Clinical evaluation of the QuietTrak blood pressure recorder according to the protocol of the British Hypertension Society.

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Pietro Amedeo Modesti, Alessandro Costoli, Ilaria Cecioni, Simone Toccafondi, Alessandro Carnemolla and Gian Gastone Neri Serneri

Methods The QuietTrak ambulatory blood pressure recorder (Tycos-Welch-Allyn, Arden, North Carolina, USA) was evaluated according to the protocol of the British Hypertension Society (BHS). QuietTrak, a lightweight (355 g), automatic, programmable device uses an auscultatory measuring system. The protocol of the BHS was composed of subsequent phases with QuietTrak and two observers taking simultaneous measurements on the same arm.

Results No interdevice differences were observed at analysis of variance test either before or after a 1-month period of routine clinical use. The average difference between mercury sphygmomanometer and QuietTrak for systolic and diastolic blood pressures was -0.6 ± 3.6 and -0.4 ± 3.6 mmHg before and -0.7 ± 3.3 mmHg and 0.6 ± 3.8 mmHg after the 1-month use. At the main static device validation procedure, performed in 85 subjects, the average difference between observers and QuietTrak was -0.3 ± 3.4 and 0.1 ± 3.5 mmHg for systolic and diastolic blood pressures. Eighty-nine per cent and 99% of systolic and 88% and 98% of diastolic QuietTrak readings were within 5 and 10 mmHg of observers, determinations (Class A). In children (n=33) 87% of systolic and 90% of diastolic QuietTrak readings differed by less than 5 mmHg from the observers' readings (average difference -1.1 ± 3.9 and 0.1 ± 3.6 mmHg, respectively). In the elderly (n=30), 95% and 92% of systolic and diastolic readings were within 5 mmHg of mercury column determinations (average difference -0.8 ± 3.2 and -0.2 ± 4.5 mmHg). In pregnancy (n=30) 93% of systolic and 100% of diastolic readings were within 5 mmHg of mercury column determination (average difference -0.3 ± 3.4 and 0.1 ± 2.9 mmHg). Device reliability was not affected by posture. Ninety-six per cent and 89% of systolic and diastolic readings differed by less than 5 mmHg from the mercury column determinations in the supine position, 90% and 90% in the standing position and 88% and 90% in the sitting position. During the treadmill exercise test (Bruce protocol), 69% and 88% of systolic and 56% and 83% of diastolic QuietTrak readings differed by less than 5 and 10 mmHg from the observers' measurements.

Conclusion The QuietTrak achieved A rating for systolic blood pressure and A rating for diastolic blood pressure according to the criteria of the BHS protocol. The device was acceptable to patients because of its small size, light weight and noiseless performance.

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From the Clinica Medica e Cardiologia, Center for Heart and Thrombosis Research, University of Florence, Florence, Italy.

Requests for reprints to Dr Pietro Amedeo Modesti, Clinica Medica e Cardiologia, Center for Heart and Thrombosis Research, Viale Morgagni 85, 50134 Florence, Italy.

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Introduction

The progressively wider application of ambulatory blood pressure monitoring for clinical practice has led to the introduction of an increased number of new ambulatory devices. Initially instruments were very expensive but recently cheaper automatic instruments have been produced. A proper clinical validation of these devices is mandatory to ensure they have the same reliability as that already assessed for earlier devices before they can be recommended for routine use.

The Association for the Advancement of Medical Instruments (AAMI) originally proposed a standard for automated blood pressure measuring devices [1], including a protocol for the evaluation of device accuracy, which has been recently updated [2]. To facilitate comparison of one device with another, the British Hypertension Society (BHS) in 1990 proposed a protocol to standardize device validation [3], which has also been recently updated [4,5]. This protocol, which has been employed for the validation of a number of devices [6–15], takes particular care to ensure that observers are trained to a very high standard, makes provision for special group validation and recommends after-use validation of devices and calibration agreements of three devices.

The QuietTrak is a newly introduced, relatively low-cost ambulatory blood pressure recorder (Tycos-Welch-Allyn, Arden, North Carolina, USA) that has been recently validated according to the AAMI protocol [16]. In the present study its reliabiliy was clinically assessed according to the BHS protocol [4,5].

Methods

The QuietTrak is a lightweight (355 g), totally automatic, non-invasive, programmable portable blood pressure recorder that measures blood pressure by a microphone system enclosed in a sphygmomanometer cuff. At the end of the measurement period data stored can be transferred to an IBM-compatible personal computer and analysed using dedicated software. The devices used for the tests were kindly given by the local distributor of Welch Allyn instruments (Olinto Martelli SpA, Florence, Italy).

Blood pressure was measured simultaneously on the same arm, in the sitting position, by a mercury sphygmomanometer and QuietTrak auscultation. All measurements were performed simultaneously by two trained physicians who were blinded to the values recorded by the automatic device. The latter were recorded by a third observer. The test device and the mercury standard were connected to each other by a T-tube. When the QuietTrak is connected in series to the mercury column sphygmomanometer, the display can be observed during deflation at 3 mmHg/s until the first Korotkoff sound is detected, then at 3 mmHg for each Korotkoff sound. Thus measurements were taken on the same arm, to the nearest 2 mmHg, by the two observers via a standard teaching stethoscope (using phase V, diastolic). All tests were performed with rechargeable nickel-cadmium batteries.

The protocol of the BHS for the clinical evaluation of ambulatory blood pressure devices consists of subsequent separate phases. Specifically, after preliminary observer training and assessment (phase 1), before-use interdevice variability assessment (phase 2), in-use assessment (phase 3), and after-use interdevice variability assessment (phase 4) were performed. Static device validation (phase 5) was then performed in a control population, in special groups (children, pregnant women, the elderly), and under special circumstances (exercise, specific postures).

The level of agreement between the observers and the QuietTrak was assessed by calculating the percentages of all determinations within 5 and 10 mmHg of each other. The evaluation criteria for grading are reported in Table 1.

Table 1 British Hypertension Society criteria.

		Difference between standard and test device (mmHg)		
	Grade	≤5	≤10	≤15
Cumulative % of readings	A	60	90	95
	B	65	85	95
	C	45	75	90
	D		Worse than C	

Part 1

Before-use assessment

Measurements were performed in 54 volunteers (26 normotensive and 28 hypertensive) aged 50 ± 16 years, using three different devices. A total of 162 measurements (3 × 54) for each device were available for analysis during this step.

In-use assessment

During the 1-month use period, 30 subjects of different ages and blood pressure underwent 24 h ambulatory monitoring. The recordings were programmed to occur every 15 min. The number and codes of the errors recorded during the 24 h period (with a total of 2880 measurements) were recorded.

After-use assessment

After the 1-month use period the three devices were retested for interdevice variability as in the before-use variability test. Fifty-three volunteers (27 normotensive and 26 hypertensive) aged 50 ± 16 years were studied, and a total of 159 measurements (3 × 53) for each device were available during this step.

Static device validation

After 1 month of clinical use the main static device validation phase was started. Measurements were performed in 89 volunteers aged from 15 to 80 years (48 ± 18 years), with an arm size, measured as the mid-biceps circumference, of 28 ± 6 cm (20% had an arm larger than 34 cm or smaller than 25 cm and the range was 17–41 cm). Care was taken to include a wide variety of blood pressure levels and heart rate in the study population, as recommended in the BHS protocol. A total of 356 measurements, taken in the sitting position (4 × 89), were available for analysis during this step.

Part 2

Special group validation

Static device validation was also performed in 33 children aged 3–8 years, in 30 pregnant women aged 21–36 years and in 30 elderly persons aged 65–92 years.

Validation under special circumstances

Posture. The effect of posture was assessed in the 85 volunteers used for the main validation. Measurements were taken in the supine, the sitting and the standing position.

Exercise. Thirty-two volunteers consecutively undergoing an exercise stress test (18 men and 14 women) aged 50.2 ± 16.4 years (range 21–70), body weight 71.7 ± 17.5 kg (range 49–91) were investigated. The ambulatory device was fitted to the non-dominant arm as previously described. Patients then exercised on a treadmill (CASE 12; Marquette Electronics Inc, Milwaukee, Wisconsin, USA), according to the Bruce protocol [17]. Measurements were

simultaneously taken on the same arm by the QuietTrak and the two observers at the end of the second minute of each stage.

Statistical analysis

All values are expressed as means ± SD unless otherwise stated. The statistical tests included one-way analysis of variance (ANOVA) and Student's t-test where appropriate. All statistical analyses were performed using BMDP statistical software (BMDP Statistical Software, Los Angeles, California, USA).

Results

Phase 1

Device assessment before and after use

Observer versus QuietTrak measurements before use are shown in Table 2. The difference between device and observers was less than 5 mmHg in 88 and 87% of total measurements for systolic and diastolic pressure respectively. Error codes recorded during the 24 h ambulatory monitoring period are reported in Table 3.

Observer versus QuietTrak measurement after use are also shown in Table 2. Difference between device and observers was less than 5 mmHg in 87 and 86% of measurements for systolic and diastolic pressure, respectively.

The interdevice comparison showed no significant differences between measurements performed using the three different devices both before and after the 1-month use period for systolic and diastolic pressure ($F = 0.97$ and 0.94 on ANOVA, respectively; NS for both variables).

Static device validation

In the 85 volunteers investigated, there were no significant differences between the observers and the QuietTrak (Table 4; Fig. 1). Eighty-nine per cent of all systolic readings and 88% of all diastolic readings obtained by QuietTrak were within 5 mmHg of the mercury column determinations. Furthermore, 99% of all systolic readings and 98% of all diastolic readings obtained by QuietTrak were within 10 mmHg of the mercury column determinations (Table 4).

Table 3 Error codes during 24 h ambulatory monitoring in 30 ambulatory subjects (2760 total measurements).

Types of error codes	Total	Range	%
01 (manual interruption)	33	0–5	1.19
02 (air leak)	22	0–5	0.79
03 (low battery)	15	0–2	0.54
04 (autozero failure)	0	–	–
05 (kinked air hose)	1	–	–
06 (overpressure)	0	–	–
07 (cuff pressure baseline > 10 mmHg)	0	–	–
08 (noisy artifact)	14	0–3	0.50
09 (no Korotkoff sounds)	0	–	–
10 (weak Korotkoff sounds)	6	0–1	0.22
11 (loud Korotkoff sounds)	3	0–1	0.11
12 (blood pressure out of system range)	16	0–1	0.57
13 (did not pump above systolic pressure)	3	0–1	0.11

Phase 2

Special group validation

In the 33 children the average difference between the observers and the QuietTrak was -1.1 ± 3.9 mmHg (range -8 to 8 mmHg) for systolic and 0.1 ± 3.6 mmHg (range -7 to 6 mmHg) for diastolic pressure, and 0.3 ± 4.2 beats/min (range -7 to 11 beats/min) for heart rate. The agreement within 5 mmHg between QuietTrak and mercury column determinations was 87% for systolic blood pressure and 90% for diastolic. The agreement within 10 mmHg was 100% for systolic blood pressure and 100% for diastolic.

In the elderly, the average difference between the observers and the QuietTrak was -0.8 ± 3.2 mmHg (NS) (range -6 to 11 mmHg) for systolic and -0.2 ± 4.5 mmHg (NS) (range -26 to 6 mmHg) for diastolic pressure and -1.0 ± 3.7 beats/min (range -8 to 11 beats/min) for heart rate. Ninety-five per cent of systolic readings and 92% of the diastolic readings were within 5 mmHg of mercury column determinations. Additionally, 98% of all systolic readings and 98% of the diastolic readings were within 10 mmHg of mercury column determination.

In pregnant women, the average difference between the observers and the QuietTrak was -0.3 ± 3.4 mmHg (range -6 to 5 mmHg) for systolic and 0.1 ± 2.9 mmHg (range -4 to 5 mmHg) for diastolic pressure and -3.4 ± 4.1 beats/min (range -8 to 7 beats/min) for heart rate (NS for all). Ninety-three per cent of the systolic readings and 100% of

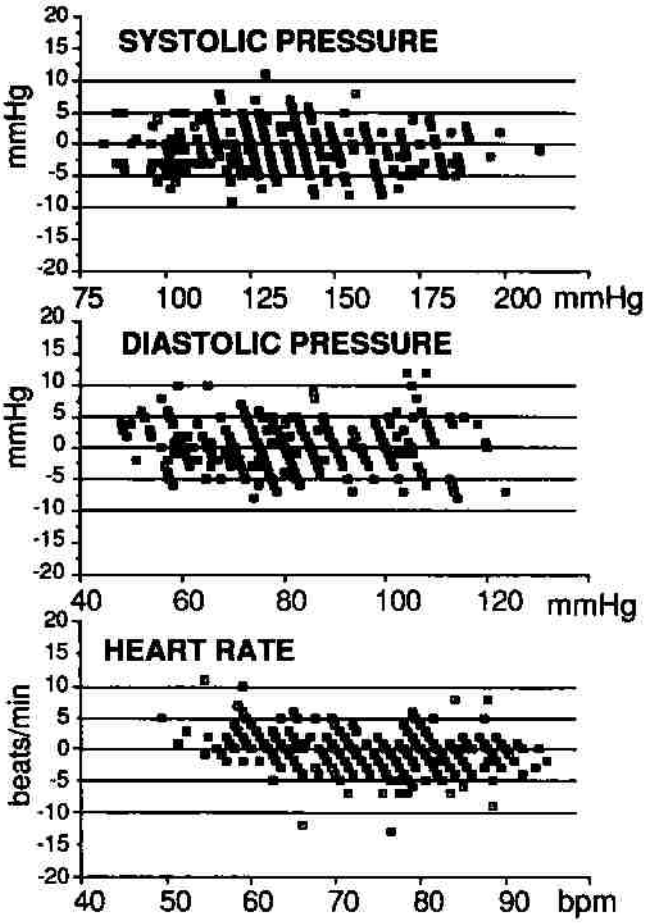
Table 2 Device assessment before use and after a 1-month period of routine clinical use.

			Differences between standard and test device				
	Observer	QuietTrak	Average difference	Range	<5	<10	Grade
Before use							
Systolic (mmHg)	141 ± 26	142 ± 26	−0.6 ± 3.6	−8/11	88%	99%	A
Diastolic (mmHg)	86 ± 18	87 ± 18	−0.4 ± 3.6	−8/12	87%	99%	A
Heart rate (beats/min)	74 ± 10	74 ± 11	0.3 ± 2.7	9/8	97%	100%	A
After use							
Systolic (mmHg)	141 ± 27	142 ± 27	−0.7 ± 3.3	−8/7	87%	100%	A
Diastolic (mmHg)	87 ± 18	86 ± 18	0.6 ± 3.8	−7/12	86%	99%	A
Heart rate (beats/min)	74 ± 10	74 ± 11	0.1 ± 3.3	−7/11	92%	99%	A

Table 4 Static comparison between observers and QuietTrak measurements performed in 85 subjects.

			Differences between standard and test device				
	Observer	QuietTrak	Average difference	Range	≤5	≤10	Grade
Systolic (mmHg)	135±26	135±26	−0.3±3.4	−9/11	89%	99%	A
Diastolic (mmHg)	82±16	82±16	0.1±3.5	−8/12	88%	98%	A
Heart rate (beats/min)	73±10	74±10	−0.5±3.3	−14/11	94%	98%	A

Fig. 1.



Static device validation performed in 85 subjects.

the diastolic readings were within 5 mmHg of mercury column determination, whereas 100% of the systolic readings and 100% of the diastolic readings were within 10 mmHg of mercury column determination.

Special circumstances

Posture. Observer measurement values in the supine position are compared with those using Quiet'Trak in Table 5. Ninety-six per cent of the systolic readings and 89% of the diastolic readings obtained by Quiet'Trak were within 5 mmHg of the mercury column determinations. Additionally, 100% of the systolic readings and 100% of the diastolic readings were within 10 mmHg of the mercury column determinations. Observer measurement values in the standing position are compared with those using Quiet'Trak in Table 5. The agreement within 5 mmHg between Quiet'Trak and mercury column determinations was 90% for the systolic readings and 90% for the diastolic readings. Additionally, the agreement within 10 mmHg was 100% for systolic readings and 98% for diastolic readings.

Exercise. In all subjects the device was able to record reliable values. In three subjects, the microphone needed to be removed and fixed again on the arm during the test. In particular, 1.2% of total systolic and 2% of total diastolic measurements differed by more than 40 mmHg from values measured using a sphygmomanometer. However, at immediately subsequent pressure determination, 88% (24 out of 198) and 83% (32 out of 198) of systolic and diastolic measurements differed less than 10 mmHg from that performed by sphygmomanometer. Overall differences of 3.1±5.7 (range −8 to 35 mmHg) and 4.9±6.2 mmHg (range −8 to 29 mmHg) for systolic and diastolic pressure were observed between manual and automatic readings (Tables 6 and 7).

Discussion

The Quiet'Trak achieved A rating for systolic blood pressure and A rating for diastolic blood pressure according to the criteria of the BHS Protocol [4,5] and fulfilled the criteria of the AAMI standard [2,16]. The performance characteristics were good and the device was acceptable to patients because of its small size (11.43×8.6×4.1 cm) and light weight (355 g with batteries), and its almost noiseless performance.

The recent evaluation of Quiet'Trak according to the protocol proposed by the AAMI [16] showed a very small difference between automated and manual measurements as in our report. In addition, the BHS protocol enabled us to exclude differences in special group populations such as children, elderly people or pregnant women, in whom an accurate measurement of diastolic pressure is often difficult. Moreover, the effect of intense clinical use on the reliability of the device was assessed and no differences between new and used instruments were detected.

Table 5 Effect of posture

	Observer	QuietTrak	Differences between standard and test device: Average difference	Range	≤5	≤10	Grade
Systolic (mmHg)							
Sitting	136±23	137±23	−1.4±3.1	−8/11	88%	99%	A
Standing	130±28	131±28	−0.4±3.4	−9/8	90%	100%	A
Supine	138±25	137±26	1.3±3.0	−8/6	96%	100%	A
Diastolic (mmHg)							
Sitting	85±17	86±16	−0.4±3.4	−8/10	90%	99%	A
Standing	79±15	79±15	0.3±3.6	−8/12	90%	98%	A
Supine	81±16	81±17	0.7±3.5	−7/10	89%	100%	A
Heart rate (beats/min)							
Sitting	73±9	73±10	−0.3±2.6	−12/6	97%	99%	A
Standing	76±10	77±11	0.9±4.0	−14/11	92%	97%	A
Supine	71±9	72±10	−0.2±3.2	−7/10	91%	100%	A

Table 6 Effect of exercise (overall results)

	Observer	QuietTrak	Differences between standard and test device: Average difference	Range	≤5	≤10	Grade
Systolic (mmHg)	177±28	174±28	3.1±5.7	−8/35	69%	88%	B
Diastolic (mmHg)	92±19	88±16	4.9±6.2	−8/29	56%	83%	C
Heart rate (beats/min)	107±26	107±26	0.3±4.9	−12/11	74%	91%	B

Table 7 Effect of exercise (stage by stage)

Stage	No. patients	Grade (%)	Miles/h	Min	Observer	QuietTrak	≤5	≤10	Grade
Systolic (mmHg)									
I	32	0.0	1.7	3	148±25	147±27	88%	97%	A
II	32	5.0	1.7	3	157±22	155±23	78%	91%	B
III	32	10.0	1.7	3	170±28	166±27	66%	97%	B
IV	32	12.0	2.5	3	189±18	185±19	59%	88%	C
V	31	14.0	3.4	3	195±12	192±11	65%	84%	C
VI	23	16.0	4.2	3	198±13	193±13	74%	91%	B
VII	16	18.0	5.0	3	203±14	198±16	56%	81%	C
Diastolic (mmHg)									
I	32	0.0	1.7	3	87±14	83±15	69%	97%	B
II	32	5.0	1.7	3	88±12	84±13	50%	84%	C
III	32	10.0	1.7	3	91±23	86±21	69%	81%	C
IV	32	12.0	2.5	3	90±21	87±19	53%	94%	C
V	31	14.0	3.4	3	97±18	90±17	52%	71%	C
VI	23	16.0	4.2	3	99±21	92±21	35%	78%	D
VII	16	18.0	5.0	3	104±21	97±18	63%	75%	C

Although the accuracy of the QuietTrak recorder was similar to that of other available automatic monitors [6–15], its lower cost and the ability to use it independently of a dedicated computer-assisted decoding system seem to be the greatest advantages of QuietTrak.

On the basis of these results, the QuietTrak can be recommended for clinical use not only in a hypertension center or in hospitals but also in the field by the family physician.

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