

RETRACTED ARTICLE: Validation of the BPLab[®] 24-hour blood pressure monitoring system according to the European standard BS EN 1060-4:2004 and British Hypertension Society protocol

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Introduction: Automatic blood pressure (BP) measuring devices are more and more often used in BP self-checks and in 24-hour BP monitoring. Nowadays, 24-hour BP monitoring is a necessary procedure in arterial hypertension treatment. The aim of this study was to validate the BPLab[®] ambulatory blood pressure monitoring device according to the European standard BS EN 1060-4:2004 and the British Hypertension Society (BHS) protocol, as well as to work out solutions regarding the suitability of using this device in clinical practice.

Methods: A group of 85 patients of both sexes and different ages, who voluntarily agreed to take part in the tests and were given detailed instructions on the measurement technique were recruited for this study. The results of the BP measurement obtained by a qualified operator using the BPLab[®] device were compared with the BP values measured using the Korotkov auscultatory method. Data were obtained simultaneously by two experts with experience of over 10 years and had completed a noninvasive BP measurement standardization training course. Discrepancies in the systolic and diastolic BP measurements (N = 510; 255 for each expert) were analyzed according to the criteria specified in the BHS-93 protocol.

Results: The device passed the requirements of the European Standard BS EN 1060-4:2004 and was graded 'A' according to the criteria of the BHS protocol for both systolic BP and diastolic BP.

Conclusion: The BPLab[®] 24-hour ambulatory blood pressure monitoring device may be recommended for extensive clinical use.

Keywords: 24-hour blood pressure monitoring, device, validation, BPLab[®]

Introduction

Automatic blood pressure (BP) measuring devices are more and more often used for BP self-checks and in 24-hour BP monitoring. According to the experts of European Society of Hypertension, 24-hour BP monitoring has been used for research purposes and at present it is mandatorily used in clinical and pharmacological studies and in evaluation of the efficiency of new antihypertensive medical products. Nowadays, 24-hour BP monitoring becomes an obligatory procedure in arterial hypertension detection. Considering the abovementioned, it is essential to objectively evaluate the accuracy of measurements performed by 24-hour BP monitoring devices offered in the market.

In 1990, the British Hypertension Society published a protocol, the purpose of which was to standardize the validation of noninvasive BP measuring instruments.¹

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This protocol was revised in 1993 and has gained international status.² In 2004, the British Hypertension Society together with European Society of Hypertension (ESH) published an international standard for the validation of noninvasive sphygmomanometers.³ The principles recommended in the documents provided the basis for work aimed at the validation of the 24-hour BP monitoring device, BPLab® (Petr Telegin Ltd, Nizhny Novgorod, Russia). The results of this validation are given below.

Methods

Subject selection

Subject selection was based on the requirements of the Standard EN 1060-4:2004.³ A group of 85 patients of both sexes and different ages, who voluntarily agreed to take part in the tests and were given detailed instructions on the measurement technique, were recruited to participate in this study. All participants provided verbal informed consent of study participation.

The statistical distribution of the patients' clinical profile parameters is given in Table 1, and their distribution according to the BP level in Table 2.

Exclusion criteria include: heart failure; significant rhythm disturbances or presence of an artificial pacemaker; pregnancy; and body mass index (BMI) >30 kg/m².

Test measurement conditions

In accordance with the requirements of the EN ISO-93, the results of the BP measurement obtained by a qualified operator using the BPLab device were compared with the BP values measured using the Korotkov auscultatory method simultaneously by two expert medical specialists with over 10 years of experience, who had completed a noninvasive BP measurement standardization training course. The measurements were taken in the morning in comfortable settings (ambient temperature 18°C–25°C, no stimulatory sights or sounds, etc.) after the patients had been relaxing in a seated position for 10 minutes. The patients were prohibited

Table 2 Distribution of patients according to BP level

SBP	Range, mmHg	<90	90–129	130–160	161–180	>180
No		8	22	23	20	9
%		9.4	25.9	27.1	23.5	10.6
DBP	Range, mmHg	<60	60–79	80–100	101–110	>110
No		8	21	26	20	10
%		9.4	24.7	30.6	23.5	11.8

Abbreviations: BP, blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure.

to take alcohol <24 hours beforehand or to smoke or take stimulants (tea, coffee, etc) <8 hours before the measurement; they were only allowed to have a light breakfast not less than half an hour before the test. Additionally, taking medication that has a strong effect on the cardiovascular system was not allowed on the day of the measurements.

Expert BP measurements were performed by two experts simultaneously with usage of a high-quality auscultoscope with one head and two headbands and two individual calibrated sphygmomanometers. The collar dimension depended on the patient's shoulder girth.

Measurement schedule

The BP of each patient was measured nine times – alternating between the experts and the tested device – according to the following schedule:

- Measurement A: expert
- Measurement B: instrument
- Measurement 1: expert
- Measurement 2: instrument
- Measurement 3: expert
- Measurement 4: instrument
- Measurement 5: expert
- Measurement 6: instrument
- Measurement 7: expert

The BP was measured on the nondominant arm. The interval between measurements was 30–60 seconds. The BP values obtained by the experts were recorded by each of them according to their own protocol. Three measurement error values were calculated for each patient (for systolic BP [SBP] and diastolic BP [DBP], separately) according to the following formulae:

$$\Delta BP_1 = \min(BP_2 - BP_1, BP_2 - BP_3),$$

$$\Delta BP_2 = \min(BP_4 - BP_3, BP_4 - BP_5),$$

$$\Delta BP_3 = \min(BP_6 - BP_5, BP_6 - BP_7),$$

where BP_n is a BP measurement result corresponding to the measurement number n. Measurement A was used to refer

Table 1 Patients' clinical profile parameters

Parameter	Mean	SD	Min	Max
Age	37	15	18	87
SBP, mmHg	134	25	64	198
DBP, mmHg	85	16	44	122
Arm circumference, cm	31	7	21	44
Sex	Male		Female	
	49		36	

Abbreviations: SD, standard deviation; BP, blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure.

Table 3 Study results

		Difference between standard and test device (%)			Grade	AAMI criteria		Result
		≤5 mmHg	≤10 mmHg	≤15 mmHg		Mean difference, mmHg	SD of difference, mmHg	
Observer 1								
SBP	65	89	98	A	1.2	6.5		Passed
DBP	61	87	97	A	−1.2	7.1		Passed
Observer 2								
SBP	66	90	98	A	1.1	6.4		Passed
DBP	60	86	96	A	−1.4	7.4		Passed
Final grading								
SBP	66	90	98	A	1.1	6.4		Passed
DBP	61	87	97	A	−1.2	7.1		Passed
Observer comparison								
SBP	84	99	100		0.2	2.2		
DBP	81	95	100		−0.9	3.8		

Abbreviations: SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure; AAMI, Association for the Advancement of Medical Instrumentation.

a patient to this or that group according to their BP level; measurement B was treated as a calibration measurement.

Discrepancies in the systolic and diastolic BP measurements (N = 510; 255 for each expert) were subsequently analyzed according to the criteria specified in the BHS-93 protocol.

Results

Detailed results of the data analysis are given in Table 3 in the form recommended by the BHS-93 protocol.² The number of measurement error values which are within the ranges envisaged by the protocol is indicated in the form of a percentage ratio in relation to the total number of measurements.

Figure 1 is a graphical illustration of discrepancies of each measurement depending on the relevant BP value (separately for SBP and DBP). As recommended in the BHS-93 protocol, the figures show only the results of comparison with the expert who obtained closer results (for SBP – observer 2, for DBP – observer 1).

Discussion

Recently, the accuracy of conventional sphygmomanometers for the measurement of BP has been called into question, and much effort has been made to improve the quality of automatic device measurements.⁵ Ambulatory BP monitoring is being increasingly recommended for routine clinical practice because it provides valued prognostic data.^{6,7} The accuracy of BP measuring devices is of great importance and should be validated before devices are put into operation. The aim of this study was to validate the accuracy of the BPLab® 24-hour ambulatory BP monitoring device (Petr Telegin Ltd, Nizhny Novgorod, Russia).

The results of this study suggest that the BPLab® 24-hour ambulatory BP monitoring device passes the test carried out in a mixed group of patients in accordance with the requirements of the European Standard BS EN 1060-4:2004

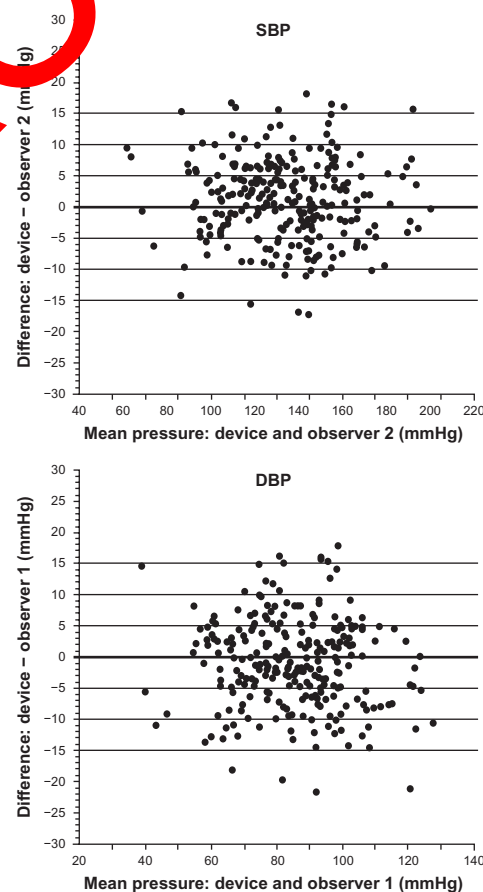


Figure 1 Plot of pressure difference between the better observer and the test device, and mean pressure.

Abbreviations: SBP, systolic; DBP, diastolic blood pressure.

and the BHS-93 protocol, and may be categorized in the 'A' accuracy class according to the abovementioned protocol. The tested device may be recommended for extensive clinical use.

Disclosure

The authors report no conflicts of interest in this work.

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