CLINICAL VALIDATION OF A NOVEL CUFFLESS BLOOD PRESSURE MONITOR

N Boubouchairopoulou, A Kollias, S Lagou, P Anestis, GS Stergiou

Hypertension Center STRIDE-7, National and Kapodistrian University of Athens, Third Department of Medicine, Sotiria Hospital, Athens, Greece

OBJECTIVE

- A pocket-size cuffless device for self-measurement of blood pressure (BP) has been developed (Freescan, Maisense, Taiwan ROC).
- The device requires individualized initial calibration based on a standard arm BP measurement performed using a validated arm BP monitor and calculates systolic (SBP) and diastolic BP (DBP) through the radial pulse using three electrodes and one force-sensor.
- An interim analysis of a clinical validation study was performed.

METHODS

- Three BP measurements were taken simultaneously by 2 observers (Y-tube connected mercury sphygmomanometers) and the last 2 were averaged for test 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 protocols were applied.

RESULTS

- 64 subjects were recruited.
- 43 subjects with complete BP data were analysed.
- Men: 31 (72.1%)
- Age: mean 48.4±10.9 (±SD)
- Entry BP (mmHg)
  - SBP: 134.0±15.8 (105-174)
  - DBP: 88.6±12.5 (54-126)

| CRITERION 1 Mean±SD device-observers difference (allowable mean±SD: 5.0±8.0 mmHg) |
|-----------------------------------|-----------------|-----------------|-----------------|
| SBP                              | 2.3±6.7 mmHg    | Pass            |
| DBP                              | 1.1±4.0 mmHg    | Pass            |

| CRITERION 2 Inter-subject variability (SDs) (allowable SD: SBP 6.55; DBP 6.86) |
|-----------------------------------|-----------------|-----------------|
| SBP                              | 5.93 mmHg       | Pass            |
| DBP                              | 3.68 mmHg       | Pass            |

CONCLUSION

- These preliminary results suggest that the Freescan cuffless BP monitor seems to achieve a pass grade after calibration according to both the ANSI/AAMI/ISO 2013 and ESH-IP 2010 validation protocols.
- This novel technology has challenging potential for portable self-monitoring of BP by patients with hypertension.