

A New Noninvasive Method to Measure Blood Pressure

Results of a Multicenter Trial

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Background: Blood pressure (BP) monitoring with arterial waveform display requires an arterial cannula. We evaluated a new noninvasive device, Vasotrac (Medwave, Arden Hills, MN) that provides BP measurements approximately every 12–15 beats and displays pulse rate and a calibrated arterial waveform for each BP measurement.

Methods: Surgical and critically ill patients (n = 80) served as subjects for the study. BPs, pulse waveforms, and pulse rates measured *via* a radial artery catheter were compared with those obtained by the Vasotrac from the opposite radial artery. Data were analyzed to determine agreement between the two systems of measurement.

Results: Blood pressure measured noninvasively by the Vasotrac demonstrated excellent correlation ($P < 0.01$) with BP measured *via* a radial arterial catheter (systolic $r^2 = 0.93$; diastolic $r^2 = 0.89$; mean $r^2 = 0.95$). Differences in BP measured by the Vasotrac *versus* the radial arterial catheter were small. The mean \pm SD bias and precision were as follows: systolic BP 0.02 ± 5.4 mmHg and 3.9 ± 3.7 mmHg; diastolic BP -0.39 ± 3.9 mmHg and 2.7 ± 2.8 mmHg; mean BP -0.21 ± 3.0 mmHg and 2.1 ± 2.2 mmHg compared with radial artery measurements. The Vasotrac pulse rates were almost identical to those measured directly ($r^2 = 0.95$). The Vasotrac BP waveform resembled those directly obtained radial artery pulsatile waveforms.

Conclusions: In surgical and critically ill patients, the Vasotrac measured BP, pulse rate, and displayed radial artery waveform, which was similar to direct radial arterial measurements. It should be a suitable device to measure BP frequently in a noninvasive fashion. (Key words: Blood pressure; equipment; measurement techniques; oscillometry; tonometry.)

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Received from the Departments of Anesthesiology and Pediatrics, University of Minnesota, Minneapolis, Minnesota; the Department of Anesthesiology, Tokyo Women's Medical College, Tokyo, Japan; University of California, San Francisco, California; University of Vienna, Vienna, Austria; University of Lille, Lille, France; St. Antoine Hospital, Paris, France; and Medwave, Inc., Arden Hills, Minnesota. Submitted for publication August 19, 1998. Accepted for publication May 5, 1999. Supported by Medwave, Inc., Arden Hills, Minnesota. Presented in part at the annual meeting of the American Society of Anesthesiologists, Orlando, Florida, October 17–21, 1998.

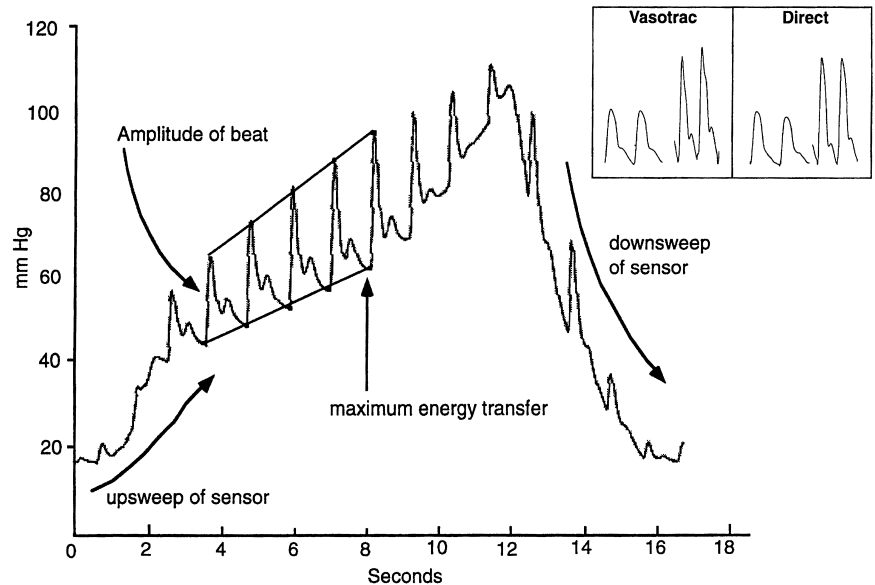
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‡‡ American Society of Anesthesiologists: ASA Standards, Guidelines and Statements, October 1997. The American Society of Anesthesiologists, 1998, pp 2-3.

BLOOD pressure (BP) is routinely checked intermittently during the perioperative care of patients.‡‡ The most common method to measure BP uses the oscillometric principle that consists of the application of an upper arm cuff, which is automatically inflated and deflated to yield a numeric display of systolic, diastolic, and mean BPs.¹ The oscillometric method can be cycled every minute if necessary to provide rapid intermittent BP readings.² If continuous monitoring of BP is required, an arterial catheter is inserted for beat-to-beat display of the pressure waveform and numeric display of BP. Because the procedure is invasive and sometimes results in injury³ the Colin tonometer (Colin Electronics, Komaki, Japan) and Finapres (TNO-Biomedical Instrumentation, Amsterdam, The Netherlands) systems^{4,5} were introduced. Both provide beat-to-beat arterial BP and wave-

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Fig. 1. Generation of the pressure pulse signal elicited by the transducer during compression and release over the radial pulse. The pulsatile waveform detected during the period of maximum energy transfer (elicitation of the maximum pressure pulse wave with minimal sensor compression) is used to provide accurate blood pressure information. Shown in the inset are two samples of waveforms of blood pressure readings (Vasotrac, *left*, and intraarterial BP, *right*) of a patient intraoperatively at different times during surgery. Note the similarity in the waveforms.



form display. In this report, we describe a new commercially available noninvasive method, Vasotrac (Medwave, Arden Hills, MN) to measure BP and arterial waveform frequently. The instrument uses a novel patented technique and algorithm⁶ that utilize frequent gentle compression and decompression of the radial artery at the wrist to detect the zero load state around which multiple parameters of the pressure signal are measured. The information is used to detect and then display arterial pressure and waveform every 12–15 beats. Heart rate is measured with the use of a proprietary beat counter. Thus, this device may prove to be a suitable alternative to oscillometric cuff BP, providing many of the advantages of direct BP measurement. This study was done in surgical and critically ill patients to study the accuracy of the device compared with BP measured with an arterial catheter. We hypothesized that the device would measure BP and heart rate and display a radial arterial waveform with acceptable accuracy compared with that obtained with a radial arterial catheter/transducer system.

Materials and Methods

Study Protocol

After institutional review board approval and patient consent, the study was conducted in a wide variety of patients being cared for in the surgical suites or intensive care units at six large surgical centers in four countries. Eligibility criteria for inclusion in the trial were (1) pres-

ence of bilateral radial pulses; (2) minimal (≤ 5 mmHg) arm-to-arm differences in BP between the upper extremities as measured by the automatic oscillometric cuff method and with two Vasotrac machines; (3) presence of a properly functioning radial arterial catheter to allow for comparison with the Vasotrac placed on the other extremity. Patients were excluded if it was not possible to monitor BP with both arms at the same height relative to the heart and if there were congenital or acquired anatomic differences between the wrists.

All radial artery catheters were 20 g in diameter and 5 cm long and were connected to a transducer by means of either a 2- or 4-ft, low-volume, noncompliant length of tubing. Prior to the study the arterial catheter tubing and transducer were carefully inspected to assure that there were no air bubbles and that there was an optimum dynamic response (natural frequency 12–25 Hz; damping coefficient 0.2–0.3).⁷ This was calculated before each study by performing the “flush test” after placement of the intraarterial catheter. The tracing obtained during several quick flushes was recorded on the computer. Natural frequency and amplitude ratio were calculated to determine the damping coefficient as explained by Gardner.⁷

The Vasotrac unit consists of a nondisposable hydraulically driven sensing device, a wrist holder, and a monitor containing processing, display, and control modules. The sensor requires a zero adjustment and a hydraulic-system leak check prior to use. The gain of the sensor remains stable over a large pressure range. When the

sensor is placed over the radial artery and activated, it applies increasing pressure until enough beats past the maximum energy transfer period have been recorded (fig. 1). The recorded beats are used to estimate systolic, diastolic, and mean BPs. Approximately 12 pulse cycles are required for each BP determination, with BP being updated several times a minute. During the period of maximum energy transfer (*i.e.*, derivation of the maximum pressure pulse signal with minimal sensor pressure over the radial pulse) the Vasotrac retains three beats for further processing. A number of parameters are extracted from each of these three beats. Using a set of predetermined coefficients, based on clinical data, BP values are displayed. A disposable adhesive-backed Vasoguide strip (Medwave Inc., Arden Hills, MN) helps to position and hold the sensor centrally over the radial arterial site. The system is extremely sensitive to motion artifact, and for accurate measurement and waveform display the arm has to be still. A motion-detection algorithm detects artifact in the input signal received from the pressure transducer over the radial artery. If such artifact is detected during the upswing excursion of the pressure transducer, the sweep is automatically discarded and a new sweep begun. After digitally identifying the point of maximum impulse of the radial artery at the wrist and with the use of the Vasoguide, the wrist module was secured by one of the investigators and not moved during the study unless there was displacement because of movement or bumping. All investigators were trained in the use and application of the sensor in volunteers, and each application was supervised by at least one or both of two authors (K.B. or M.P.) who were well versed in sensor placement.

Blood pressure measurements from both the Vasotrac and radial artery catheter were collected for a period of time ranging from 30 min to 6.2 h depending upon the length of the surgical procedure or intervention in the intensive care unit. In the surgical patients, BP recording was started before induction and continued during periods of major BP changes (*e.g.*, induction, endotracheal intubation, clamping, and retraction of blood vessels). Thus, if patients were stable, even though the Vasotrac was providing BP readings, the recording was turned off. Recording was again instituted if BP was expected to change because of either use of drugs or a surgical intervention. Because the Vasotrac utilizes three beats to calculate and display BP, it was possible with the aid of a computer to compare the BP displayed by the Vasotrac to the BP obtained *via* the radial artery during the matched three consecutive beats.

Data Analysis

With the exception of artifacts (electrocautery interference, flushing of arterial catheter, blood sampling from arterial catheter, or oscillometric cuff reading interference), all paired readings obtained during data collection were utilized for analysis by several methods. A scatter plot comparing the two methods of measurement was made for systolic, diastolic, and mean BPs. Correlation, bias (mean error),⁸ and precision (mean absolute value of error)⁸ were calculated.

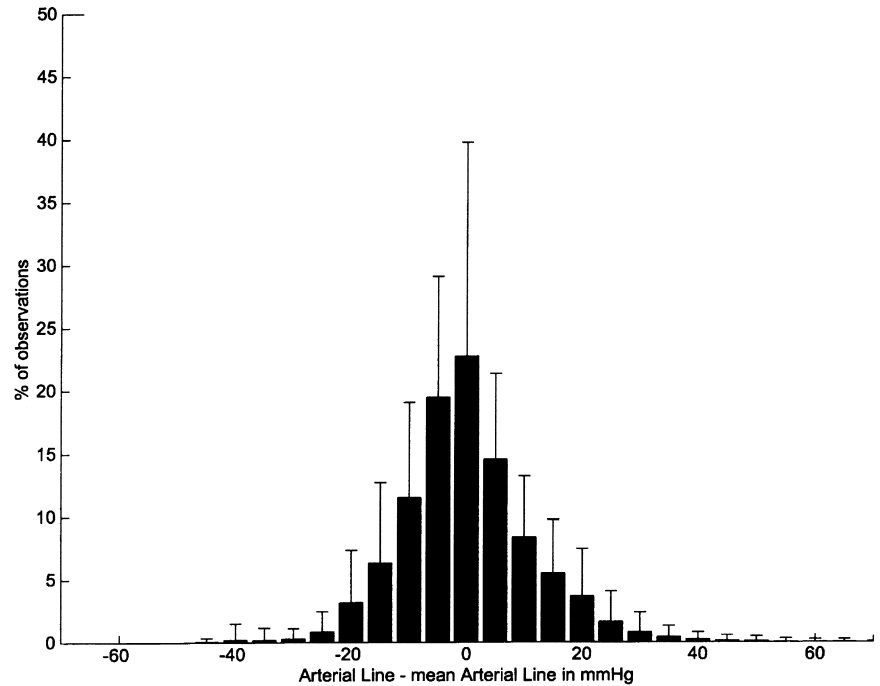
$P < 0.01$ was considered significant. A Bland-Altman plot was constructed for systolic, diastolic, and mean BPs to allow visual observation of data for agreement between the two methods of measurement over a wide range of pressures. In addition, to check for differences in readings between the two methods and as previously reported by Siegel *et al.*,⁹ each determination of Vasotrac BP – intraarterial BP was categorized into pressure intervals spanning 5 mmHg centered around multiples of 5 mmHg (*e.g.*, -12.5 – -7.5 centered around -10 mmHg; -7.5 – -2.5 centered around 5 mmHg; -2.5 – 2.5 centered around 0 mmHg). Similarly, the variability of BP during the study was determined by comparing each of the recorded intraarterial measured mean BPs with the mean for the entire case and categorizing the difference into a specific range spanning 5 mmHg. For each patient, the distribution was computed as a percentage of the total number of measurements. All of these distributions were then combined to produce an average \pm SD distribution of the difference between intraarterial and mean intraarterial BP. For pulse-rate analysis, the pulse rate displayed during each Vasotrac recording was compared with the calculated pulse rate from the simultaneous intraarterial beats. Correlation, bias, and precision were then calculated. The intraarterial waveform display was qualitatively compared to the Vasotrac BP waveform display by the investigators in an unblinded fashion.

Results

A total of 107 patients were enrolled. Of these, 27 were excluded (arm-to-arm differences, 10; hardware problems [recording cable malfunction; wrongly connected sensor cable, or transducer malfunction], 6; patient withdrawal from study, 2 [patients had agreed during preoperative assessment but withdrew on the morning of surgery—no reason given]; scheduling error, 1; inability to place arterial catheter, 2; patient movement, 1 [intensive care unit patient on vibrating

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Fig. 2. The variability of intraarterial blood pressure (BP) measurement was determined by comparing each intraarterial BP (mean) value with the mean for the entire case and categorizing the difference into a specific range spanning 5 mmHg (x-axis). For each patient, the distribution was computed as a percentage of the total number of measurements. All of these distributions were then combined to produce an average distribution of the difference between intraarterial BP (mean) values and mean intraarterial BP (shown as mean \pm SD). Thus the bar centered over 0 mm Hg represents a difference of 0 ± 2.5 mm Hg; the bar adjacent to this is a difference of 5 ± 2.5 mmHg. This distribution demonstrates that intraarterial BP (mean) values differed from mean intraarterial BP by >10 mmHg for 31.9% of the measurements.



bed]; failure to meet protocol, 1 [no arterial line placed]; improper arm positioning, 2; anatomic reasons, 2 [prior hand surgery near the wrist]). Of the remaining 80 patients (55.5 ± 16 yr and 69 ± 17 kg), 33 were female and 47 male. They were classified as American Society of Anesthesiologists physical status I ($n = 5$), 2 ($n = 29$), 3 ($n = 35$), 4 ($n = 9$), or 5 ($n = 2$) and were critically ill ($n = 9$) or underwent thoracic surgery ($n = 19$), orthopedic surgery ($n = 1$), laparotomy ($n = 30$), neurologic surgery ($n = 7$) or miscellaneous other procedures ($n = 14$).

A total of 17,468 measurements were available for analysis in the 80 patients studied. The distribution of intraarterial BP measurements with the mean intraarterial BP for the entire case is shown in figure 2. The observed variability of intraarterial BP was >10 mmHg for 31.9% of the measurements. The Vasotrac BP measurements correlated ($P < 0.01$) with intraarterial BP (systolic $r^2 = 0.93$; diastolic $r^2 = 0.89$; mean $r^2 = 0.95$). The difference in BP measured by the Vasotrac and the radial arterial catheter was small (table 1). The mean \pm SD bias and precision were as follows: systolic BP 0.02 ± 5.4 mmHg and 3.9 ± 3.7 mmHg; diastolic BP -0.39 ± 3.9 mmHg and 2.7 ± 2.8 mmHg; mean BP -0.21 ± 3.0 mmHg and 2.1 ± 2.2 mmHg compared with intraarterial measurements. This is exemplified in the bar diagrams (fig. 3), which show the differences in BP between

intraarterial and Vasotrac measurements. As seen in the bar diagrams, the majority of the readings for systolic, diastolic and mean BP were within ± 2.5 mmHg. The Bland-Altman plots displayed in figure 3 reveal that there was close agreement between the readings obtained by the two methods of measurement over a wide range of BP. This agreement was best for mean BP, followed by diastolic BP and then systolic BP. The pulse rate displayed by the Vasotrac correlated significantly with the calculated pulse rate from the simultaneous intraarterial beats ($r^2 = 0.95$; $P < 0.01$). The bias \pm SD and precision \pm SD were 0.57 ± 1.4 and 0.97 ± 1.2 , respectively.

Table 1. Average, Bias (Mean \pm SD of the Difference) and Precision (Mean \pm SD of Absolute Difference) of All Systolic, Mean, and Diastolic Readings Obtained by the Arterial Line and the Vasotrac in the 80 Patients

Blood Pressure (mmHg)	Direct	Vasotrac	Bias*	Precision
Systolic	118.3 ± 22	118.3 ± 21	0.0 ± 5.4	3.9 ± 3.7
Mean	85.4 ± 16.1	85.2 ± 15.6	-0.2 ± 3.0	2.1 ± 2.2
Diastolic	66.0 ± 12.5	65.6 ± 11.8	-0.4 ± 3.9	2.7 ± 2.8

* This should be ± 5 mmHg or less with a SD of 8 mmHg or less (AAMI Standards and Recommended Practices, Biomedical equipment. Part 2. Monitoring and diagnostic equipment. Arlington, VA: Association for the Advancement of Medical Instrumentation; 1995: 637-681).

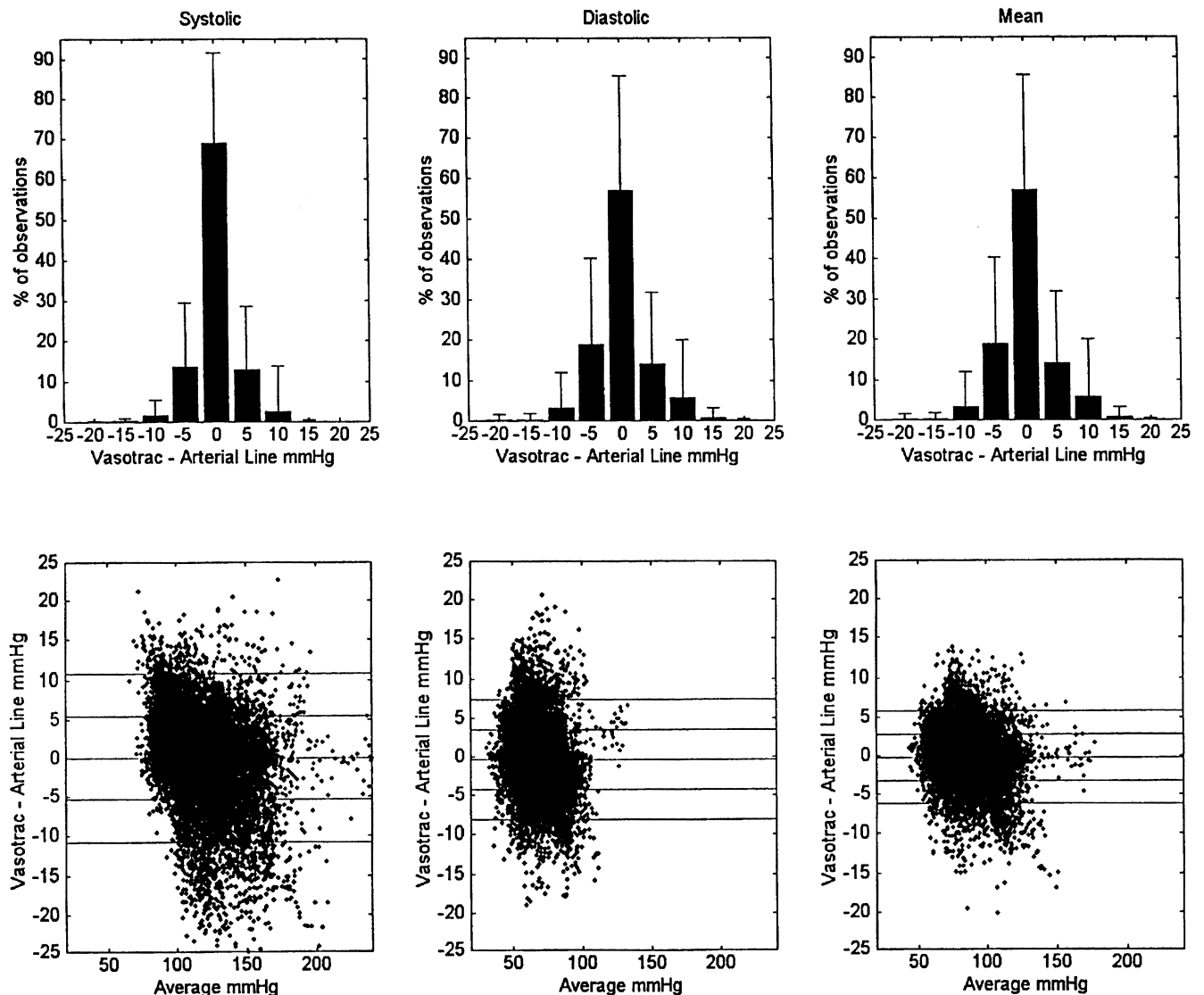


Fig. 3. (Top) Bar plot distribution of the difference \pm SD between Vasotrac and directly measured blood pressure (BP) readings for systolic, diastolic, and mean BP measurements. Each difference between the Vasotrac and intraarterial BP measurements was categorized into a specific range spanning 5 mmHg. For each patient, the distribution was then computed as a percentage of the total number of measurements. All of these distributions were combined to produce an average distribution of Vasotrac – intraarterial BP (shown as mean \pm SD). (Bottom) Bland–Altman Plots for systolic, diastolic, and mean BP showing level of agreement over the entire range of BP measurements between 17,468 simultaneous readings obtained by the Vasotrac and intraarterially. The horizontal lines represent the mean difference along with one SD and two SDs of this difference. There is a paucity of data points < 45 mmHg mean BP.

Discussion

During the perioperative and intensive care of patients the continuous monitoring of heart rate, respirations, and pulse oximetry is commonplace. An arterial catheter is usually inserted if continuous BP monitoring is required. The Vasotrac, although not beat-to-beat, provides an easy-to-use method for more

frequent monitoring of BP than is possible with the traditional oscillometric arm cuff method. It is designed to make BP readings frequently enough to negate the usual dissatisfaction with intermittence in BP monitoring during the care of critically ill patients. The Vasotrac method evaluated in this study differs from previous methods of noninvasive BP measure-

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ment, namely, oscillometric, tonometric, and the "volume clamping" (Penaz) methods. Although the oscillometric arm cuff method functions by intermittent total occlusion of the brachial artery, the Vasotrac directly compresses the radial artery in a cyclical fashion and determines the pressure at which maximum energy transfer occurs. Unlike the oscillometric method, the Vasotrac sensor is designed to isolate the transversal component of the pressure pulse. This allows the Vasotrac to reproduce an accurate pressure waveform.

If used in the rapid mode, the oscillometric method can check BP once every minute. However, prolonged use of "stat" measurements has resulted in compression injuries (skin avulsion, ulnar neuropathy, and venostasis) in the arm.¹⁰⁻¹³ To reduce the likelihood of compression morbidity, such readings are usually used only for brief periods, namely during induction of anesthesia or if rapidly changing BP is anticipated. The Vasotrac on the other hand measures BP much more frequently than is possible with an arm cuff and without significant limb compression. Hence, it is expected that compression injury is less likely with the Vasotrac, but this needs to be proven.

In this first clinical study, conducted in a wide variety of patients in multiple surgical centers, we found that the Vasotrac accurately measured BP and displayed a waveform and heart rate that were similar to BP measured intraarterially. Although BP is not measured beat-by-beat with the Vasotrac, the system updated BP readings approximately every 12-15 pulse beats and in this respect accurately tracked the systolic, diastolic, and mean BPs in surgical and critically ill patients. It should be noted, however, that the waveform produced by the Vasotrac was compared only qualitatively (by unblinded investigators) with that produced directly by the arterial catheter.

Because the Vasotrac measures pulsatile energy by the direct application of pressure to the anterior wall of the radial artery, the only calibration required is a zero check if there is no surface pressure on the transducer prior to use. Recalibration is not required even though BP may be changing rapidly. This was well illustrated in our patients during their perioperative and critical care. Thus, it differs from the tonometric method⁴ (Colin Electronics, Komaki, Japan), which requires initial calibration with an upper-arm cuff and frequent recalibrations, whenever there is a change in vessel diameter. One of the drawbacks of the Vasotrac is that it does not display beat-to-beat readings as provided by the tonometric and the Finapres systems. Our protocol did not in-

clude a formal evaluation of sensor-related injury to the wrist. Despite this, we noted on the wrists of our patients minor pressure marks conforming to the shape of the sensor and its supporting pads. The Finapres system, however, has been reported to be associated with troublesome venous congestion¹⁴ during prolonged applications. Also, as observed by Wesseling,⁵ there may be problems related to the peripheral site of the measurement with the Finapres system. The Finapres device is associated with significant pulse waveform distortion and a pressure gradient compared with radial or brachial artery measurements. The radial artery at the distal end of the radius, which is the site employed by the Vasotrac, is not as peripheral as the arteries supplying the digits of the hand. However, we feel that additional studies and detailed clinical evaluation are required to assess Vasotrac performance during states of hemorrhage or other forms of hypotension or vasoconstriction and during prolonged application periods longer than assessed in this study. Even though the Vasotrac applies cyclical pressure over the radial artery, this pressure is not circumferential and constricting, as is the oscillometric cuff method. In fact, even though we did not specifically address the issue of pulse oximetry measurement in this study, it was our experience that the Vasotrac did not interfere with pulse oximetry monitoring if the pulse oximeter probe was applied on a digit on the same side as the Vasotrac. In addition, we also observed that during Vasotrac use there was minimal interference with the flow of intravenous fluids as long as the intravenous catheters were not directly under the sensor or the strap of the wrist module. On the other hand, oscillometric cuff inflation frequently interferes with pulse oximetry monitoring and flow of intravenous fluids if the pulse oximeter sensor and intravenous catheter are placed on the ipsilateral side as the cuff.

The use of the Vasotrac should help in the better tracking of most patients during the administration of anesthesia or whenever more frequent BP monitoring is required in the intensive care unit. However, it cannot be used to measure BP in certain situations such as if there is a congenital absence of the radial pulse or excessive patient movement. In addition, training and expertise is required to find the best point over the radial pulse for accurate readings. According to the manufacturer, the sensor has been designed to work best over the radial artery at the distal end of the radius. The flattened bony background of the distal end of the radius provides a firm base over which the sensor can press on the radial pulse to obtain the pulsatile information from

the radial artery. This limits the sites from which BP can be obtained with the Vasotrac. The adult sensor is too large for use in infants and children. The Vasotrac requires pulsatility to measure the change in energy transfer as counterpressure is applied over the pulse. For this reason, it is not able to measure BP if the patient is on nonpulsatile cardiopulmonary bypass. During the studies in our patients we ensured that the hands were at the same level as the heart. During clinical use, any hydrostatic differences should be adjusted for when the Vasotrac is used. None of the patients in this study had significant dysrhythmias. The performance of the Vasotrac in the presence of dysrhythmias requires formal evaluation. In this study, we were unable to evaluate Vasotrac performance at very low BP (< 45 mmHg). Thus, additional studies are necessary to report its utility at low BP.

In conclusion, the Vasotrac, utilizing new methodology, accurately measured radial artery BP that was very similar to intraarterial BP in a wide variety of surgical and critically ill patients. This new method is simple to use, and, unlike the intermittent oscillometric occlusive cuff method, the device does not apply circumferential pressure. In addition, the instrument displays an accurate heart rate and a scaled arterial waveform of each BP reading measured.

The authors thank the following individuals for allowing the study to take place in their institutions: Drs. Y. Camus and A. Lienhart, St. Antoine Hospital, Paris, France; Dr. R. Krivosic-Horber, University of Lille, Lille, France; Dr. H. Suzuki, Tokyo Women's Medical College, Tokyo, Japan; and Dr. M. Zimpfer, University of Vienna, Vienna, Austria.

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