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First-in-Human Study for Evaluating the Accuracy of Smart Ring Based Cuffless Blood Pressure Measurement

Jihoon Kim, Sung-A Chang, and Seung Woo Park

Division of Cardiology, Heart Vascular Stroke Institute, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea

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- **PRESENTED BY HOUDA GHANNEY MD**
- **EMERGENCY DEPARTMENT OF MONASTIR**

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1- INTRODUCTION

- HYPERTENSION (HTN) IS A GLOBAL HEALTH CHALLENGE AFFECTING BILLIONS AND IS A MAJOR RISK FACTOR FOR CARDIOVASCULAR DISEASES.
- ACCURATE BLOOD PRESSURE (BP) MEASUREMENT IS ESSENTIAL FOR EFFECTIVE MANAGEMENT
- YET TRADITIONAL CUFF-BASED METHODS HAVE LIMITATIONS, INCLUDING DISCOMFORT AND THE INABILITY TO MONITOR CONTINUOUS BP VARIABILITY.
- RECENTLY, A RING-TYPE BP DEVICE UTILIZING PHOTOPLETHYSMOGRAPHY (PPG) HAS BEEN DEVELOPED, OFFERING A MORE CONVENIENT AND ACCESSIBLE ALTERNATIVE.

2 -Objective

- THE PRIMARY GOAL OF THE STUDY WAS TO EVALUATE THE ACCURACY AND RELIABILITY OF THE RING-TYPE BP MONITORING DEVICE COMPARED TO THE STANDARD AUSCULTATORY METHOD.

3- METHODS AND MATERIALS

- **3.1 STUDY DESIGN**
- **STUDY TYPE**: PROSPECTIVE, SINGLE-CENTER, SINGLE-ARM, FIRST-IN-HUMAN CLINICAL TRIAL.
- **STUDY SETTING** : THIS STUDY WAS CONDUCTED AT SAMSUNG MEDICAL CENTER, LOCATED IN SEOUL, SOUTH KOREA. THE STUDY INVOLVED PARTICIPANTS PRIMARILY FROM KOREAN AND AFRICAN POPULATIONS.

3-2 PARTICIPANTS:

Enrolled 100 participants; 89 included in the final analysis.

INCLUSION CRITERIA

- AGE ≥ 19 YEARS.
- VOLUNTARY CONSENT TO PARTICIPATE AND COMPLY WITH THE STUDY PROTOCOL.

EXCLUSION CRITERIA

- KOROTKOFF SOUND (K5) NOT AUDIBLE DURING BP MEASUREMENT.
- UNSTABLE HEART CONDITIONS (E.G., RECENT MYOCARDIAL INFARCTION, ARRHYTHMIAS).
- ARM CIRCUMFERENCE > 42 CM.
- HYPERSENSITIVITY TO DEVICE MATERIALS (E.G., POLYCARBONATE).
- PHYSICAL LIMITATIONS PREVENTING RING APPLICATION.
- PREGNANCY.
- CONCURRENT OR RECENT (WITHIN 30 DAYS) PARTICIPATION IN ANOTHER CLINICAL TRIAL.

3- METHODS AND MATERIALS

3.3 -DEVICES AND MEASUREMENTS

TEST DEVICE:

- **CART-I PLUS**: SMART RING MEASURES BP USING PHOTOPLETHYSMOGRAPHY (PPG).
- RECORDS PPG SIGNALS, ECG, PULSE WAVE, HEART RATE, AND SPO_2.
- DATA TRANSMITTED WIRELESSLY VIA BLUETOOTH TO A CONNECTED SMARTPHONE (CART-APP).

REFERENCE DEVICE:

- STANDARD AUSCULTATORY SPHYGMOMANOMETER WITH TRAINED PERSONNEL PERFORMING MEASUREMENTS.

3- METHODS AND MATERIALS

3.4- STUDY PROTOCOL

PARTICIPANTS UNDERWENT **TWO SETS OF BP MEASUREMENTS** FOR CALIBRATION:

- **REFERENCE METHOD**: A STANDARD AUSCULTATORY SPHYGMOMANOMETER ON ONE ARM.
- **TEST DEVICE**: CART-I PLUS ON THE OPPOSITE ARM.

RESULTS WERE ENTERED INTO THE **CART-APP** LINKED TO THE DEVICE FOR CALIBRATION.

AFTER CALIBRATION, BP MEASUREMENTS WERE CONDUCTED FOR **UP TO THREE SETS PER ARM**:

- BOTH DEVICES MEASURED BP SIMULTANEOUSLY.
- AFTER COMPLETING MEASUREMENTS ON ONE ARM, THE CUFF AND TEST DEVICE WERE SWITCHED TO THE OTHER ARM.
- THE PROCESS WAS REPEATED, STARTING WITH CALIBRATION AND FOLLOWED BY ACCURACY EVALUATION

3- METHODS AND MATERIALS

3.5-ETHICS STATEMENT

- THE SAMSUNG MEDICAL CENTER INSTITUTIONAL REVIEW BOARD (SMC 2022-03-165-010) APPROVED THE STUDY.
- ALL PARTICIPANTS GAVE INFORMED CONSENT,
- THE STUDY COMPLIED WITH THE DECLARATION OF HELSINKI AND INSTITUTIONAL ETHICAL STANDARDS

4-Results

4.1-BASELINE CHARACTERISTICS

Table 1. Baseline characteristics of subjects in the full analysis set (N = 89)

Variables	Values
Age, yr	40.1 ± 12.0
Male	42 (47.2)
Height, cm	167.5 ± 8.6
Weight, kg	72.1 ± 15.1
BMI, kg/m²	25.6 ± 4.3
Heart rate, per minute	80.4 ± 10.6
SBP, mmHg	120.6 ± 20.9
≤ 100	17 (19.1)
≥ 100 and < 140	54 (60.7)
≥ 140 and < 160	12 (13.5)
≥ 160	6 (6.7)
DBP, mmHg	77.0 ± 15.1
≤ 60	13 (14.6)
≥ 60 and < 85	51 (57.3)
≥ 85 and < 100	19 (21.3)
≥ 100	6 (6.7)
Fitzpatrick scale	
1	0 (0)
2	22 (24.7)
3	38 (42.7)
4	17 (19.1)
5	6 (6.7)
6	6 (6.7)
Cardiovascular medications	
RAS blockades	10 (11.2)
Calcium channel blockers	5 (5.6)
Beta blockers	3 (3.4)

Values are presented as number (%) or mean ± standard deviation.
BMI = body mass index, SBP = systolic blood pressure, DBP = diastolic blood pressure, RAS = renin-angiotensin-aldosterone system.

- 89 participants were included in the FA set with a mean age of 40.1± 12years, 42 (47.2%) males
- The mean SBP and DBP were 120.6± 20.9mmHg and 77.0± 15.1 mmHg respectively.

4-Results

4.2-ACCURACY OF TEST DEVICE COMPARED TO AUSCULTATORY METHOD

Table 2. Sample- and subject-wise comparison of blood pressure measured by the ring-type device and the reference auscultatory method

Variables	Sample-wise		Subject-wise	
	SBP (n = 526)	DBP (n = 513)	Test device (n = 89)	Reference (n = 89)
Test device	115.8 ± 17.2	75.8 ± 15.2	115.9 ± 16.8	76.0 ± 15.1
Reference	115.6 ± 18.0	75.9 ± 13.9	115.7 ± 17.6	76.0 ± 13.7
Mean difference ± SD	0.16 ± 5.90	−0.07 ± 4.68	0.17 ± 3.67	0.02 ± 3.21

SBP = systolic blood pressure, DBP = diastolic blood pressure, SD = standard deviation.

Table 3. Absolute differences in blood pressure measurements between the ring-type device and reference auscultation method

Absolute difference, mmHg	Sample-wise		Subject-wise	
	SBP (n = 526)	DBP (n = 513)	SBP (n = 89)	DBP (n = 89)
≤ 5	353 (67.1)	393 (76.6)	76 (85.4)	77 (86.5)
≤ 8	450 (85.6)	475 (92.6)	86 (96.6)	87 (97.8)
≤ 10	485 (92.2)	497 (96.9)	88 (98.9)	89 (100)
≤ 15	517 (98.3)	511 (99.6)	89 (100)	89 (100)

Values are presented as number (%).
SBP = systolic blood pressure, DBP = diastolic blood pressure.

❖**In sample-wise comparison:** The mean difference in SBP and DBP between the test device and the reference was 0.16 ± 5.90 mmHg and −0.07 ± 4.6 mmHg, respectively.

❖**in subject-wise comparison:** The mean difference was 0.17 ± 3.67 mmHg and 0.02 ± 3.21 mmHg, respectively

❖When comparing the test device to the reference the absolute difference was 5 mmHg or less .

❖ The test device showed minimal bias in both SBP and DBP measurements compared to the reference, with mean differences very close to zero.

4-Results

4.3-Correlation of BP measurement

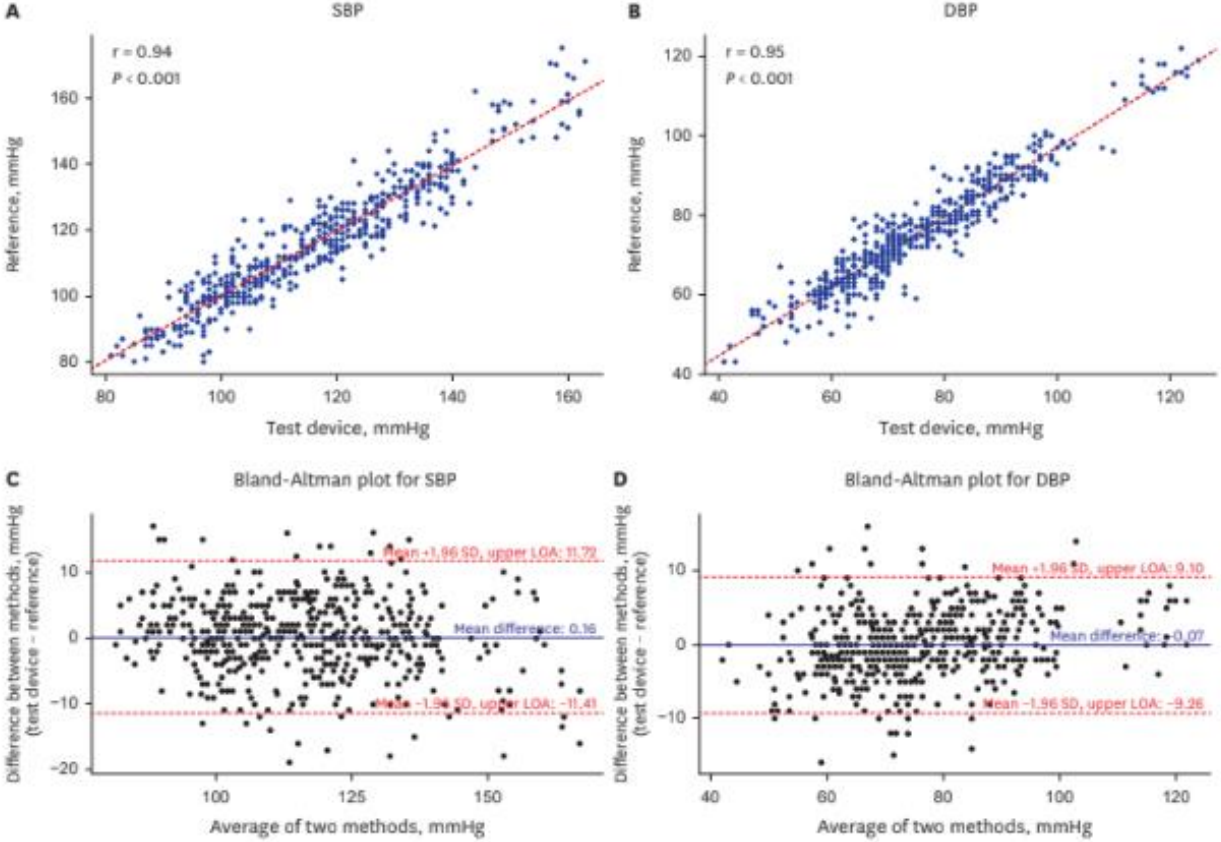

Fig. 3. Correlation of blood pressure measures between the ring-type device and auscultatory method. (**A**) Correlation for SBP between the test device and reference, (**B**) correlation for DBP between the test device and reference, (**C**) Bland-Altman plot for SBP between the methods, (**D**) Bland-Altman plot for DBP between the methods.
SBP = systolic blood pressure, DBP = diastolic blood pressure, LOA = limits of agreement, SD = standard deviation.

High Correlation indicates that the test device measurements are consistent with the reference measurements.

Correlation Coefficients:

SBP: r=0.94

DBP: r=0.95

4-Results

4.4-SAFETY ASSESSMENT

- IN THIS STUDY, THERE WERE NO ADVERSE REACTIONS REPORTED DURING OR AFTER THE USE OF THE TEST DEVICE.
- THIS INDICATES THAT THE DEVICE IS SAFE FOR USE
- SAFETY OUTCOMES FURTHER SUPPORT THE TEST DEVICE'S VIABILITY FOR BROADER CLINICAL OR CONSUMER USE, PROVIDED SIMILAR CONDITIONS ARE MAINTAINED

5- DISCUSSION

ADVANTAGES

- VALIDATION AGAINST A GOLD STANDARD
- IT MAINTAINS ACCURACY ACROSS DIVERSE SUBGROUPS, INCLUDING THOSE WITH UNDERLYING MEDICAL CONDITIONS
- CLINICAL UTILITY : 24-HOUR BP VARIABILITY MONITORING PROVIDES VALUABLE INSIGHTS FOR CARDIOVASCULAR HEALTH MANAGEMENT AND PERSONALIZED TREATMENT

LIMITATIONS

- SMALL SAMPLE SIZE LIMITS THE ROBUSTNESS OF THE FINDINGS. LARGER, MORE DIVERSE COHORTS ARE NEEDED FOR BROADER VALIDATION.
- POPULATION REPRESENTATION : THE STUDY WAS CONDUCTED ON KOREAN AND AFRICAN POPULATIONS, WITH A NEED FOR VALIDATION IN WESTERN POPULATIONS.
- MEASUREMENT SITE VARIABILITY : MEASUREMENTS WERE LIMITED TO THE PROXIMAL PHALANX AND THE UPPER ARM DIFFERENCES IN BP ACROSS MEASUREMENT SITES (E.G., ARM VS. FINGER) AND BETWEEN CUFF AND INTRA-ARTERIAL MEASUREMENTS WERE NOT ADDRESSED.

14

6- CONCLUSION

- THE STUDY SHOWED THAT THE RING-TYPE CUFFLESS BLOOD PRESSURE DEVICE IS ACCURATE, SAFE, AND RELIABLE, WITH RESULTS CLOSELY MATCHING STANDARD METHODS. IT OFFERS A CONVENIENT WAY TO MONITOR BLOOD PRESSURE WITHOUT ADVERSE REACTIONS, MAKING IT SUITABLE FOR DAILY USE.

THANK YOU