout 24 hours. These data can be stored as many as 600 times in the recorder's semiconductor memory. After measurement, mean values; standard deviations (SD); and trendograms of SBP, DBP, and HR are printed out by means of an appurtenant, miniature analyzer measuring $5 \times 7.5 \times 15$ cm.

A comparison of values obtained with this new instrument and the values obtained with a conventional auscultatory method showed average errors of -1.2 ± 4.7 (SD) mmHg for SBP and -2.7 ± 5.0 mmHg for DBP. The correlation coefficient (r) of values obtained by two methods was $r = 0.99$ for SBP and $r = 0.96$ for DBP ($n = 185$). In 38 male and 31 female normotensive subjects (average casual BP: male $126 \pm 11/76 \pm 7$ mmHg; female $116 \pm 13/69 \pm 10$ mmHg), average 24-hour BP values recorded by the new recorder were 115 ± 7.5 (SBP)/ 70 ± 6 (DBP) mmHg for the males and $106 \pm 6/63 \pm 5$ mmHg for the females. The new recorder seems to be convenient, easy to operate, and clinically useful in ambulatory monitoring.

From the Second Department of Internal Medicine, School of Medicine, Yokohama City University, Yokohama, Japan.

Address for reprint: Osamu Tochikubo, M.D., Second Department of Internal Medicine, School of Medicine, Yokohama City University, 3-46 Urafune-cho, Minami-ku, Yokohama 232, Japan.

* Research & Development Section, Takeda Medical, Inc., 2-16-20 Shimura, Itabashi-ku, Tokyo 174, Japan.

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RECENTLY, general opinion has come to regard ambulatory 24-hour blood pressure (BP) as more relevant than casual BP measured in outpatient clinics for the prognosis and severity of hypertension.^{1)–3)} The authors have developed various invasive and noninvasive BP recorders,^{4)–6)} and have reported on the significance of 24-hour BP monitoring, on measurement of circadian variations,⁷⁾ on BP during sleep,⁸⁾ and on evaluating the efficiency of antihypertensive drugs.⁹⁾

Although ambulatory recording of 24-hour continuous intra-arterial BP provides an accurate evaluation of blood-pressure profiles,^{10)–12)} unfortunately application of this method to daily clinical practice is limited.

Various kinds of noninvasive, 24-hour BP recorders have been developed,^{6),13)–16)} but their weights and shapes have put a considerable burden on patients using them. Moreover, certain doubts about their accuracy and measurement errors remain unresolved.¹³⁾

The authors' newly developed, portable BP recorder (TM-2420) is smaller and lighter than any of its predecessors, requires very little time for each measurement, and has a low noise level. Furthermore, it is simple and convenient to operate; and its analyzer, which provides an output of measurement results, is small and portable. Since it promises to be useful in outpatient clinics, we present this report on its basic features, precision, and clinical applicability.

METHODS

1. Instrumentation

The apparatus is composed of (1) a sphygmomanometer cuff, (2) a BP and heart-rate recorder (TM-2420), (3) a compact analyzer with a printer processing unit, (4) an adapter for attachment to a waist belt, (5) a carrying case, (6) a charging unit, and (7) a personal computer. In addition, a communications (RS-232C) cable for expanding the system by attachment to a personal computer and processing media is available.

(a) Blood-pressure recorder

The compact BP recorder (TM-2420) weighs approximately 390 g and measures 4×6.5×14 cm (Fig. 1). Items (4) and (5) enable the patient to carry the apparatus with little burden or discomfort (Fig. 2). For the

Fig. 1. TM-2420 blood-pressure and heart-rate recorder and a compact analyzer with a printer processing unit.

Fig. 2. Using the carrying case to attach the TM-2420.

sake of carrying ease, the internal structure consists of small, sturdy, compactly arranged parts.

Determination of BP is effected by means of two microphones that eliminate the effects of noise and recognize Korotkoff sounds. More specifically, one microphone (MIK #1), positioned over the brachial artery detects Korotkoff sounds or external noises. Another microphone (MIK #2), located within the cuff away from the artery detects pulse pressure or noises of external origin. After passing through their respective amplifiers and band-pass filters, signals detected by these microphones are converted to digital values by an analog-to-digital (A/D) converter (Fig. 3). Then, on the basis of the special characteristics of digitalized Korotkoff-sound wave

Fig. 3. Block diagram of the TM-2420 (SIO=serial I/O communication; S-RAM=static random-access memory; SV=solenoid valve; Ni-Cd=nickel-cadmium battery; Beep=buzzer; DC/DC=direct-current to direct-current converter; A/D=analog-to-digital converter; MIK#1=Korotkoff-sound detector; MIK#2=noise detector; K-sound=Korotkoff sound; LCD=liquid-crystal display; CPU=central processing unit).

Fig. 4. Eliminating externally caused noise (detected by MIK#2) from true Korotkoff sounds (detected by MIK#1). Fluctuation in both sound signals indicates the presence of noise.

forms, the signals are used in determining systolic and diastolic blood pressures within the central processing unit (CPU). Elimination of the effects of externally caused noises is accomplished by utilizing the time lag and difference in wave forms between signals from MIK #1 and MIK #2 for comparison and discrimination (Fig. 4). Cuff pressurization is effected by means of a low-noise, rotary micropump; approximately 10 sec are required

Fig. 5. Cuff pressurization and depressurization during measurement.

to pressurize up to 200 mmHg. The pump sound-noise level (less than 40 dB/m) causes no discomfort in the ordinary daily-life environment. Cuff pressure is initially applied up to approximately 30 mmHg above a value that depends on the previously measured value of systolic blood pressure. The cuff is then depressurized step by step by means of a solenoid valve: it is reduced at a rate of from 3 to 4 mmHg/sec until Korotkoff sounds are recognized. Cuff pressure is measured at the moment when the initial Korotkoff sound is recognized to be systolic blood pressure (SBP). Thereafter, pressure is reduced at the rate of 3 mmHg/pulse in synchronization with Korotkoff sounds. After the detection of three Korotkoff-sounds, enough air is rapidly exhausted by opening the solenoid valve down to a pressure determined with reference to the last measured value of the diastolic blood pressure (i.e., intermediate rapid exhaustion). Next, while Korotkoff-sound detection continues, cuff pressure is further reduced, at a rate of 3 mmHg/pulse. The cuff pressure measured when Korotkoff sounds disappear (Korotkoff-phase V) is considered to be diastolic blood pressure (DBP). Thereafter, air is rapidly exhausted in the manner described in intermediate rapid exhaustion. Utilization of this pressurization-depressurization sequence (Fig. 5) reduces the time required for blood-pressure measurement to approximately 30% less than what it is in the conventional method.

The time interval between successive measurements may be arbitrarily set between a minimum of 1 min and a maximum of 60 min. Moreover, each 24-hour period may be subdivided into as many as 4 separate blocks for measurement purposes.

Other features incorporated in the apparatus include ON/OFF selectors

for the digital liquid-crystal display (LCD), for a buzzer that sounds 15 sec before the beginning of measurement, and for automatic suppression of the buzzer sound during the night.

Up to 600 measured SBP, DBP, and HR values as well as measurement times may be stored in the internal, 8KB semiconductor memory. Because approximately 300 BP measurements may be performed with a single battery charge, it is possible to make measurements at 10-min intervals over a 24-hour period. If the battery is recharged once during this period, measurements may be performed at intervals of as little as from 3 to 5 min.

(b) Analyzer

The compact analyzer ($5 \times 7.5 \times 15$ cm in size, 200 g in weight) used in conjunction with TN-2420 recorder handles settings of initial conditions, printer output, and interface output to an external computer.

Initial conditions requiring setting comprise inter-measurement time interval, ON/OFF state of the LCD and the buzzer, personal identification (ID) number input, and time setting. The printer provides printouts of tabular recorded data, trendograms, and statements of the setting used in the measurements.

The recorder can be connected to a commercially available personal computer (NEC PC-9801) by means of an RS232C cable.

2. Evaluation of measurement accuracy

BP values recorded with this apparatus were compared with those obtained with the conventional auscultatory method.

Subjects tested comprised 62 individuals (32 males, 30 females), ranging in age from 25 to 60 years (35 ± 12 , mean $\pm$ SD). Of these, 40 subjects were normotensive and 22 were patients with essential hypertension.

With the subject resting in a seated position, the cuff of the recorder was fastened to the left brachia; and cuff pressure was transmitted to a mercury sphygmomanometer through a 3-way valve. During the process of measuring with the TM-2420, the measurer could not see the measured values. Simultaneously with these measurements, SBP and DBP (Korotkoff-phase V) were measured independently by means of a mercury sphygmomanometer and a stethoscope according to the conventional auscultatory method. Values obtained from these measurements were subsequently compared with those obtained by means of the new recorder.

To investigate erratic measurements caused by external sources during exercise, blood pressure measurements were taken at 1-min intervals from 10 normotensive individuals riding a bicycle ergometer. After measurements

Table I. 24-hour BP of Normotensive Subjects

Sex		Male	Female
No. of Subjects		38	31
Age	(years)	28.4 ± 3.7	25.4 ± 6.0
Height	(cm)	167.9 ± 5.7	155.4 ± 4.3
Weight	(kg)	59.6 ± 7.2	48.8 ± 5.5
Casual BP			
SBP	(mmHg)	126.3 ± 11.4	116.2 ± 12.7
DBP	(mmHg)	76.0 ± 7.4	69.4 ± 10.4
Mean of 24-hr BP			
SBP	(mmHg)	115.6 ± 7.9	105.5 ± 5.9
DBP	(mmHg)	70.3 ± 6.0	63.0 ± 4.9

Mean $\pm$ SD

BP=blood pressure measured every 15 min; SBP=systolic BP; DBP=diastolic BP.

had been taken for 4 min with the ergometer at rest, further measuring was continued for an additional period of about 10 min under loads of from 70 to 140 watts. After the load was discontinued, recovery characteristics were measured for another 10 min.

For the sake of statistical analysis, the linear correlation coefficients of measurement values obtained with the conventional auscultatory method and those obtained with the new recording apparatus were computed in the usual manner; and the distribution of differences between the two values was examined.

3. Clinical application

In 69 normotensive subjects (38 males, 31 females) ranging in age from 20 to 35 years, measurements with the TM-2420 were performed every 15 min for 24 hours. Mean casual BP measured on two occasions before and after the 24-hour recording is shown in Table I. Subjects were requested to refrain from moving the left brachia, around which the cuff was applied, while the apparatus was in operation during measurement.

RESULTS

1. Comparison with the conventional auscultatory method

The correlation between values (T) measured by the TM-2420 and values (A) measured according to the conventional auscultatory method was $r=0.99$ ($n=185$) for SBP and $r=0.96$ for DBP (Figs. 6 and 7). When error is represented by the difference (T-A) of these 2 values, the mean and standard deviation of the error was -1.2 ± 4.7 mmHg for SBP and -2.7 ± 5.0 mmHg

Fig. 6 (left). Correlation between SBP values measured from patients at rest with the TM-2420 (Ts) and those measured with a conventional auscultatory method (As), plus a histogram of the errors (Ts-As).

Fig. 7 (right). Correlation between DBP values measured from patients at rest with the TM-2420 (Td) and those measured with a conventional auscultatory method (Ad), plus a histogram of the errors (Td-Ad).

for DBP. Figure 8 shows an example of values measured under ergometer load by means of both the conventional auscultatory method and the TM-2420. In the case of blood-pressure values measured for 10 cases over a period of 10 min during exercise, correlation between values measured by the 2 methods was $r = 0.88$ for SBP and $r = 0.72$ for DBP (Fig. 9), or somewhat lower than correlations obtained for BP measurements taken from resting subjects. Error was computed in the same manner as in the case of resting seated patients; and error values were comparatively large: -4.1 ± 8.0 mmHg for SBP and -3.9 ± 7.4 mmHg for DBP.

2. Clinical applicability

A typical example of 24-hour measurement is shown in Fig. 10. Figure 11, on the other hand, shows a case in which BP-measurement efficacy was poor. In this second case, a male who continued engaging in normal daily employment, had to undergo measurements at 30-min intervals during the

Fig. 8. Comparison between blood pressure values obtained by using TM-2420 and an auscultatory method during ergometer load exercise.

Fig. 9. Correlation between BP values measured with TM-2420 and those with conventional auscultatory method during ergometer load exercise.

Fig. 10. A typical example of ambulatory 24-hour blood pressure and heart rate trendogram measured at 15 min intervals from a 40 year old male with essential hypertension. Upper and lower ends of bars represent systolic and diastolic blood pressure, respectively, and dots represent heart rate.

Fig. 11. One of the rare cases in which measurement was unsatisfactory because the subject moved his arm or the microphone became malpositioned during the measuring process.

night. During the day, because he was active, his arm did not remain still during measurement; consequently, errors occurred at 11:00, 13:00, and 16:00 hours. During sleep, microphone positions shifted improperly, making it impossible to obtain measurements between 4:00 and 7:00 hours. When all cases are considered collectively, the proportion of presumably erroneously measured values for a given individual ranged from 0 to 20%, averaging 6 ± 9 (SD) %.

The present apparatus permits analysis of printout tables of measured values and corresponding measurement times as well as histograms displaying values measured over an arbitrarily established interval.

The results of the 24-hour BP measurements made at 15 min intervals for normotensive subjects are shown in the table. Average 24-hour BP was approximately 11/6 mmHg lower than values obtained from casual BP meas-

Fig. 12. An example of measurements performed at 5 min intervals in a normotensive individual (28 year old male).

urements. For young normotensive males, the 95% confidence upper range was 130/82 mmHg; that for young normotensive females was 117/72 mmHg.

DISCUSSION

In the past, various kinds of portable, noninvasive, BP recording apparatuses have been developed. During the early 1960s, semiautomatic devices of this kind employed tape recorders to record Korotkoff sounds and pressure values from a cuff pressurized by means of a manually operated pump.¹⁴⁾ This procedure did not, however, permit measurement during sleep. Subsequently, another automatic device appearing during the 1970s replaced the hand pump with pressurization provided by a small nitrogen cartridge. In this case too, Korotkoff sound and pressure values were recorded on a tape recorder,¹⁵⁾ but this device was never practically implemented because it was heavy and complicated to manipulate. Nevertheless, since the gas-pressurization method has the advantage of eliminating pump noise, in 1985, the present authors developed a pressurizing device⁶⁾ employing a miniature carbon-dioxide cylinder and a small, eminently practical BP monitoring unit incorporating a digital semiconductor memory. Although eventually marketed by the Takeda Medical, Inc., this apparatus was somewhat heavy (1 kg). Moreover, the number of possible consecutive measurements was limited to somewhere between 50 and 70, depending on gas-cartridge capacity. This constituted another disadvantage.

A slightly smaller apparatus of the same type, subsequently marketed by the Nippon Corin Company, is hampered by the same disadvantages: the apparatus weighs 0.83 kg, which is still somewhat heavy; and the number of measurements performable with a single gas cartridge is limited to between 50 and 70.

American and European ambulatory BP monitoring units¹⁶⁾ employing a rotary pump for cuff pressurization are quite heavy (from about 0.6 to 2 kg), and their high pump-noise levels interfere with sleep and make measurement awkward in public places.

To solve these problems, the authors have developed a new portable BP recorder with the following characteristics: (1) The recorder weighs only 390 g, and is the lightest such apparatus to date. (2) The pump operates at a low noise level of less than 40 dB/m. (3) Use of two microphones enables the detector to discriminate between Korotkoff sounds and external noises, and is therefore comparatively insensitive to external noises. (4) During measurements, the air-exhaustion rate can be maintained at a constant value of 3 mmHg/pulse by using the solenoid valve. (5) A rapid air-exhaustion rate between detection of SBP and DBP reduces measurement time below what was necessary with previously developed recorders. (6) The memory is capable of recording as many as 600 measurements, 300 data-measurement recordings can be made with a single battery charge, and a small portable analyzer can process recorded data.

Measurement error with this apparatus is of the same magnitude as that of previous portable BP recorders.^{6),13),14),16)} With this recorder, as with its predecessors, appreciable errors in measurement made during exercise (Fig. 8) continue to be a problem.

As shown in Fig. 9, correlation is not especially good between BP values obtained under an exercise load with the conventional auscultatory method and those obtained with the TM-2420 apparatus. This is due partly to the difficulties involved in making auscultatory measurements during exercise and partly to error arising from the TM-2420 apparatus used during exercise. The combination of these two factors results in poor correlation. Apparently, hereafter it will be necessary to evaluate the precision of the TM-2420 more certainly in comparison with direct blood-pressure measurement instead of with an indirect auscultatory method.

Another difficulty with the new apparatus is the possible loss of measuring capability resulting from occasional shifting of the cuff position and deviation of the microphones from their proper locations over the artery (Fig. 11). Error can be minimized, however, by holding the brachia motionless and securing the microphones in place with plaster. Provided these conditions are ensured, measurements can be made for a 24-hour period with few errors (Fig. 12), therefore, the TM-2420 portable blood-pressure recorder appears to be a clinically applicable, useful apparatus in monitoring ambulatory blood pressure.

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