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ORIGINAL RESEARCH

Feasibility of Blood Pressure Measurement With a Wearable (Watch-Type) Monitor During Impending Syncopal Episodes

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BACKGROUND: We assessed the reliability and feasibility of blood pressure (BP) measurements by means of a new wearable watch-type BP monitor (HeartGuide) in detecting episodes of hypotensive (pre)syncope induced by tilt table test.

METHODS AND RESULTS: An intrapatient comparison between systolic BP (SBP) measured by means of the HeartGuide device and noninvasive finger beat-to-beat BP monitoring was undertaken both at baseline in supine position and repeatedly during tilt table test in patients evaluated for reflex syncope. Intrapatient fall of systolic BP from baseline was measured. Eighty-one patients (mean age, 61±19 years; 46 women) were included. Overall, HeartGuide was able to yield BP values at the time of BP nadir in 58 (72%) patients (average HeartGuide SBP 102±18 mm Hg, versus finger SBP 101±19 mm Hg). Compared with baseline, the maximum SBP decrease was on average −28.5±27.8 and −30.3±33.9 mm Hg respectively (Lin's concordance correlation coefficient=0.78, r=0.79, P=0.001). In the subgroup of 38 patients with tilt table test induced (pre)syncope, the average HeartGuide SBP during symptoms was 97±16 mm Hg, and the finger SBP was 94±18 mm Hg. Compared with baseline, the maximum SBP decrease was on average −35.2±29.3 and −43.3±31.8 mm Hg, respectively (Lin's concordance correlation coefficient=0.83, r=0.87, P=0.001).

CONCLUSIONS: Our data indicate that the HeartGuide BP monitor can detect low BP during presyncope and that its measure of SBP change is consistent with that simultaneously obtained through continuous BP monitoring, despite some intrapatient variability. Thus, this device might be useful in determining the hypotensive nature of spontaneous (pre)syncopal symptoms, a possibility that should be verified by field studies.

Key Words: blood pressure monitoring ■ finger blood pressure ■ syncope ■ wearable (watch-type) monitor

Reflex (neurally mediated) syncope is the most frequent cause of transient loss of consciousness. Traditionally, reflex syncope is identified by its pathogenesis and clinical presentation. Given that the efficacy of therapy is determined by the mechanisms of syncope (either hypotensive or bradycardic phenotype) rather than by its pathogenesis or clinical presentation, the careful assessment of these mechanisms is mandatory for a proper choice of treatment. Recent progress in technology can now offer the possibility to characterize spontaneous (pre)syncopal events in daily life, thus improving our ability to make a diagnosis based on the documentation of spontaneous hypotensive or bradycardic events.[1]

While ECG monitoring is a reliable and established method that allows the detection of bradycardia in a substantial proportion of patients affected by cardioinhibitory reflex syncope, the documentation of a

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CLINICAL PERSPECTIVE

What Is New?

- A novel wearable watch-type blood pressure monitor can provide reliable systolic blood pressure values at the time of impending tilt-induced vasovagal syncope in most patients.
- Given the high prevalence of syncopal events in daily life, there is a strong need for wearable devices able to easily and reliably identify blood pressure changes that might anticipate such events.
- To date, no commercially available device has been able to achieve this goal in clinical practice.

What Are the Clinical Implications?

- This wearable watch-type blood pressure monitor could be properly activated by patients themselves during the (pre)syncopal phase of a spontaneous event, thus offering the possibility to identify its hypotensive mechanism aimed at avoiding syncope.

Nonstandard Abbreviations and Acronyms

ABPM	ambulatory blood pressure monitoring
DBP	diastolic blood pressure
PR	pulse rate
SBP	systolic blood pressure
TTT	tilt table test

transient hypotension is only seldom achieved in patients affected by hypotensive syncope. Conventional ambulatory blood pressure (BP) monitoring (ABPM) has important limitations in this regard, because of the short period of monitoring (usually 24–48 hours), the frequent unavailability of patients to accept repeated 24-hour recordings and the intermittent nature of BP measurements (usually every 15–20 minutes). These features do not allow rapid phasic changes in BP occurring erratically in daily life to be identified. For these reasons, 24-hour ABPM is not recommended for the diagnosis of unexplained syncope by current syncope guidelines[2] nor by guidelines on arterial hypertension[3] of the European Society of Cardiology/European Society of Hypertension. Thus, new BP monitoring devices able to overcome these limitations, are warranted.

The purpose of this study was to assess the feasibility and reliability of a new wearable watch-type BP monitor (HeartGuide; Omron Healthcare, Kyoto, Japan), which allows BP measurements to be taken in daily life conditions, in detecting episodes of hypotensive (pre)syncope induced by tilt table test (TTT). The study hypothesis was that this wearable watch-type BP monitor can reliably measure systolic BP (SBP) changes in such critical conditions. In perspective, this demonstration could support the use of this device in determining the hypotensive nature of spontaneous (pre)syncopal symptoms.

METHODS

The data that support the findings of this study are available from the corresponding author upon reasonable request. The study presents an intrapatient comparison between SBP measured by means of a wearable watch-type BP monitor (HeartGuide) and SBP values obtained through noninvasive finger beat-to-beat BP monitoring, both recorded at baseline in supine position and repeatedly during TTT performed in patients evaluated for suspected reflex syncope. The study was performed in the Syncope Unit of Istituto Auxologico Italiano, Milan, Italy and Azienda Ospedaliera Universitaria Careggi, Florence, Italy.

The study protocol was approved by the institutional review board. All participants provided a written informed consent.

Description of the Study Devices

The investigational device was the Omron HeartGuide 6410T (Figure 1), an automated oscillometric device for wrist BP measurement over a SBP range of 60 to 230 mm Hg, diastolic BP (DBP) range of 40 to 160 mm Hg, and pulse rate (PR) range of 40 to 180 beats per minute. The device estimates SBP, DBP, and PR during the cuff inflation period. It analyzes the pulse wave detected during inflation using an algorithm for determining SBP and DBP values. The cuff is inflated automatically by an electric pump and then deflated by a mechanical valve. The cuff can be used for wrist circumferences in the range of 16.0 to 19.0 cm for 6410Tmodel. Omron HeartGuide was validated in sitting rest conditions against a cuff oscillometric reference standard device.[4] The results fulfilled the validation criteria 1 and 2 of the American National Standards Institute, Inc/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) with between device mean differences of −0.9±7.6/−1.1±6.1 mm Hg for SBP/DBP for criterion 1, and −0.9±6.8/−1.1±5.5 mm Hg for SBP/DBP for criterion 2, respectively.[5,6] The device was also compared with at least 10 daytime measurements provided by a conventional 24-hour ABPM.[7] The results indicate that the mean difference between the 2 devices was acceptable.

Depending on the BP level, HeartGuide takes around 50 to 60 seconds to measure BP. Approximately, during the first 10 seconds HeartGuide will do a position check. If the HeartGuide cuff is in the correct position, at heart level, it will start to inflate. During inflation,

Figure 1. Watch-type wearable blood pressure monitor HeartGuide.

DBP is estimated first, followed by SBP estimation (Figure 2). The inflation speed is on average 4 mm Hg/s. This means that, with a SBP of 120 mm Hg, it will take 40 seconds. During this period, the arm of the patient must be held in the same position at the heart level.

BP measurements taken with the HeartGuide were compared against noninvasive beat-to-beat BP values provided by commercially available devices for continuous finger BP monitoring (Finometer; Finapres Medical Systems, Enchede, The Netherlands, and Task Force monitor, CNSystem, Graz, Austria), based on the photoplethysmographic volume clamp method.[8,9] These devices are widely used in syncope facilities and are recommended as reference standard for BP monitoring

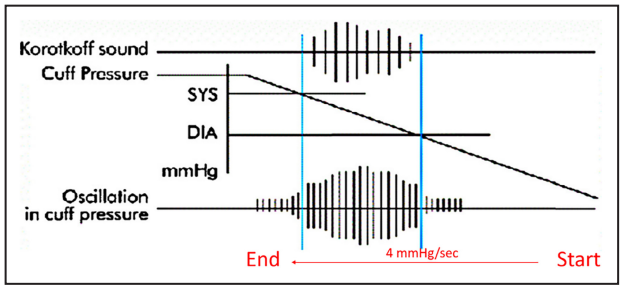

Figure 2. Method of measurement of blood pressure by HeartGuide (see text).

during TTT by a recent consensus document.[10] The Finapres device provides reliable information on BP values and even more so on BP fluctuations as compared with intra-arterial recordings at rest and during tests known to induce fast changes in BP.[11,12] The Task Force BP technology is similar to the CNAP technology used and compared in critical care with intra-arterial recording.[13] In addition, the Task Force monitor showed a good BP correlation with intra-arterial recording and other validated devices, including Finapres, and achieved the criteria for the "Quality Mark" (Gütesiegel) of the German Hypertension League.[14] Cuff BP measurements with a validated oscillometric arm cuff device (AND Medical UA-651) was also performed at baseline, before and after the HeartGuide measurement, and compared with the BP values obtained with HeartGuide and finger BP monitoring, respectively.

Study Design

The study was based on an intrapatient comparison of BP values measured before TTT and repeatedly during the test by means of the HeartGuide device and through beat-to-beat finger BP monitoring.

Patients aged >18 years, referred for TTT for suspected reflex syncope were eligible for inclusion in the study. Patients who, for any technical reason (eg, irregular pulse rate, wrist circumferences outside the allotted range[4]), were unable to obtain reproducible BP values with HeartGuide at rest were excluded. A screening log was kept.

TTT was performed according to the Italian protocol.[14] Positive TTT response was defined as reproduction of spontaneous (pre)syncopal symptoms in the presence of typical haemodynamic pattern. Continuous finger BP monitoring was started at baseline in the supine position and performed during the whole test period. BP and PR measurements by means of the HeartGuide device were performed at baseline, shortly after 60° head-up tilting (after 1 minute), at the time of impending syncope (ie, onset of [pre]syncope symptoms) or, alternatively, at the time of maximum hypotension (nadir BP) recorded at beat–to-beat finger BP monitoring (if [pre]syncope did not occur), and finally during the recovery period after returning to the supine position. Cuff BP with a validated oscillometric arm cuff device was also measured at baseline, before and after the HeartGuide measurement, and compared with the BP values obtained with HeartGuide and finger BP monitoring, respectively.

After excluding significant interarm BP differences (≥5 mm Hg SBP), before and during TTT, SBP was measured simultaneously in both arms, on one side with HeartGuide and on the other side through beat-to-beat finger BP monitoring. To synchronize as much as possible the BP values provided by the different measurement

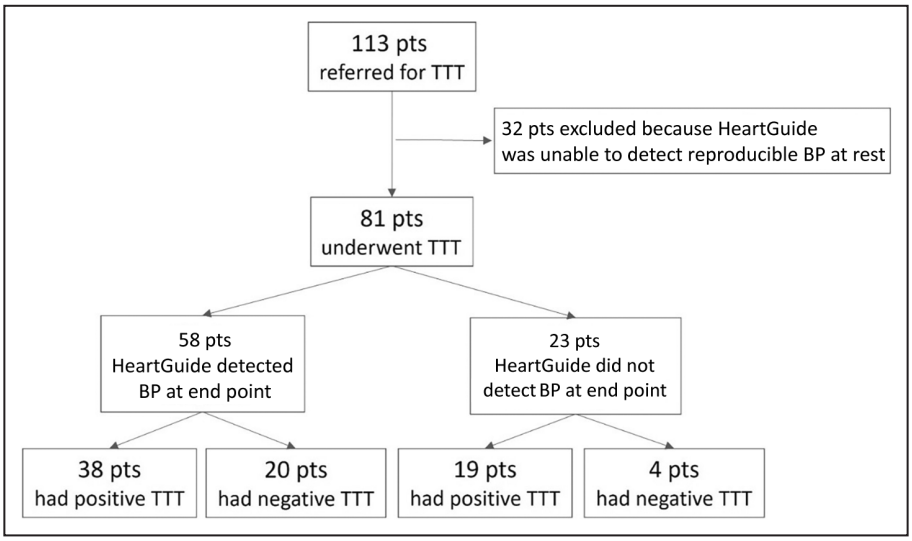

Figure 3. Screening log and patient flow.
BP indicates blood pressure; and TTT, tilt table test.

techniques, beat-to-beat finger SBP was defined as the mean of SBP values recorded during the 10 seconds immediately before the appearence of HeartGuide BP value on the watch screen, while arm cuff BP was defined as the mean between the 2 measures performed before and after the HeartGuide activation.

End Points

Primary end point was the comparison of SBP changes from baseline (pre-TTT) to (pre)syncope or to nadir BP levels, measured by HeartGuide and finger BP monitoring, respectively. Pre-syncope is defined as the prodromes of syncope that occur before unconsciousness.

Secondary end point was the demonstration of the ability of HeartGuide to detect BP at the time of (pre) syncopal symptoms or nadir BP values during TTT (with no error signal from the HeartGuide device).

Statistical Analysis and Sample Size

Continuous data are shown as means±SDs or medians (25th–75th percentile), as appropriate. Proportions were compared by means of the Fisher exact test. The agreement among BP techniques in measuring the SBP changes from baseline (supine) to maximum change during upright position was reported graphically by means of Bland–Altman plot and quantified by Lin's concordance correlation coefficient[15] (with relative 95% confidence interval). Linear relationship between SBP change measurements by the 2 devices was quantified by Pearson correlation coefficient.

Noninferiority of HeartGuide with respect to finger BP change was evaluated comparing the lower 95% CI limit of the mean difference between HeartGuide and finger BP drop with the prespecified noninferiority margin of −4 mm Hg used to estimate the sample size. The sample size was evaluated to test the noninferiority of HeartGuide versus finger BP measurement. A sample size of 49 patients with complete data would have achieved 80% power to detect noninferiority using a 1-sided t-test when the margin of noninferiority is −4.0 mm Hg, the true difference between the mean and the reference value is 0, the SD of SBP changes paired difference is 11 mm Hg and assuming a significant level alpha of 0.05.

RESULTS

A total of 113 patients referred for TTT were screened. Among these, 32 were excluded from the analysis, as the HeartGuide was unable to detect reproducible BP values at rest (Figure 3). Thus, 81 patients (mean age, 61±20 years; 46 women) were included in the study (Table 1). TTT was positive in 57 (70%) cases.

With reference to baseline cuff measurements from the overall sample, either HeartGuide and finger BP showed a good strength of agreement for BP measurement and a good strength of agreement for PR. The corresponding Bland–Altman plots are shown in Figures S1 through S3. SBP either with HeartGuide or with finger BP was higher than the reference arm cuff measurement, consistently with their more distal site of measurement.

HeartGuide was able to detect BP at the time of the primary end point in 58/81 (72%) patients (mean age, 64±19 years, 35 women), when their finger SBP was 102±18 mm Hg; 57 of these patients had complete data from finger BP monitoring and were compared with HeartGuide. In these patients, SBP decreased during TTT as compared with baseline by 28.5 mm Hg (27.8) according to HeartGuide and by 30.8 mm Hg

Table 1. Baseline (Supine) Values in 81 Patients Included in the Study

	Mean±SD		Mean±SD	CCC
SBP, mm Hg				
Arm cuff*	122±16	HeartGuide	130±20	0.64 (0.51–0.74)
Arm cuff*		Finger BP†	132±20	0.69 (0.58–0.77)
DBP, mm Hg				
Arm cuff*	75±10	HeartGuide	76±14	0.49 (0.32–0.63)
Arm cuff*		Finger BP†	73±11	0.55 (0.38–0.68)
PR, bpm				
Arm cuff*	65±11	HeartGuide	66±10	0.91 (0.86–0.94)
Arm cuff*		Finger BP†	66±11	0.93 (0.89–0.95)

BP indicates blood pressure; CCC, Lin's concordance correlation coefficient; DBP, diastolic blood pressure; PR, pulse rate; and SBP, systolic blood pressure.

*Average of 2 measurements.

†Average of 10 seconds finger BP recording.

(33.1) according to finger BP (Figure 4A). The SBP drop measured by HeartGuide and finger BP differed by 1.7 mm Hg (95% CI, –1.1 to 4.5). The between device agreement in assessing the SBP maximum fall was 0.78 (95% CI, 0.66–0.86), indicating a quite good strength of agreement but with high variability; the correlation index between measurements by the 2 devices was also significant (r=0.79, P=0.001) (Figure 5A). The mean difference between HeartGuide and finger BP at the nadir of SBP was –0.1 mm Hg (95% CI, –4.3 to 4.1).

In 28% of patients HeartGuide was unable to provide any BP measurement at the time of the primary end point and an "error" signal appeared on the screen. Among these patients, 13 had finger SBP measured at the time of the primary end point, corresponding to a mean SBP value of 79±19 mm Hg. Finger SBP could not be obtained in the remaining 10 cases because of technical problems. Failure rate was basically higher in patients with symptoms than in those without; however, this difference was not statistically significant (33% versus 17%, P=0.18).

Among patients for whom HeartGuide measurements were available at the time of the primary end point, 67% of them (38/57) had a positive TTT response and HeartGuide was active at the onset of vasovagal symptoms, yielding an average SBP of 97±16 mm Hg. Compared with baseline, SBP decreased during TTT by 35.2 mm Hg (29.3) according to HeartGuide and by 43.3 mm Hg (31.8) according to beat-to-beat finger BP monitoring (Figure 4B). The between device agreement in assessing the BP maximum fall was 0.83 (95% CI, 0.71–0.91), indicating a good strength of agreement but with high variability; the correlation index between the measurements of the 2 devices was also significant (r=0.87, P=0.001) (Figure 5B). The mean difference between HeartGuide and finger BP at the nadir of SBP was –2.6 mm Hg (95% CI, –7.4 to 2.2).

DISCUSSION

Our study provides for the first time a proof of concept that a novel wearable watch-type BP monitor, which allows BP measurements by patients, can provide reliable SBP measurements at the time of impending TTT-induced vasovagal syncope in 72% of tested individuals in whom a wrist BP measure was possible in baseline conditions. The absolute minimum SBP value and the maximum change of SBP from baseline provided by HeartGuide during TTT were fairly similar to those obtained from noninvasive beat-to-beat finger BP monitoring, although a high intrapatient variability between the SBP measurements provided by

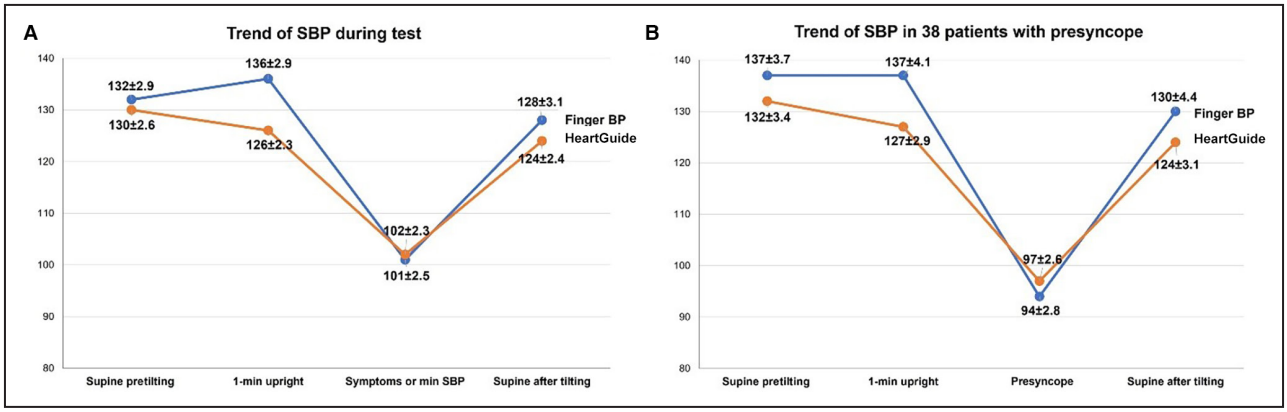

Figure 4. Trend in systolic blood pressure (SBP) in patients who had HeartGuide measurements available at the time of the primary end point.

A, Trend in SBP in 58 patients who had HeartGuide measurements available at the time of the primary end point. The mean finger SBP value at the nadir is derived from 57 patients (one patient missing). The mean SBP value at 1-minute upright tilt table test is related to 57 patients in the HeartGuide group and to 57 patients in the control group (1 patient missing in each group, because of artifacts). **B**, Trend in HeartGuide SBP and finger SBP in 38 patients who had (pre)syncope (positive response) during tilt table test. BP indicates blood pressure; and SBP, systolic blood pressure.

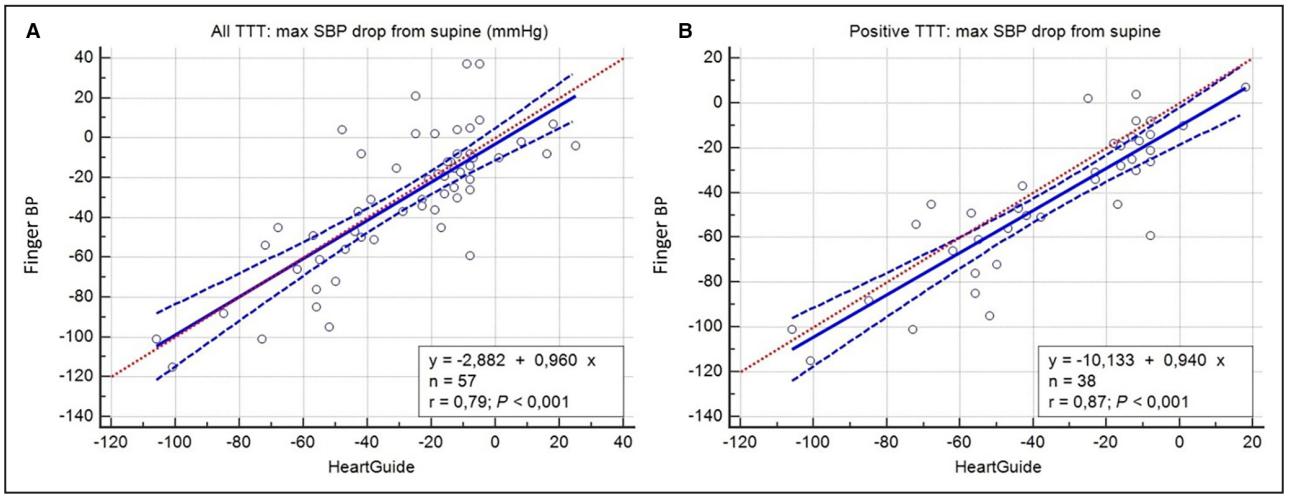

Figure 5. Scatter diagrams with regression line (continuous blue), 95% CI (dotted blue) and line of equity (thin red line). **A**, Data from 57 patients who had measurable HeartGuide values during tilt table test. Finger blood pressure was not available in 1 patient. **B**, Data from 38 patients who had (pre)syncope (positive response) during tilt table test. BP indicates blood pressure; SBP, systolic blood pressure; and TTT, tilt table test.

the 2 devices was observed. The current version of the device is limited in its clinical use by problems related to the long time it takes to measure BP and by the failure to provide reliable BP measurements in a significant proportion of individuals, either in baseline resting conditions and at the time of impending syncope. The actual performance of this device in case of impending syncope in daily life conditions has to be specifically tested in future field studies.

We found that in 28% of cases, HeartGuide was unable to provide SBP measurements at the time of impending syncope. There are several reasons already reported in the literature for that,[4] including body movements, irregular PR, and wrist circumference outside the allotted range. In particular, in the present study, the failure rate was higher when patients had symptoms of impending syncope and their SBP was lower. Indeed, in such circumstances, the patient fainted before the measurement could be accomplished. As a consequence, the wrist wearing the HeartGuide was displaced from the correct position at heart level, being responsible also for movement artifacts, leading to the appearance of an error code.

Since HeartGuide requires ≈60 seconds to measure BP, the main limitation to its use in patients with syncopal episodes, is the need of a sufficiently long (pre)syncopal period to allow for the BP measure to be taken. Therefore, this device may not be suitable in patients suffering from syncope with short or no prodromes. However, even with this limitation, the wearable HeartGuide device represents progress in syncope management compared with the currently adopted ABPM technology. Indeed, owing to the sporadic nature and brief duration of syncopal spells, conventional ABPM has significant limitations because of the short period of monitoring (usually 24–48 hours), the frequent unwillingness of patients to have the 24-hour BP recording repeated over time, and the intermittent nature of the BP measurements it provides (usually every 15–30 minutes). Thus, HeartGuide might thus represent a suitable complement to traditional ABPM, because it offers the possibility to obtain multiple readings over multiple days and can be activated by patients at the time of symptoms. Moreover, it is more comfortable, less intrusive, and less burdensome than an ABPM device.

The new clinical application of HeartGuide suggested by our paper, however, needs to be confirmed and validated by an ad hoc designed prospective study in a large number of patients facing spontaneous syncopal episodes in daily life.

As a limitation of our study, we must acknowledge the lack of a gold standard reference method of BP monitoring (eg, intra-arterial BP recording) against which to check the performance of the HeartGuide both before and during TTT. However, this approach would not have been feasible in the context of the routine clinical assessments performed in the syncope facilities participating in our study. Despite this limitation, our study was nevertheless able to show a high degree of concordance between the HeartGuide and the BP measurement technique most used during TTT.

We did not assess the reproducibility of HeartGuide measures during impending syncope. To determine the reproducibility of our findings would have required the repetition of TTT, which was not feasible in the patients investigated in our syncope center.

We assumed similar changes when comparing radial BP and finger BP behavior during impending syncope despite 2 measurements reflecting different

vascular phenomena. This was done based on previous evidence[11] that the difference between finger and radial SBP changes when facing hypotensive stimuli appears to be of small magnitude, thus unlikely to affect sample size calculation. In the same paper[11] we indeed showed the absence of significant finger radial SBP differences when SBP was significantly lowered through nitroglycerin bolus intravenous injection.

Future technological advances of the HeartGuide device will hopefully be able to reduce the percentage of failure in BP measurements (indicated by error messages), which are currently due in most cases to prolonged cuff insufflation time, body movements, irregular PR, and wrist circumferences outside the allotted range.

There is a continuously increasing number of wearable devices, most of which based on cuffless technologies, which are being proposed for clinical application. However, these approaches are still based on immature technologies that need further improvement and proper validation to be considered for reliable clinical use.[16] At present, the HeartGuide represents the only validated wearable device, providing oscillometric BP measurements in different daily life conditions. Our study adds to the available validation studies by testing the performance of this technology in a specific and clinically important field, ie, the prevention and treatment of syncopal events. Owing to its capability of transmitting the measured BP value to a smartphone and then to the web, the wearable HeartGuide monitor also allows the remote exchange of medical data between patients and health care providers,[17] shifting from traditional methods (ambulatory and home blood pressure monitoring) to wearable devices and advanced digital health information technology.[18]

CONCLUSIONS

In conclusion, our data provide evidence that the wearable watch-type HeartGuide BP monitor can measure BP in critical conditions such as (pre)syncope, providing a reliable documentation of BP change during TTT-induced syncope in most of the patients tested. This might represent a potentially important further step in improving diagnosis of hypotensive reflex syncope, especially if the current relatively high failure rate in estimating BP during such challenging conditions will be reduced by further progress in technology.

PERSPECTIVES

Given the high prevalence of syncopal episodes in daily life, there is a strong need for devices able to easily identify BP changes that might anticipate such events. To date, no commercially available device has been able to achieve this goal in clinical practice. The HeartGuide device might offer a solution to this need in patients with impending syncope. The results of our study do indeed suggest that this wearable watch-type BP monitor could be properly activated by the patients themselves during the (pre)syncopal phase of a spontaneous event, thus offering the possibility to document its possible hypotensive mechanism. However, since the current version of HeartGuide device available requires almost 60 seconds to measure BP, the main limitation to its use in patients with syncopal episodes is the need of a sufficiently long (pre)syncopal period to allow for the BP measure to be taken. Therefore, patients suffering from syncope with shorter or no prodromes may not benefit from this technology. Excluding these conditions, potential applications of the HeartGuide device might include all those conditions where a cause-effect relationship between symptoms and BP changes needs to be established, such as postprandial syncope, orthostatic intolerance, postural orthostatic tachycardia syndrome. All these possibilities will have to be tested through ad hoc field studies.

ARTICLE INFORMATION

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Disclosures

None.

Supplemental Material

Figures S1–S3

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Supplemental Material

Figure S1. Bland-Altman plots for the differences in SBP between HeartGuide® and Arm cuff measurements at baseline (supine) in 81 patients.

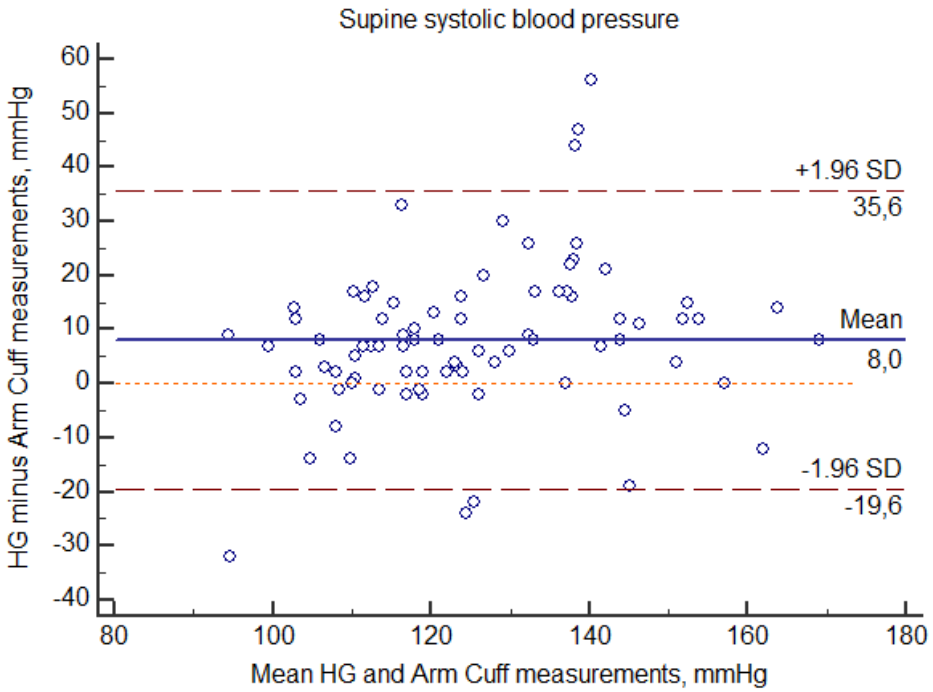

Figure S2. Bland-Altman plots for the differences in SBP between Finger BP measurements and Arm cuff measurements at baseline (supine) in 81 patients.

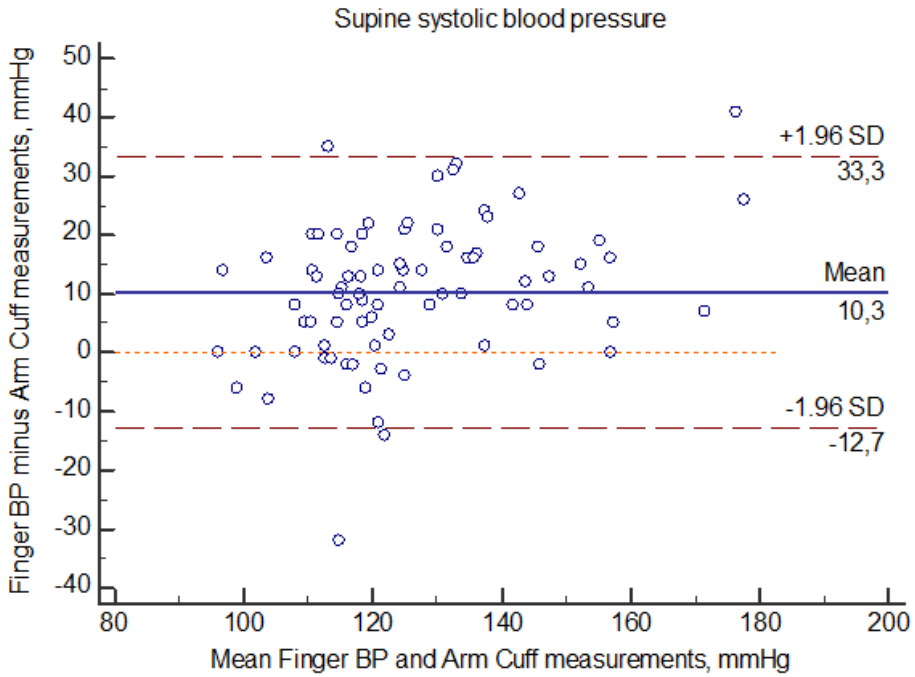

Figure S3. Bland-Altman plots for the differences in SBP between HeartGuide® and Finger BP measurements at baseline (supine) in 81 patients.