Validation of the SEJOY BP-1307 upper arm blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol revision 2010

Short title: Validation of the SEJOY BP-1307 blood pressure monitor

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Abstract

Objective The present study aimed to evaluate the accuracy of the automated oscillometric upper arm blood pressure monitor SEJOY BP-1307 (also called JOYTECH DBP-1307) for home blood pressure monitoring according to the International Protocol of the European Society of Hypertension revision 2010.

Method Systolic and diastolic blood pressures were sequentially measured in 33 adult Chinese (13 women, 45.1 years of mean age) using a mercury sphygmomanometer (two observers) and the SEJOY BP-1307 device (one supervisor). Ninety-nine pairs of comparisons were obtained from 33 participants for judgments in two parts with three grading phases.

Results The SEJOY BP-1307 device achieved the targets in part 1 of the validation study. The number of absolute differences between device and observers within 5, 10 and 15 mmHg was 84/99, 96/99, and 98/99, respectively, for systolic blood pressure, and 74/99, 96/99, and 98/99, respectively, for diastolic blood pressure. The device also achieved the criteria in part 2 of the validation study. Twenty-nine and 27 participants for systolic and diastolic blood pressure, respectively, had at least two of the three device-observers differences within 5 mmHg (required ≥24). Only one participant for diastolic blood pressure had all the three device-observers comparisons greater than 5 mmHg.

Conclusions The SEJOY upper arm blood pressure monitor BP-1307 has passed the requirements of the International Protocol revision 2010, and hence can be recommended for home use in adults.

Key words: SEJOY BP-1307, blood pressure measurement, blood pressure monitor, validation study, European Society of Hypertension International Protocol

Introduction

Current guidelines recommend the use of upper arm blood pressure monitors for home blood pressure monitoring and indicate that only validated blood pressure monitors should be used [1, 2]. SEJOY is a manufacturer of automated oscillometric blood pressure monitors under its own brand name and as an original equipment manufacturer. In the present study, we assessed the accuracy of the upper-arm blood pressure monitor SEJOY BP-1307 for blood pressure measurement in adult Chinese according to the revision 2010 of the European Society of Hypertension International Protocol (ESH-IP2010) for validation of BP measuring devices in adults [3].

Methods

Familiarisation

Twelve test measurements were carried out and no problems were encountered.

Participants

Study participants were men and women between 26 and 84 years of age, and were randomly recruited from the staff and hypertensive patients in Ruijin Hospital (Shanghai, China). We excluded individuals with cardiac arrhythmias and peripheral arterial disease. For practical reasons, we also excluded patients with known heart disease or diagnosed secondary hypertension. The Ethics Committee of Ruijin Hospital, Shanghai Jiaotong University School of Medicine, approved the study protocol. All participants gave informed written consent. We administered a short questionnaire to collect information on medical history, and measured body height, body weight and arm circumference.

The selected participants were categorized fitting three systolic blood pressure ranges (≤129, 130–160, and ≥161 mmHg) and three diastolic blood pressure ranges (≤79, 80–100, and ≥101 mmHg) required by the International Protocol rules [3].

The SEJOY BP-1307 device

The SEJOY BP-1307 device is an automated electronic digital upper arm blood pressure monitor. The device operates through oscillometric technique, and is designed mainly for self-blood pressure measurement at home. The device requires four 1.5 V AA alkaline batteries as energy source or uses the adapter to input external power (6.0 volts, 600 mA). The device has a semi-conductive pressure sensor designed to measure blood pressure values ranging from 0 to 300 mmHg and pulse rate values from 30 to 180 beats per minute. The declared specific accuracy is ±3 mmHg for blood pressure and ±5% for pulse rate. The device has two memory zones and a memory capacity of 60 readings each. The cuff is suitable for upper arm circumferences from 22.0 to 42.0 cm. During measurement, the bottom edge of the cuff should be positioned approximately one inch above the elbow joint, meanwhile the forearm and the device should be on a table with the palm facing up and the device at the heart level. The manufacturer provided three blood pressure monitors, one of which was randomly selected for the validation process.

Validation procedure

The validation procedure strictly followed the International Protocol revision 2010, and

was carried out by a team of three investigators experienced in blood pressure measurement and trained repeatedly by the use of an educational video program for blood pressure measurement produced by the British Society of Hypertension (Registered Charity Number 287635). Blood pressure was measured in the sitting position with the forearm at the level of the heart according to the European recommendations [4]. For each subject, blood pressure was sequentially measured using a mercury sphygmomanometer (two observers) and the SEJOY BP-1307 device (one supervisor). During the whole process, the two observers used a Y-tubing dual head stethoscope to obtain the blood pressure readings separately and did not know each other's readings and the device readings. A pause of 30–60 seconds was allowed between two successive measurements.

In addition, the digital signals of the pressure and the oscillations were recorded during the device measurement for the real-time monitoring of pulse rhythm.

Data analysis

For each of the three systolic and three diastolic blood pressure readings recorded by the device, two absolute differences were calculated by subtracting, respectively, the mean of the preceding and the following measurements taken by the two observers with the mercury sphygmomanometer. The smaller one of the two absolute differences was used and categorized into one of the three bands (≤5, ≤10 and ≤15 mm Hg) according to its rounded value [3]. These differences were presented in numbers in tabular format and against the mean of the device and observers' measurements in scatter plots.

Results

Demographic and clinical data

Of the 42 consecutively screened participants, 9 were excluded for reasons detailed in **Table 1**, leaving 33 participants enrolled in the study. All 33 subjects had systolic and diastolic blood pressure in the required ranges. The study was conducted on the left upper arm in all subjects. During the study, there was no measurement failure for the device.

The 33 study participants (20 men and 13 women) had a mean (±SD) age of 45.1±15.5 years (range, 26.0 to 84.0 years) and a mean body mass index of 24.5 ± 3.6 kg/m². The arm circumference was 28.0 ± 2.1 cm (range, 22.0 to 32.0 cm). Mean systolic/diastolic blood pressures at recruitment were 145.8 ± 25.1/88.6 ± 20.9 mmHg (**Table 2**).

Validation of the SEJOY BP-1307 device

The SEJOY BP-1307 device achieved the targets in part 1 of the validation study. The number of observer test measurements in each pressure range was between 27 and 39, and hence the difference between the range with the highest count and that with the lowest count was 12. The overall systolic blood pressure range was from 88 to 184 mmHg and the overall diastolic blood pressure range from 49 to 124 mmHg (**Table 3**). There was only one subject with systolic blood pressure outside the range from 90-180 mmHg and none with diastolic blood pressure outside the range from 40-130 mmHg.

The observer differences for systolic and diastolic blood pressure were within -4 to 4 mmHg, with a mean (±standard deviation) value of -0.5 ± 1.7 mmHg and -0.5 ± 1.7 mmHg, respectively. For all the included subjects, twelve repeated measurements were obtained (**Table 4)**.

The number of absolute differences between device and observers within 5, 10, and 15 mmHg was 84/99, 96/99, and 98/99, respectively, for systolic blood pressure, and 74/99, 96/99, and 98/99, respectively, for diastolic blood pressure (**Table 5 and Figure 1**). Twenty-nine participants for systolic blood pressure and 27 for diastolic blood pressure had at least two of the three device-observers differences within 5 mmHg (required ≥24). One participant for diastolic blood pressure had all the three device-observers comparisons greater than 5 mmHg (**Table 5**).

Device-observers mean differences

The average (±SD) of the device-observers differences was 0.2 ± 4.1 mmHg and -1.7 ± 4.7 mmHg for systolic and diastolic blood pressure, respectively (**Table 5**). **Figure 1** presents the scatter plots of device-observers differences against the average of device and observers values for the 99 pairs of comparisons.

Discussion

The results of the present study demonstrated that the SEJOY upper arm blood pressure monitor BP-1307 passed the validation for both systolic and diastolic blood pressures according to the International Protocol revision 2010 [3].

In our study, the graphical presentations of the device-observers differences in systolic

and diastolic blood pressures showed a fair agreement between the mercury sphygmomanometer and the SEJOY BP-1307 device. Only one dot each for systolic and diastolic blood pressure was outside the ±15 mmHg limits and only one subject had all the three device-observers differences greater than 5 mm Hg for diastolic blood pressure. The SEJOY BP-1307 device has a so-called whole range cuff, which is suitable for arm circumferences from 22 cm to 42 cm. It would be possible for overweight and obese subjects to measure their blood pressures with the same cuff.

Conclusion

The SEJOY upper arm blood pressure monitor BP-1307 has passed the International Protocol revision 2010 requirements, and hence can be recommended for blood pressure measurement at home in adults.

Acknowledgement

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Conflicts of interest

Dr Wang reports receiving lecture and consulting fees from A&D, Novartis, Omron, Pfizer, Sankyo, Servier, and Takeda. For the remaining authors，there are no conflicts of interest.

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Figure legend

Fig. 1 Scatter plots of the (a) systolic and (b) diastolic blood pressure differences between the SEJOY BP-1307 device and observers (y-axis) against the average of device and observers pressure values (x-axis).

Table 1. Screening and recruitment details

Screening and recruitment				Recruitment ranges		
Total screened	42			mmHg	Number of subjects	Number of subjects on antihypertensive drugs
Total excluded	9		Low	<90	0	5
Ranges complete	0			90–129	10	
Range adjustment	6	SBP	Medium	130–160	12	11
Arrhythmias	1		High	161–180	10	10
Device failure	0			>180	1	
Poor quality sounds	1					
Peripheral arterial disease	1					
Cuff size unavailable	0		Low	<40	0	8
Observer disagreement	0			40–79	11	
Distribution	0	DBP	Medium	80–100	10	8
Other reasons	0		High	101–130	12	10
Total recruited	33			>130	0	

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

Table 2. Participants' details

Sex	Male : female	20 : 13
Age (years)	Range (low : high)	26 : 84
	Mean (SD)	45.1 (15.5)
Arm circumference (cm)	Range (low : high)	22 : 32
	Mean (SD)	28.0 (2.1)
Cuff for tested device	22-42 cm (arm)	33
BP range (mmHg) (low : high)	SBP	98 : 182
	DBP	46 : 124
Mean (SD)	SBP	145.8 (25.1)
	DBP	88.6 (20.9)

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

Table 3. Observer measurements in each recruitment range

SBP (mmHg)		DBP (mmHg)	
Overall range (low : high)	88 : 184	Overall range (low : high)	49 : 124
Low (< 130)	29	Low (< 80)	39
Medium (130-160)	37	Medium (80-100)	33
High (>160)	33	High (>100)	27
Maximum difference	8	Maximum difference	12

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

Table 4. Differences in observers' measurements

Observer 2–observer 1	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Range (low : high)	–4 : +4	–4 : +4	12
Mean (SD)	–0.5 (1.7)	–0.5 (1.7)	

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

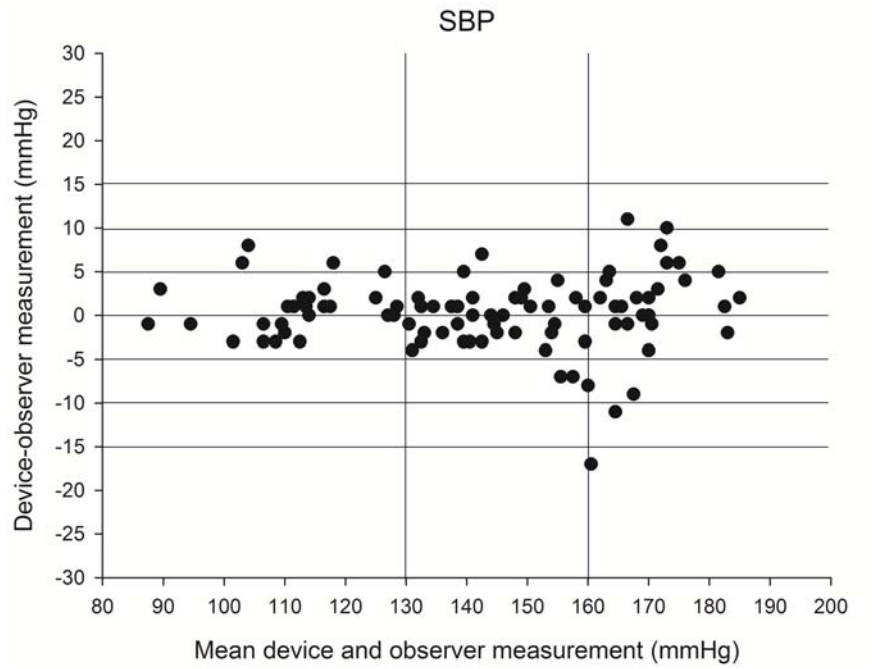
Table 5. Accuracy of the SEJOY BP1307 device according to the International Protocol revision 2010 for the validation of blood pressure measuring devices in adults

	≤ 5 mmHg	≤10mmHg	≤15mmHg	Grade 1	Mean difference (mmHg)	Standard deviation (mmHg)
Part 1						
Required						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	84	96	98	Pass	0.2	4.1
DBP	74	96	98	Pass	-1.7	4.7
Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Grade 2		Grade 3
Required	≥ 24	≤ 3				
Achieved						
SBP	29	0		Pass		Pass
DBP	27	1		Pass		Pass
Part 3						Result Pass

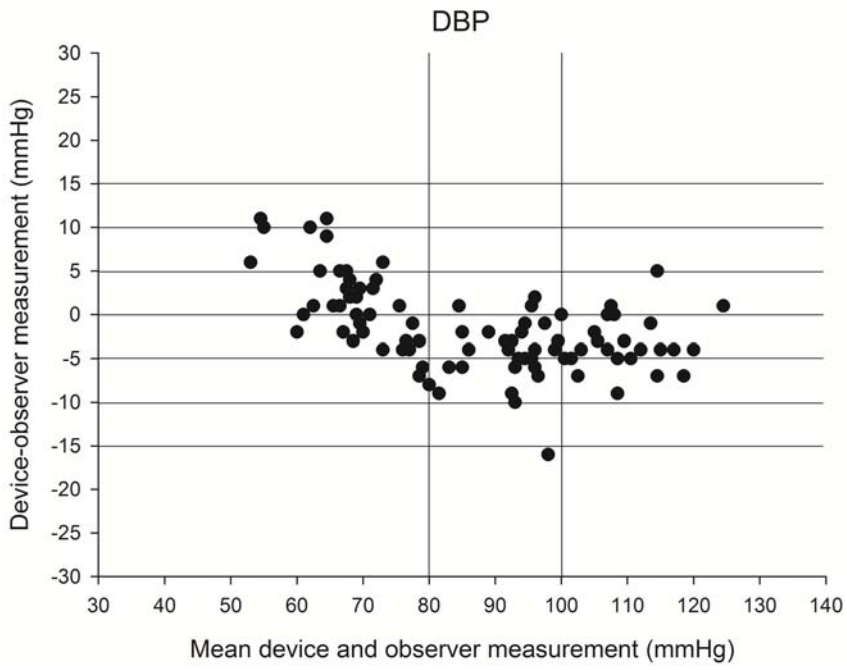
SBP, systolic blood pressure; DBP, diastolic blood pressure.

Figure 1

(a)


SBP
Device-observer measurement (mmHg)
30
25
20
15
10
5
0
-5
-10
-15
-20
-25
-30
80
90
100
110
120
130
140
150
160
170
180
190
200
Mean device and observer measurement (mmHg)

(b)


DBP
Device-observer measurement (mmHg)
30
25
20
15
10
5
0
-5
-10
-15
-20
-25
-30
30
40
50
60
70
80
90
100
110
120
130
140
Mean device and observer measurement (mmHg)