

The assessment of agreement between non-invasive, near continuous radial blood pressure measurement and conventional ambulatory blood pressure monitoring during night time sleep.

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Abstract

The objective of this study was to compare the blood pressure (BP) measurements during night time sleep of a non-invasive, near-continuous, radial BP instrument to a conventional ambulatory blood pressure monitoring (ABPM) device in a field study setting, in which individuals were not controlled for moving. In order to assess the validity of the radial BP meter in a field setting, we carried out a study in which subjects slept with both instruments: the ambulatory BP monitoring device (Numed's Mobil-O-Graph®) and the non-invasive, near continuous radial meter (Medwave's APM205A Vasotrac®). They were positioned on 7 healthy subjects, 2 males and 5 females, aged from 14 to 83, who volunteered to take part in the study. It was found that under the normal field conditions the agreement of the Vasotrac® monitor to the ambulatory Mobil-O-Graph® was relatively small. The range of the observed correlations was from 0.09 to 0.50 for systolic BP and -0.11 to 0.65 for diastolic BP. The mean difference between Vasotrac® and Mobil-O-Graph® ranged from -1.0 to 23.0 mmHg for systolic BP and -11.0 to 8.4 for diastolic BP. In conclusion, the poor agreement of the near continuous radial BP meter to the established ABPM method in the field sleep study setting shows that the first is probably not a suitable BP monitoring device in such conditions.

Key words: blood pressure measurement, ambulatory blood pressure monitoring, radial blood pressure measurement

The present night-sleep study is part of the HYENA (Hypertension and Exposure to Noise near Airports) EU project.

Introduction

The objective of this study is to compare the BP measurements during night time sleep of a non-invasive, near-continuous radial BP meter to a conventional ambulatory blood pressure monitoring (ABPM) device in a field study setting, in which individuals are not controlled for normal movements during their sleep.

The present night time sleep study is part of the HYENA (Hypertension and Exposure to Noise near Airports) EU project for which approval by the University of Athens ethical committee has been obtained. For the acute effects part of the field study, apart from precise noise measurement and noise recording, we needed to choose an appropriate instrument for BP monitoring, continuous if possible, in order to assess possible acute effects of aircraft noise events, occurring over housing areas near airports, on the inhabitants' BP during night time sleep.

The non-invasive, near continuous radial BP meter can provide very frequent BP readings and probably causes lesser disturbance to the subject than conventional ABPM devices (Friedman et al., 2004). To measure BP, it compresses its sensor over the radial artery at the distal end of the radius bone. It appears therefore attractive and appropriate for night time BP measurements and suitable for sleep laboratories permitting to assess correlations of the BP variation to external brief annoyance stimuli, which may affect BP. However, its validity in a study of individuals living under normal conditions at home has not been tested.

The radial BP meter is bulky and therefore difficult to be carried around during day time activities. It was therefore suggested to use it during night time, while for daytime monitoring a conventional ABPM device was used. In order to validate this approach, we carried out a study in which subjects slept with both instruments: the ambulatory and the near-continuous

radial BP measuring devices. The study protocol was approved by the University of Athens Medical School's Ethics Committee.

Materials and Methods

The two devices used were the Medwave's APM205A Vasotrac® and the Numed's Mobil-O-Graph®. The Numed's Mobil-O-Graph® is a validated ABPM device based on the oscillometric double I, method (Jones et al., 2000). The Medwave's APM205A Vasotrac® is a relatively new, certified (www.vasotrac.com) non invasive BP measuring device which measures BP with a sensor positioned over the subject's radial artery at the distal end of the radius bone. Maximal frequency of BP measurements is every 15 seconds.

Before the main part of the present study with the Vasotrac® and the Mobil-O-Graph®, we performed two 15 minutes' BP measurements with the Vasotrac® on two Intensive Care Unit patients of a Greek Hospital who were at the same moment monitored via arterial catheter on their controlateral wrist. We did this in order to get accustomed to the use of the Vasotrac® and to see in practice its accuracy. In spite of the short duration of the BP measurements, the correlation with the arterial catheter was very high.

For our study, we positioned the two devices on 7 healthy subjects, 2 males and 5 females, aged from 14 to 83, who volunteered to take part in the study (Table 1). One of us (AH) visited each subject before the start of their study night. Before positioning the two instruments, BP was measured in each subject on both their left and right arm by conventional sphygmomanometry and the difference between the two arms was found smaller than 5mmHg in every case. In this way, the possibility that differences in measured BP are the result of different BP between arms is eliminated. The Mobil-O-Graph® was programmed to measure BP every 10 mins (5 mins in the case of one subject, ID1). The Vasotrac® was programmed to measure every 1 min, since the instrument can hold up to 900 measurements in the memory and we needed to record BP over a normal 8 hour sleep.

The Mobil-O-Graph's cuff was positioned on the subjects' left arm and the Vasotrac®'s sensor on their right wrist. It was not preferred to set the two instruments on the same arm since the Mobil-O-Graph®, like the other ABPM devices, provokes occlusion of the brachial artery for about one minute during each measurement and this might cause problems to the Vasotrac®'s functioning. In addition, the following adjustments were made for the Vasotrac®: High Motion Tolerant (HMT) software was turned on after 5 BP measurements (i.e. according to the manufacturer's recommendations) and height adjustment was set at -10 cm, assuming that the wrist's usual position during sleep is that of the bed surface, about 10 cm lower than heart level. This setting is also in accordance with the observation that in conventional BP measurement in the supine position, not holding the arm at heart level results in overestimation of the BP (European Society 2003). This setting of -10 cm does not influence BP measurements but only BP readings, subtracting the same amount to all BP readings. All subjects were instructed and trained before the examination on how to take off the Vasotrac® in the lying position and reposition it in case they needed to get up during night-time. They were also instructed to switch off the Vasotrac® monitor after getting out of bed in the morning. After the night of the examination the same person (AH) visited them again and inquired for possible incidents that could have upset them during the night or for eventual arousals from bed without previous removal of the Vasotrac®. No such cases were reported. One subject who got out of bed and tried later to reposition the Vasotrac failed to do so, no readings were obtained and he was excluded from the study.

In order to compare the BP measurements during night time sleep from both monitors, the same number of BP measurements was required, whilst we had ten times more measurements using the Vasotrac®. For this reason two different approaches of analysis were adopted. First we considered only the per 10th minute Vasotrac® BP measurements (ignoring the fact that it recorded blood pressure every 1 minute) and compared these to the every 10 minute Mobil-O-

Graph® BP measurements for each person (Approach A). In this way measurements done at the same minute by the two instruments were compared. The second approach was to calculate the mean value of 10 BP measurements by the Vasotrac® concerning 5 minutes before and 5 minutes after the Mobil-O-Graph® measurement and compare it to the per 10 minute measurements by Mobil-O-Graph® again for each person (Approach B).

The measurements were compared using Pearson correlation coefficient (r) and as a further way of examining the differences and quantifying the variability of the individual measurements the Bland & Altman limits of agreement method was applied (Altman et al., 1986). Briefly the method can be described as follows: let d be the difference between Vasotrac® and Mobil-O-Graph® blood pressure measurements, on the same subject for the same minute. The mean difference \bar{d} is the estimated bias (the systematic difference between the two monitors). The 95% limits of agreement are used to estimate how far apart measurements by the two monitors are likely to be. The 95% limits of agreement are estimated by the mean difference \bar{d} and the standard deviation of the differences sd ($\bar{d} \pm 1.96 * sd$). In order to see how precise the estimates were a 95% confidence interval for the lower and upper limit of agreement was calculated $\{ \text{limit}_{(L,U)} \} \pm 1.96 * se \{ \text{limit}_{(L,U)} \}$.

Results

The mean systolic BP for all subjects ranged from 95 to 160 mm Hg when measured by the Vasotrac® and 91 to 161 mm Hg, when monitored by the Mobil-O-Graph®. Mean diastolic BP ranged from 44 to 83 and 53 to 75 mm Hg when measured by the Vasotrac® and the Mobil-O-Graph® respectively (Table 2).

Based on the results from the Approach A, for 4 persons there was a statistically significant positive association between the Vasotrac® and the Mobil-O-Graph® for both systolic and diastolic BP measurements (Table 3). However, the value of the correlation coefficients is low (range from 0.09 to 0.50 for systolic and from -0.11 to 0.65 for diastolic BP). Considering the differences between Vasotrac® and Mobil-O-Graph® at all time points the mean difference between the two monitors BP measurements differed significantly from zero for 5 out of the 7 subjects for both systolic and diastolic blood pressure. The range of differences was from -1 to 23 mmHg for systolic and from -11 to 8.4 mmHg for diastolic blood pressure (Table 4).

The limits of agreement for the Vasotrac® and Mobil-O-Graph® BP measurements done at the same minute are shown on Table 5. For systolic BP, the width between the lower and upper limit ranged from 33 to 56 mm Hg and for diastolic BP from 27 to 38 mm Hg. These results are shown better when plotting the difference between the Vasotrac® and Mobil-O-Graph® BP measurements against the average (Fig. 1 & Fig. 2). For systolic BP, 2 measurements did not lie between the 95% limits of agreement. The upper limit was 45.7 mm Hg and the lower was -10.1 mmHg. That is, a systolic blood pressure measurement by Vasotrac® could be between 10.1 mm Hg less than a measurement by Mobil-O-Graph® and 45.7 mm Hg greater. Four diastolic blood pressure measurements were beyond the limits,

indicating poor agreement between the two monitors and the width between the lower and upper limit was 37.9 mm Hg. Specifically, a diastolic blood pressure measurement by Vasotrac® could be between 21.1 mm Hg less than a measurement by Mobil-O-Graph® and 16.8 mm Hg greater.

Approach B gave similar results but the correlations between the two instruments were smaller. There was a statistically significant positive association between the Vasotrac® and the Mobil-O-Graph® systolic and diastolic BP measurements for 4 persons, as found in the first approach. A statistically significant mean difference was found between the Vasotrac® and Mobil-O-Graph® systolic and diastolic BP measurements. For systolic BP the width between the lower and upper limit of agreement ranged from 27 to 50 mm Hg and for diastolic BP from 23 to 36 mm Hg. Three systolic BP measurements are out the 95% limits of agreement. The upper limit was 42.0 mmHg and the lower -8 mmHg. This means that a systolic blood pressure measurement by Vasotrac® would be between 8 mm Hg less than a measurement by Mobil-O-Graph® and 42.0 mm Hg greater. Two diastolic blood pressure measurements are beyond the limits, indicating poor agreement between the two monitors and the width between the lower and upper limit was 31.8 mm Hg.

Discussion

According to studies performed in the intensive care unit setting, BP measured non-invasively by the Vasotrac® has demonstrated very good correlation with BP measured via a radial arterial catheter and the Vasotrac® BP waveform resembles those directly obtained through radial artery pulsatile waveforms. Moreover, the systematic differences in BP measurements of the Vasotrac® versus the arterial catheter were small (Belani et al., 1999a; Belani et al., 1999b) We have the same experience after our preliminary study mentioned in the methods section. However, our small preliminary study as well as the aforementioned studies comparing the Vasotrac® to radial arterial catheter measurements were performed on critically ill, immobile patients, whose hand was at the same level as the heart.

A recent study (Thomas et al., 2005) showed good correlation between the Vasotrac® and ABPM measurements for patients transported by helicopter. These were again acutely ill patients, half of them intubated, and the Vasotrac® measurements were performed every 5 minutes. With regard to BP measurements, the difference of the “out-of-hospital” setting of the study compared to the hospital setting was only the presence of vibration and noise, which could have influenced the measurements of the Vasotrac®. The above study was supported by Vasotrac®’s manufacturer.

In our study we used the ABPM measurements as a reference method. Evidently, in healthy subjects living under normal conditions, invasive methods cannot be used. We chose to compare the Vasotrac® to the ABPM meter since the latter is an established method with wide application in studies of BP during sleep (Staessen et al., 2000).

The inflation of the ABPM monitor can sometimes cause sympathetic arousal and BP elevation (Davies et al., 1993). However, this elevation of BP should be measured by both instruments and thus not be the cause of BP measurement differences between them.

Our study was based on a small number of subjects. However, this is usually a weakness when non-significant outcomes may be attributed to the low power. In our case, the differences between the two instruments were so pronounced and the correlations so varied that the inclusion of more subjects would have been redundant.

Our study was performed on subjects living under normal conditions at home. It appears that under normal field conditions during sleep the agreement of the near-continuous radial BP monitor to the ABPM device is relatively small. Since the correlation coefficient for the assessment of the agreement can be misleading, as it does not address the bias (i.e. the systematic differences in BP readings), an alternative approach, based on graphical techniques and simple calculations was applied. Thus a significant bias has been observed in most subjects, with the Vasotrac® readings being higher for systolic BP, but going in both directions for diastolic. From these results, no correction factor appears applicable. The poor agreement in most subjects is likely related to movements of the wrist in relation to heart level. This can also explain the variation of the correlation coefficient among the persons tested.

The influence of the variation of the point of BP measurement in relation to heart level on the BP readings is usually underestimated in clinical practice, though most important and reported for all BP measurement techniques (apart from a few sophisticated techniques that have the capability of correcting this factor in the BP readings that they provide). Thereby, instructions for arm position in conventional BP measurement are rigorous (European Society 2003). With the manufacture of devices for the self-measurement of BP at the wrist, strict caution is given on holding the wrist at heart level during measurements, otherwise there will

be gross error in the BP readings (European Society 2003). The issue of arm position and BP measurements has also been raised for ABPM (Mourad et al., 2003). In sleep lab studies investigating effects of noise on beat-to-beat BP variations with a digital plethysmographic method (Finapres®), subjects slept video-monitored and their BP measurements were retained for analysis only when there was no movement of the hand from a predetermined position (Davies, 1993).

In practice, in our study, the problem of the effect of arm movements on BP readings proved significant. We observed, though we did not analyze this in a systematic way, that in subjects sitting or lying on bed the minor arm or forearm movements, that altered the height of the wrist -where the sensor is positioned- in relation to the heart, cause important changes in BP readings. However it was hoped that in the supine position during sleep the wrist would maintain a relatively constant level (that of the bed surface) in relation to the heart and that BP readings would not be affected much by hand position. The results of our study support the opposite.

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Table 1: Descriptive characteristics of study population

Person	Sex	Age	Height (m)	Weight (kg)	Night time sleep (hours)
1	Male	67	1.78	74	6
2	Female	45	1.60	62	8
3	Male	59	1.65	80	9.5
4	Female	49	1.56	84	10
5	Female	51	1.61	62	6
6	Female	83	1.65	74	9.5
7	Female	14	1.67	54	7

Table 2: Descriptive data on the blood pressure measurements (mm Hg)

Person	Systolic				Diastolic			
	Vasotrac		Mobil-O-Graph		Vasotrac		Mobil-O-Graph	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
1*	110	7.4	96	9.6	59	6.1	62	6.1
2	105	8.3	98	9.0	52	4.9	63	6.8
3	121	12.5	103	14.1	62	9.0	64	10.1
4	134	11.6	111	7.8	73	7.7	66	7.0
5	95	12.2	96	9.3	44	5.7	53	7.3
6	160	13.1	161	10.3	83	8.5	75	4.9
7	113	6.0	91	6.9	60	5.7	56	7.6

* BP measurements every 5 min. by the Mobil-O-Graph

Table 3: Correlation coefficient (r) between Vasotrac and Mobil-O-Graph blood pressure measurements done at the same minute

Person	n	Systolic		Diastolic	
		r	p-value	r	p-value
1*	77	0.087	0.476	-0.111	0.362
2	52	0.198	0.160	0.146	0.301
3	58	0.436	0.001	0.496	<0.001
4	61	0.444	<0.001	0.377	0.003
5	36	0.500	0.002	0.650	<0.001
6	48	0.351	0.015	0.450	0.001
7	24	0.089	0.680	0.262	0.216

* BP measurements every 5 min. by the Mobil-O-Graph

Table 4: Mean difference (95% C.I.) between Vasotrac and Mobil-O-Graph blood pressure measurements (mm Hg) done at the same minute

Person	Systolic	Diastolic
1*	14.0 (11.9 , 17.3)	-3.0 (-4.2 , 0.0)
2	7.0 (4.2 , 10.1)	-11.0 (-12.7 , -8.4)
3	18.0 (14.1 , 21.5)	-2.0 (-4.7 , 0.3)
4	23.0 (20.7 , 26.1)	7.0 (5.4 , 9.5)
5	-1.0 (-4.6 , 2.6)	-9.0 (-11.3 , -6.7)
6	-1.0 (-4.9 , 2.9)	8.4 (6.2 , 10.6)
7	21.8 (18.4 , 25.2)	4.9 (1.8 , 7.9)

* BP measurements every 5 min. by the Mobil-O-Graph

Table 5: 95% lower limit (LL) & upper limit (UL) of agreement (95% C.I.) between Vasotrac and Mobil-O-Graph BP measurements (mm Hg) done at the same minute

Person	Systolic			Diastolic		
	LL	UL	Width	LL	UL	Width
	(95% C.I.)	(95% C.I.)	LL-UL	(95% C.I.)	(95% C.I.)	LL-UL
1*	-8.1 (-12.8,-3.4)	37.3 (32.6,42.0)	45.4	-20.0 (-23.7,-16.3)	15.8 (12.1,19.5)	35.8
2	-14.3 (-19.5,-9.2)	28.6 (23.5,33.8)	42.9	-20.0 (-23.7,-16.3)	4.8 (1.1,8.5)	30.6
3	-10.1 (-16.4,-3.8)	45.7 (39.3,52.0)	55.8	-21.1 (-25.4,-16.8)	16.8 (12.5,21.1)	37.9
4	2.4 (-2.3,7.0)	44.4 (39.8,49.1)	42.0	-8.7 (-12.3,-5.1)	23.6 (20.0,27.2)	32.3
5	-22.8 (-29.1,-16.5)	20.8 (14.5,27.1)	43.6	-22.5 (-26.5,-18.5)	4.9 (0.9,8.9)	27.4
6	-27.6 (-34.2,-21.0)	25.6 (19.0,32.2)	53.2	-6.7 (-10.5,-2.9)	23.3 (19.5,27.1)	30.0
7	5.2 (-0.7,11.1)	38.4 (32.5,44.3)	33.2	-10.2 (-15.5,-4.9)	19.9 (14.6,25.2)	30.1

* BP measurements every 5 min. by the Mobil-O-Graph

Figure 2: Difference in Diastolic against Mean and 95% Limits of Agreement.

