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The Accuracy of Finapres™ Noninvasive Mean Arterial Pressure Measurements in Anesthetized Patients

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The Finapres™ (FIN) is a new noninvasive blood pressure monitor that provides continuous arterial waveform display with the use of a finger cuff. The authors assessed the accuracy of FIN mean arterial pressure (MAP) measurements relative to simultaneous direct radial arterial pressures in 20 patients undergoing general anesthesia for major elective surgery. Data were collected digitally with the use of RS-232 communications over a total of 16.2 h. The data were processed into 6012 interference-free time samples, each spanning 6 s. The authors determined the difference between FIN and direct MAPs during each time sample. The authors calculated not only the bias of FIN measurements, but also the frequency, magnitude, and duration of discrepancies between simultaneous FIN and direct MAPs. The overall bias of the FIN MAP was −0.5 ± 1.0 mmHg, which was not significantly different from zero. However, 32.3 ± 6.2% of all MAP comparisons differed by greater than ±10 mmHg, and 5.0 ± 1.1% differed by greater than ±20 mmHg. Moreover, there was an average of one episode every 2 patient-hours when the FIN MAP differed by greater than ±20 mmHg for more than 1 min. Although the MAP measured by FIN accurately reflected direct MAPs most of the time, there were occasional discrepancies of different magnitude such that clinical usefulness may be limited in patients in whom continuous accurate blood pressure measurements are essential. (Key words: Measurement technique: blood pressure. Noninvasive equipment: accuracy; bias; Finapres™.)

DURING ANESTHESIA there are often fluctuations in the systemic blood pressure that result from the direct effects of anesthetic agents or from variations in the level of surgical stimulation.[1] These fluctuations are usually minor in healthy patients and are of little clinical significance. However, in patients who have cardiovascular disease, or who are undergoing major surgery, large changes in blood pressure can occur suddenly, with potentially serious sequelae.[1,2] In such patients, or during certain surgical procedures, it may be necessary to obtain accurate blood pressure measurements on a beat-to-beat basis.[1,2] Inaccurate information, even if short-lived, may prompt inappropriate intervention by the anesthesiologist or expose patients to occult but dangerous levels of hypotension or hypertension. Currently, the only method of accurately monitoring systemic blood pressure on a beat-to-beat basis is by invasive arterial cannulation and direct transduction of the systemic arterial pressure waveform.[1–3] This method is considered the "gold standard" because, if performed correctly, it is accurate and reliable.[3] However, it produces discomfort to patients and is associated with a small but appreciable risk of local infection, hematoma formation, or thrombosis.[4]

The Finapres™ (model 2300; Ohmeda, Denver, CO) (FIN) is a new noninvasive automatic blood pressure monitor that provides continuous blood pressure measurement and arterial pressure waveform display with the use of a finger cuff[5] and avoids the discomfort and risks of invasive monitoring.[5–8] However, these advantages are inconsequential unless the FIN accurately and reliably reflects the direct arterial pressure (ART). Several studies have examined the accuracy of the FIN and have shown that the *mean* difference between FIN and ART measurements over a large number of determinations is small.[5–7] Other studies have shown a high correlation coefficient between FIN and ART measurements.[8–10] However, these overall estimates of the accuracy of the FIN do not give specific information on the frequency of discrepancies between FIN and ART measurements. For example, a discrepancy of +10 mmHg between FIN and ART measurements lasting 3 min in each hour will have little effect on the *mean* difference between FIN and ART measurements (especially if there is a similar period when the difference is −10 mmHg). However, this amount of error may be sufficient to preclude the use of the FIN in certain patients. As such, discrepancies between FIN and ART measurements need to be fully characterized before the FIN can be used confidently in all patients. The aim of the current study was to examine the frequency, magnitude, and duration of discrepancies between FIN and direct mean arterial pressure (MAP) measurements in anesthetized patients undergoing major surgery.

Materials and Methods

After Institutional Review Board approval, we studied 20 patients undergoing elective cardiac or abdominal aortic reconstructive surgery in whom ART monitoring was planned. The mean age of the patients was 64.6 years (range, 40–77 years). There were 14 men and six women.

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For each patient, equal systolic and diastolic blood pressures in both arms were confirmed preoperatively by auscultation of Korotkoff sounds.

Before the induction of anesthesia, a 20-g Teflon® cannula was inserted into a radial artery and connected to a disposable high-fidelity pressure transducer (model 63-600F; Baxter Edwards, Santa Ana, CA) using 180-cm-long, 1.5-mm internal diameter, low-compliance tubing. The tubing system incorporated one three-way stopcock at the patient end and two at the transducer end. The transducer–tubing–stopcock system was set up by an experienced anesthesia technician and was checked by an anesthesiologist in all cases. Air bubbles were carefully flushed from the system before data collection. The zero level for the ART was taken as the right atrium. The ART waveform was displayed on a Hewlett-Packard (HP) 78534C monitor (Hewlett-Packard, Waltham, MA). The calibration of each transducer was checked against a mercury column.

An appropriate-sized FIN cuff was placed on the middle phalanx of the middle finger of the hand contralateral to the arterial cannula and was connected to a FIN device (serial FAMP00030). Strict attention was paid to the manufacturer's instructions in the placement of the cuff, and both arms were protected from external compression. The hydrostatic pressure produced by a fluid-filled tube extending from the level of the right atrium to the FIN cuff was monitored (in millimeters mercury) with the use of a separate transducer system and was subtracted from all FIN values. Thus, all corrected FIN values reflected the pressure at the level of the right atrium, regardless of changes in patient position.

Every 2 s a laboratory computer (IBM PC/AT®), using custom-designed software, collected the digital MAP values simultaneously from the FIN and the ART with the use of RS-232 communications. The digital output through the RS-232 communications of both devices is the same as the digital data displayed. However, the FIN output is updated every two heart beats, whereas the HP output is updated every second. The data were recorded directly onto a disk. Data collection started before the induction of anesthesia and continued for 60 min or, in the patients undergoing cardiac surgery, until the institution of cardiopulmonary bypass (whichever was less). In patients undergoing aortic surgery, data collection was always complete before application of the aortic cross-clamp. With the use of a computer program, the data were processed off-line to remove invalid data points caused by artifact (*e.g.*, periods when the FIN was performing a lock-adjust[5]) and to smooth the valid data by averaging each three consecutive measurements (spanning 6 s). For the purposes of the study, each 6-s averaged value was considered as a one-time sample for comparison of FIN and ART measurements. A comment code was entered into the computer each time there was interference with either monitoring system (*e.g.*, collection of blood from the arterial line or repositioning of either arm). All time samples from both the FIN and the ART were deleted if any such interference occurred.

Statistical Analysis

The processed data were analyzed with the use of the SAS® system (SAS Institute, Inc., Cary, NC) to determine the differences between simultaneous FIN and ART measurements during each time sample. We chose the following three-step approach to assess the accuracy and the bias of the FIN relative to ART and the duration of discrepancies between the two, both within and among patients.

Step 1: Estimating the Accuracy within and among Subjects

We classified the paired FIN–ART differences into specific discrepancy ranges, each spanning 5 mmHg (*e.g.*, −10 to −5.1 mmHg; −5 to −0.1 mmHg; 0 to +5 mmHg; 5.1 to 10 mmHg). For each patient we calculated the percentage of readings in each of the 5 mmHg ranges. We used these percentages to calculate the probability, for each patient, that a given reading would fall into the following ranges: 1) less than ±5 mmHg; 2) less than ±10 mmHg; 3) greater than ±10 mmHg; 4) greater than ±20 mmHg; and 5) greater than ±30 mmHg. The estimate of accuracy of the FIN readings is the average of the above probabilities across the 20 patients.

Step 2: Estimating Bias within and among Subjects

We estimated the bias of the readings from each patient from the average discrepancy between FIN and ART readings over the set of paired time samples for that patient. We then obtained the mean and standard deviation of the bias estimates from all 20 patients. We used a one-sample *t* test to test the hypothesis that the population mean bias was zero. We then developed a prediction curve for the probability of bias for a future patient drawn from the same population, using the following formula[11]:

$$\bar{Y} \pm st(1 + 1/N)^{1/2}$$

where

$\bar{Y}$ = the sample mean bias;
s = the sample standard deviation;
t = the value of the *t* distribution for 19 degrees of freedom, generated for levels of probability from 0 to 1; and
N = the sample size of 20.

This prediction interval for the mean bias of a future

patient uses the tendency of means to follow a normal distribution.[11]

Step 3: The Duration of "Runs" of Discrepancies

We defined the term "run" to mean the occurrence of two or more contiguous time samples during which the difference between the FIN and ART measurements was greater than a certain value. For each patient we determined the duration of "runs" greater than ±10 mmHg and those greater than ±20 mmHg. We then calculated the number of runs lasting less than 1 min, 1–5 min, and greater than 5 min per hour of monitoring and summarized these findings across patients.

Results

Twenty-nine thousand, two hundred forty-five pairs of simultaneous FIN and ART measurements were collected from the 20 patients over a total of 16.2 h and were processed into 6012 6-s averaged time samples for comparison. This represented a mean of 301 time sample comparisons per patient and an average of one comparison every 9.6 s. The minimum MAP recorded from any patient during the period of the study was 35 mmHg, and the maximum was 130 mmHg.

Figure 1 shows the frequency of various magnitudes of discrepancy between FIN and ART measurements; 42.1 ± 6.2% of all MAP comparisons had a difference less than ±5 mmHg, and 67.7 ± 8.1% had a difference less than ±10 mmHg; 32.3 ± 6.2% of all MAP comparisons had a difference greater than ±10 mmHg, and 5.0 ± 1.1% had a difference greater than ±20 mmHg. Only

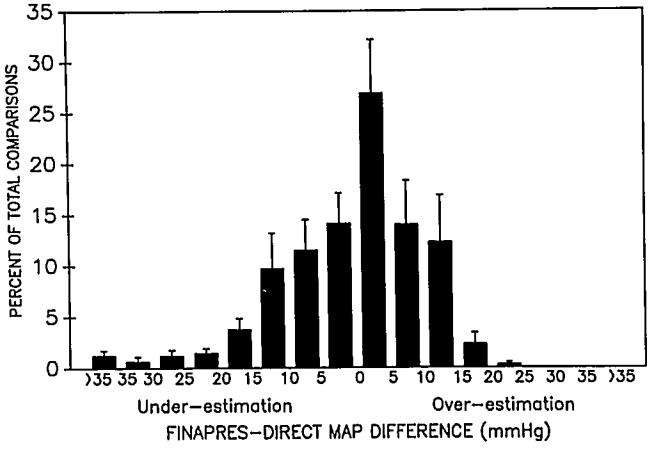

FIG. 1. The percentage of total Finapres®-Direct MAP comparisons in 5-mmHg difference ranges. Bars indicate mean percentages ± SEM. (Bars to the right of zero indicate that the Finapres overestimated the direct MAP by 0–5.1–1.0, 10.1–15 mmHg, *etc.* Similarly, values to the left of zero indicate underestimation).

TABLE 1. The Effect of the Direct Arterial Pressure Range on the Percentage of Finapres MAP Readings in Specific Discrepancy Ranges

Discrepancy Range (mmHg)	Direct Mean Arterial Pressure Range (mmHg)			Total
	<70	70–100	>100	
< ±5	42.2 ± 9.3	43.9 ± 6.5	35.6 ± 10.9	42.1 ± 6.2
< ±10	66.5 ± 12.6	68.3 ± 8.4	60.0 ± 14.5	67.7 ± 8.1
> ±10	33.5 ± 9.2	31.7 ± 6.2	40.0 ± 10.1	32.3 ± 6.2
> ±20	1.1 ± 0.8	4.0 ± 0.8	17.2 ± 7.0	5.0 ± 1.1
> ±30	0.0 ± 0.0	1.6 ± 0.6	11.0 ± 6.4	2.1 ± 0.7

Mean percentages ± SEM (n = 20 patients).

2.1 ± 0.7% of MAP comparisons had a difference greater than ±30 mmHg. Table 1 summarizes these data and also shows the effect of the ART range on the percentage of MAP comparisons in specific discrepancy ranges. There was a higher percentage of MAP comparisons in the larger discrepancy ranges when the ART was greater than 100 mmHg. However, large discrepancies between FIN and ART measurements occurred in all ART ranges.

The estimated degree of bias in FIN readings relative to the ART, and the effect of the ART range on this bias, is given in table 2. The total MAP readings did not show significant bias over all 20 subjects. However, when the ART MAP was greater than 100 mmHg, the bias for MAP was −6.4 ± 3.0 ($P < 0.01$). The FIN did not show significant bias for MAP if ART measurements were less than 70 mmHg or were between 70 and 100 mmHg. Figure 2 demonstrates the implications of these mean biases and standard errors on the prediction of accuracy for a future patient. The 95% prediction interval for MAP bias is −10.43 to +9.39, and the probability that the bias for a future patient will be in the interval from −5 to +5 mmHg is 0.49.

The durations of continuous runs of discrepancy greater than ±10 mmHg and greater than ±20 mmHg are shown in figure 3. Most runs lasted less than 1 min and were less than ±20 mmHg. There were 3.2 runs per patient-hour greater than ±10 mmHg that lasted more than 1 min. Of these, there was an average of only one run every 3 patient-hours that lasted more than 5 min.

TABLE 2. The Effect of the Direct Arterial Pressure Range on the Bias of Finapres Mean Arterial Pressure Readings

	Direct Mean Arterial Pressure Range (mmHg)			Total
	<70	70–100	>100	
Bias (mmHg)	0.1 ± 1.5	−0.5 ± 1.0	−6.4 ± 3.0	−0.5 ± 1.0
P	=0.95	=0.63	<0.01	=0.62

Means ± SEM (n = 20 patients).
P values were obtained with two-tailed *t* tests relative to the null hypothesis that the population mean bias is zero.

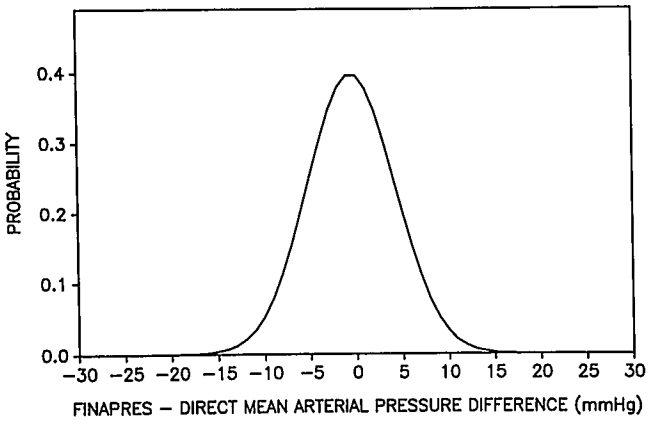

FIG. 2. The predicted bias of Finapres®-Direct MAP measurements for a future patient drawn from the same population. The curve shows the distribution of probility of bias relative to the direct MAP. The 95% prediction interval for MAP bias is −10.43 to +9.39, and the probability that the bias for a future patient will be in the interval −5 to +5 mmHg is 0.49.

There was an average of one run every 2 patient-hours greater than ±20 mmHg that lasted more than 1 min. None of these lasted more than 5 min.

Discussion

Blood pressure is a biologic variable that normally fluctuates within a narrow range from moment to moment but can change abruptly in response to a variety of stimuli.[12] A change of a few millimeters mercury is of little or no clinical significance and is often within the error of the measuring technique. Larger changes in blood pressure may result from many factors and must be interpreted in the clinical setting in which they occur. It is difficult to state categorically when errors in blood pressure measurement become clinically significant. However, in our institution all anesthesiologists agree that an error greater than ±20 mmHg is unacceptable, and most anesthesiologists are concerned about errors greater than ±10 mmHg. The duration of errors is also important. Errors lasting less than 1 min are likely to be less significant than those that persist for 5 min or more. It is because of the difficulties in defining "a clinically significant error" that it is necessary to obtain specific information on the frequency, magnitude, and duration of errors associated with a new monitoring technique. Only then is it possible for clinicians to decide for themselves whether the new technique is sufficiently accurate for their particular purpose.

The assessment of a new monitoring device requires a large number of comparisons between the new device and the "gold standard" over a wide range of clinical conditions. We made more than 6,000 comparisons of MAP between FIN and ART measurements in 20 patients undergoing major surgery. Patients undergoing aortic or cardiac surgery invariably have underlying cardiac or atherosclerotic disease[13] and may respond unpredictably to anesthetic agents and/or interventions.[1,2] Moreover, the induction of anesthesia, the intubation of the trachea, and the initial surgical incision (and/or sternotomy) are all times when acute hemodynamic changes are likely to occur.[1,2] Therefore, we were able to assess the ability of the FIN to follow the ART over a wide range of clinical blood pressures (direct MAP, 35–130 mmHg). However, there were no periods of sustained hypotension, hypertension, shock, or dysrhythmia in our patients during the study period, and we cannot comment on the performance of the FIN in these situations.

A major consideration in assessing the accuracy of a new monitoring technique is ensuring an appropriate "gold standard" for comparison. Often no such "gold standard" exists, and the new device must be compared with the best of the existing methods.[14] At present, the most accurate method of measuring the MAP is by direct transduction of the systemic arterial pressure with computer-assisted calculation of the arithmetic mean pressure during each heart beat.[15–17] The HP-78534C samples the arterial pressure every 8 ms and calculates the arithmetic mean pressure by dividing the sum of the pressures by the number of samples during each heart beat. Therefore, the system we used to measure the direct MAP approached the "gold standard" for clinical monitoring of MAP.

In contrast, ensuring an appropriate "gold standard" for direct systolic and diastolic arterial pressures (SAP and DAP, respectively) is much more difficult. Direct SAP and DAP measurements are dependent on the fidelity of the arterial pressure waveform recording and may be inaccurate if the dynamic response characteristics of the catheter–tubing–transducer system are not ideal.[16,17] In the clinical situation, it is difficult to exclude all resonance

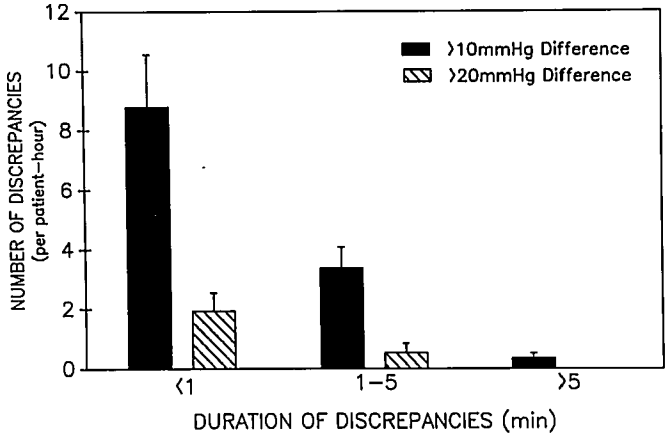

FIG. 3. The duration of discrepancies between Finapres and direct MAP. Bars indicate means ± SEM.

and damping effects over a prolonged period. Moreover, SAP and DAP change as the pressure pulse moves from the aortic root to the periphery[17] and may be different in the radial artery and finger. Ideally, the assessment of the accuracy of SAP and DAP measurements requires the simultaneous comparison of raw waveforms. For these reasons and because we did not test the dynamic response characteristics of our catheter–transducer–tubing system, we did not assess the accuracy of FIN SAP and DAP measurements in this study. Nevertheless, the assessment of the accuracy of FIN MAP measurements provides a useful guide to the overall accuracy of the FIN.

Another consideration in the comparison of MAPs from different monitoring devices is the compatibility of algorithms used to calculate the displayed MAP. The FIN samples its cuff pressure every 10 ms and calculates the arithmetic mean pressure in a manner similar to the HP-78534C. Both the FIN and the HP-78534C display the average MAP determined over the previous eight heart beats. This average is a "rolling" average, which is updated every second heart beat by the FIN and every second by the HP-78534C. Therefore, the algorithms used to calculate the MAP were similar with both devices. Moreover, because we "smoothed" the data into 6-s averaged time samples, it is unlikely that minor differences in algorithms contributed to large discrepancies between ART and FIN measurements.

Our results support the findings of several previous studies that have shown that the *mean* difference between FIN and ART measurements is small.[5–10] We found that the bias of the total FIN–MAP measurements was only -0.5 ± 1.0 mmHg, which was neither statistically nor clinically different from zero. However, when the ART was greater than 100 mmHg, there was a significant bias of -6.4 ± 3.0 (table 2). We also found that there were frequent discrepancies between FIN and ART measurements of MAP. Most of these were less than ±10 mmHg and were less than 1 min in duration (figs. 1 and 3.). However, 32.3% of MAP comparisons differed by greater than ±10 mmHg, and 5% differed by greater than ±20 mmHg (fig. 1). Moreover, there was an average of one episode every 2 patient-hours when the difference was greater than ±20 mmHg for more than 1 min (fig. 3). It is conceivable that these large and prolonged discrepancies could lead to inappropriate intraoperative management of anesthetized patients, with the potential for increased perioperative morbidity. Large discrepancies between FIN and ART measurements occurred more frequently when the ART was greater than 100 mmHg but also occurred when the ART was in the normal range (table 1). Therefore, despite the absence of overall bias, the FIN tended to underread MAP at higher ART readings, and there were isolated periods when the FIN MAP was grossly inaccurate. Moreover, although we did not formally assess the accuracy of FIN SAP and DAP measurements, it was our impression that FIN SAP and DAP measurements were not more accurate than FIN MAP measurements.

Although there have been several previous clinical assessments of the FIN, there are many reasons why it is difficult to directly compare the results of different studies. The earliest studies used prototype devices.[6,7] It is not clear to what extent these prototype devices differ from current commercial devices. There have also been several changes in FIN cuff design.[7] We used flexible FIN cuffs with an adhesive strap, but other FIN cuffs incorporate a Velcro® strap.[7] There has been little standardization determining which finger should be used for placement of the cuff. The middle phalanx of the middle finger is recommended by the manufacturer, but various sites have been used, including the thumb.[5–9] Most studies have placed the FIN cuff ipsilaterally to the aterial cannula. However, Kurki *et al.* have pointed out that this position is not necessarily preferable to the contralateral arm because both positions risk introducing artifact.[7] The actual placement of the cuff on the finger appears to be critical in obtaining a satisfactory FIN trace; therefore, variations in cuff application may explain some of the differences in the results between different investigations. In addition, there has not been consensus on whether the FIN values should be corrected if the FIN cuff is below the level of the right atrium. Kurki *et al.* corrected for hydrostatic pressure differences and reported an average bias for MAP of +0.74 mmHg.[7] However, Smith *et al.* did not correct for hydrostatic pressure effects and obtained a similar bias of +0.8 mmHg.[6] More recent studies have corrected for hydrostatic effects and have found that the FIN systematically overestimates systemic pressures by as much as 10 mmHg.[9,18] The reasons for the disparate findings are unclear, but minor variations in methods or patient selection may have contributed to the observed differences.

Another difficulty in comparing the results of different studies relates to differences in methods of statistical analysis. The multiplicity of methods of statistical analysis by different investigators suggests that no one method has proved satisfactory for data of this type. Several initial studies used regression analysis or calculated the correlation coefficient between FIN and ART measurements.[7–9] However, it has been shown by Sheiner and Beal[19] and Bland and Altman[20] that these types of analyses are inappropriate for the comparison of two measurement techniques. Epstein and Bartkowski[9] and Kermode *et al.*[21] used a graphic technique developed by Bland and Altman.[20] More recently, Huffnagle *et al.* reported the bias and the precision of FIN readings relative to the ART.[18] Although all of these methods provide some information on the accuracy of the FIN, none provides specific infor-

mation on the frequency of episodes when the FIN does not reflect the ART. Our results are presented in such a fashion that the reader can easily determine not only the bias and the accuracy of FIN MAP measurements, but also the frequency, magnitude, and duration of discrepancies between FIN MAP and ART MAP measurements. The reader can also calculate the probable bias of FIN MAP measurements in future patients drawn from this population (fig. 2). As such, our results provide a guide to the accuracy and reliability of FIN MAP measurements in anesthetized patients.

Currently, it is difficult to foresee the eventual place of the FIN in anesthetic practice. Other investigators have compared the FIN with standard methods of noninvasive automatic blood pressure measurement and have found that the FIN is at least as accurate as oscillometric techniques.[10,18] However, few studies have concluded that the FIN measurements are as accurate as ART measurements in all patients. A major problem appears to be the inability to reliably predict in which patients or in which circumstances the FIN will be inaccurate.[6,7,21] Kurki *et al.* found that the FIN tended to be less accurate in patients with poor peripheral blood flow, but that FIN inaccuracies were not limited to these patients.[7] Moreover, the FIN has not been fully assessed during emergency clinical situations such as severe hypotension or hypertension, shock, major dysrhythmia, or cardiac arrest. Therefore, at best, the FIN requires additional investigation before its place in anesthetic practice can be defined.

In summary, our results support a cautious approach to the use of the FIN as a substitute for ART monitoring. Our results show that, although most FIN MAP measurements are accurate, large discrepancies between FIN and ART MAP measurements do occur. Nevertheless, the FIN represents a major advance in noninvasive continuous blood pressure monitoring. Additional studies are needed to identify the situations in which FIN measurements are inaccurate. It is hoped that future improvements in engineering design will lead to greater reliability of FIN measurements.

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