CLINICAL VALIDATION OF A NOVEL CUFFLESSS BLOOD PRESSURE MONITOR

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Objective: A pocket-size cuffless device for self-measurement of blood pressure (BP) has been developed (Freescan, Maisense). The device requires individualized initial calibration based on a reference arm BP measurement performed by using a validated arm BP monitor, and calculates systolic and diastolic BP through the radial pulse and the ECG using electrodes and one force-sensor. An interim analysis of a clinical validation study was performed.
Method: Three BP measurements were taken simultaneously by 2 observers (Y-tube connected mercury sphygmomanometers) and the last 2 were averaged for device calibration in each individual. According to the validation protocol, 5 same arm sequential BP measurements were taken by the observers (mercury sphygmomanometers) alternately with 4 test device measurements. Validation criteria of the American National Standards Institute / Association for the Advancement of Medical Instrumentation / International Organization for Standardization (ANSI/AAMI/ISO) 2013 and the European Society of Hypertension International Protocol (ESH-IP) 2010 protocol were applied.
Results: To date 64 subjects have been recruited and 43 with complete BP data were included in the analysis (mean age 48.4±10.9 [SD], men 72.1%, entry BP range 105-174/54-126 mmHg (systolic/diastolic). For ANSI/AAMI/ISO protocol criteria, the mean device-observers difference was for systolic BP 2.3±6.7 mmHg and diastolic 1.1±4.0 mmHg (criterion 1). The estimated SDs (inter-subject variability) were 5.93 and 3.68 respectively (criterion 2). For the ESH-IP protocol criteria, the within 5, 10 and 15 mmHg device-observer systolic BP differences were 67%, 94 and 99% respectively and diastolic 89%, 99% and 100% (criterion 1). Of 43 subjects 31 had 2 of their 3 systolic BP differences ≤5 mmHg and 41 for diastolic BP (criterion 2). In addition, 2 subjects had no systolic BP differences ≤5 mmHg and 1 for diastolic (criterion 2).
Conclusions: This interim analysis suggests that the cuffless BP monitor Freescan achieves a pass grade according to both the ANSI/AAMI/ISO 2013 and ESH-IP 2010 validation protocols. This novel new technology has promising potential for portable self-monitoring of BP by patients with hypertension.