

Cross Sectional Study of comparative analysis of Blood Pressure by Mercury, Digital and LED Sphygmomanometer among Medical Students of a Tertiary Care Teaching Hospital.

Narendra R. Pathak¹, Utpalakshi Jain², Chirag B. Mistry³

¹Faculty- Department of Physiology, Medical College Baroda, The M. S. University of Baroda.

²Second MBBS Student, Medical College Baroda, The M. S. University of Baroda.

³Faculty- Department of Pharmacology, Medical College Baroda, The M. S. University of Baroda.

Corresponding Author: Dr. Chirag B. Mistry, Department of Pharmacology, Medical College Baroda, Vadodara, Gujarat, India.

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Abstract

Background: Globally there is a movement to discard mercury based equipment but various researchers have raised question on accuracy, validity, and consistency of non-mercury equipment. In India, there is lack of adequate data about young hypertensive patients and due to asymptomatic nature they are left undiagnosed.

Objectives: This study was carried out to compare records of Digital and LED sphygmomanometer as compared to Mercury sphygmomanometer for diagnosis of Normotensive, Pre-hypertensive and Hypertensive cases in medical students.

Methodology: A cross-sectional analytical study was conducted on medical students by measurement of blood pressure by Mercury, LED and Digital sphygmomanometer. Difference in Systolic, Diastolic, Pulse Pressure and Mean Arterial Pressure was statistically analyzed by one-way analysis of variance (ANOVA) and paired t test with comparison to global guideline.

Result: As per “gold standard” mercury sphygmomanometer, out of total 252 participants, overall,

10 (3.96%) participants were diagnosed **hypertensive**. On the other hand, total **18 (7.14%)** and **7(2.78%)** participant were diagnosed as hypertensive by **Digital** and **LED Sphygmomanometer** as per Indian Guideline. Overall difference in pulse pressure, mean arterial pressure and diastolic BP was highly significant as per ANOVA test ($P < 0.05$).

Conclusion: Considering variation in measurement of Blood Pressure, change in sphygmomanometer can be misleading while diagnosis of hypertension or monitoring of drug treatment response.

In absence of other comparable equipment, mercury sphygmomanometer is still considered “Gold Standard”. Moreover, large scale comparative research is needed for validity of non-mercury equipment.

Keywords: Blood Pressure, Digital, Guideline, LED, Mercury, Sphygmomanometer, Young Hypertensive.

Summary of the paper

What is already known....?

- Inappropriate recording of Blood Pressure can lead to false positive hypertensive or normotensive diagnosis and consequently irrational treatment.
- All definitions of hypertension issued by various international authorities are arbitrary as per their region that may not be applicable as per region.
- In India, there is lack of adequate data on young hypertensive patients.
- Only a fraction of the non-mercury Blood Pressure measurement devices available has been self-reliantly validated and among them very few devices met the recommendation of global guidelines.

What this study adds...?

- Observation of this study has detected significant range of difference in recording of Blood Pressure by Mercury, Digital and LED sphygmomanometer that may change grade of hypertension and treatment.
- Stage of hypertension varies based on changes of sphygmomanometer that is red flag sign for clinicians to consider for diagnosis and follow up for patient.
- Prospective monitoring of blood pressure by Non-Mercury sphygmomanometer can lead to false high or low blood pressure which can affect further treatment and outcome towards end organ damage prevention goal.
- Indian people need to be diagnosed normotensive or hypertensive based on Indian Guideline to prevent false positive cases of hypertension by following guidelines of other region or Global JNC –VIII or ACC/AHA Guidelines.
- Clinician can expect -22 to 35 mmHg range of difference while measuring blood pressure by Digital or LED Sphygmomanometer as compared to Mercury Sphygmomanometer.

Introduction

In routine clinical practice, accurate blood pressure measurement is essential before starting treatment for prevention of end organ damage. In general, evaluation and labelling of any person Hypertensive based on Western Guideline may lead to false hypertensive diagnosis and unwanted treatment to normotensive patient in India. Similarly, wrong display of very high or very low blood pressure in normotensive person can create panic and anxiety just due to temporary or permanent defect in equipment or power battery going low [1].

Clinically, increase in blood pressure (BP) is a critical risk factor for not only coronary heart disease, ischemic and hemorrhagic stroke, but also associated with numerous complications like heart failure, peripheral vascular disease, renal impairment, retinal hemorrhage and visual impairment. Moreover, literatures suggest that interventions targeted to decrease the blood pressure below the level of 140/90 mm of Hg reduce such risk [2].

It has been estimated that a rise in systolic BP by only 5 mmHg (millimeters of mercury) would result in approximately 25% increase in the probability of fatal stroke and fatal myocardial infarction [3]. On the other hand, prevalence of hypertension among adults aged 25 years or above has been estimated around 30 to 40% globally. In India, clear epidemiological data is lacking about young hypertensive patients among age group of 18 to 25 years [4].

In general, overestimation of actual blood pressure due to false reading or defective instrument can result in inappropriate treatment with anti-hypertension medications that can lead to adverse drug effects of unwanted drugs, with alteration in quality of life by psychological effects of misdiagnosis, and unnecessary cost for treatment not indicated. On the other hand, false

negative normotensive diagnosis of hypertensive may keep patients left untreated with early progress towards end organ damage. Therefore, accurate estimation of blood pressure up to the error level as low as 5 mm of Hg is of absolute importance [5 & 6].

All over the world, the auscultatory method using mercury sphygmomanometer is considered as the 'gold standard' for office blood pressure measurement. In contrary, widespread implementation of the ban in use of mercury sphygmomanometers continues to diminish the role of this technique globally especially in USA [7]. In general, various researchers have raised question on accuracy, validity, and consistency of report by electronic power or battery operated sphygmomanometer assisted blood pressure measurement which may be self-diagnosed, health care workers.

Globally, there are studies telling about overall increase in prevalence of hypertension in young population. On the other hand, Indian evidences are sparse about accuracy of digital and LED sphygmomanometer, and there is a need of more realistic and economical instruments because of large population size, cost concern and more than 70% population residing in rural area [8].

Since long time, mercury sphygmomanometers are considered as gold standard for correct estimation of BP in non-invasive setting [9]. Even though non-mercury sphygmomanometers like LED or digital ones have replaced the use of traditional Mercury instruments in many settings, their accuracy is still questionable. So this study was planned to identify prevalence of Pre hypertensive, Stage 1 hypertensive, and Stage 2 hypertensive state among medical students with age group of 18 to 25 years with identification of accuracy and comparative efficacy of LED & digital versus "gold standard" mercury sphygmomanometer.

Objectives

- To check the validity of Digital and LED sphygmomanometer for blood pressure measurements as compared to the manual blood pressure measurements by Mercury sphygmomanometer among medical students of a tertiary care teaching hospital.
- To get epidemiological data of Blood Pressure and Hypertension among medical students of a tertiary care teaching hospital by comparing stage as per Indian and Western Diagnostic Criteria.
- To identify possibility of false diagnosis of Normotensive, Pre-hypertensive and Hypertensive among normal or hypertensive participants by Digital and LED sphygmomanometer.

Material & Methods

A cross-sectional analytical study was conducted for diagnostic accuracy of standard instruments: Mercury, LED and Digital Sphygmomanometer.

Ethics Committee Permission: Permission of Institutional Ethics Committee for Human Research (EC Reg. No. ECR/85/Inst./GJ/2013/RR-16/16.04.2018) was obtained before starting this research. In this study, after taking informed written consent from the study participants (medical students studying in first, second and final year of MBBS), their blood pressure was measured through left arm by Mercury, LED and Digital sphygmomanometer.

Inclusion Criteria

- Medical Student voluntarily giving informed - written consent to participate in the study.
- Age between 16 to 25 years.

Exclusion Criteria

- Student not ready to participate in the study voluntarily.

- Known case of Hypertension on anti-hypertensive medication.

Sample Size Calculation

As per Indian study, hypertension prevalence in age group of 20 to 29 years was found to be 16.2% [1]. On the other hand, in another study conducted in rural Kerala during 1991, in the 20 plus age group for hypertension prevalence identification (criteria: $\geq 160/95$ mm of Hg), the prevalence was found to be 18% [11 & 12].

Considering prevalence of 16%, here calculated minimum sample size of participants was 166, as the sample size was calculated by formula $n = Z^2P(1-P)/d^2$ where P = expected prevalence (0.16), d is precision (0.1), z = level of confidence (95%) at its 5% confidence interval with total population of all medical students = 820. We had taken blood pressure of total 252 medical students.

Equipment for Blood Pressure Measurement

For the measurement of blood pressure in each individual three types of Standardized Non-Invasive Sphygmomanometers 1. Digital 2. LED and 3. Mercury sphygmomanometer were used. All the instruments were checked, standardized and calibrated by experts.

Measurement of Blood Pressure

Standard operating procedure for blood pressure measurement was followed. After getting informed written consent, the study participants were kept relaxed at-least for 10–15 minutes with ensuring that participants seated with legs uncrossed, back and arm supported at heart level before the measurements. For all the participants, cuff of appropriate sizes was used.

Blood pressure of each participant was measured once by each instrument from left arm. If blood pressure was found elevated, individual blood pressure measurements of that study participants was repeated on next day [7,13].

In this study, classification of stage of hypertension for participant was done according to definition of Indian Hypertension Guideline – II, “Hypertension in adults age 18 years and older is defined as systolic blood pressure (SBP) of 140 mm Hg or greater and/or diastolic blood pressure (DBP) of 90 mm Hg or greater or any level of blood pressure in patients taking antihypertensive medication”[10]. Stage wise classification of participant was compared with Joint National Committee VIII (JNC 8) and American College of Cardiology/American Heart Association Guideline for High Blood Pressure in Adults released in November 2017. Finally, prior to labeling a participant hypertensive, we had taken an average based on two or more readings obtained on more than two occasions to estimate the individual’s correct Blood Pressure [14].

Statistical Analysis

- To find out significance between mean differences of estimated blood pressures among all participants in three groups, ANOVA tests was performed at P value < 0.05 .
- To find out significance of difference between LED as compared to mercury sphygmomanometer and Digital as compared to mercury sphygmomanometer, paired t - test was performed at P value < 0.05 .

Results and Discussion

In this cross-sectional study, Blood pressure of total 252 medical students - who had voluntary given informed written consent were recorded as per standard method. There were total 114 girls and 138 boys. Furthermore, it was noted that total 53.96% students were having normal Body Mass Index, while 19.44% students were underweight, 13.09% students were overweight and 13.49% students were obese as shown in **table 1**.

Body Mass Index (kg/m ²)	Number of Students (N=252)	Participants Obesity Classification (Asian)
<18.5	49 (19.44%)	Underweight
18.5-22.9	136 (53.96%)	Normal Range
23.0-24.9	33 (13.09%)	Overweight (Pre-obese)
>25	34 (13.49%)	Obese

On repeat measurement, total three participants (3/252) were diagnosed as having Stage 2 Hypertension and they were referred to Physician for further diagnosis and treatment.

Comparison between Mercury Sphygmomanometer versus Non-Mercury (Digital/ LED)

Sphygmomanometer: As shown in table 2, comparison between Mercury Sphygmomanometer versus other (Digital/ LED) Sphygmomanometer was found statistically significant for Diastolic Blood Pressure by Paired t test at 95% Confidence Interval (P<0.0001).

Difference of Blood Pressure in same Participants by three different Sphygmomanometer	Difference between Mercury vs Digital Sphygmomanometer (N=252)	Difference between Mercury vs LED Sphygmomanometer (N=252)

Range of Systolic Blood Pressure Difference	-30 to 30 mmHg	-30 to 40 mmHg
Systolic Blood Pressure (mmHg)	Mean difference = 0.06746 P value = 0.9248 Not significant. [t = 0.09444; df = 251]	Mean difference = -0.2738 P value = 0.6694 Not significant. [t = 0.4275; df = 251]
Range of Diastolic Blood Pressure Difference	-22 to 35 mmHg	- 18 to 30 mmHg
Diastolic Blood Pressure (mmHg)	Mean difference = 4.044 P value < 0.0001 Highly Significant [t = 7.381; df = 251]	Mean difference = 2.671 P value < 0.0001 Highly Significant [t = 4.093; df = 251]

Systolic Blood Pressure: On comparative analysis of Systolic Blood Pressure in Mercury, Digital and LED Sphygmomanometer group by one-way analysis of variance (ANOVA) test, it was found that difference of systolic blood pressure among three groups was statistically not significant (P = 0.9527) as shown in table 2.

Diastolic Blood Pressure: On comparative analysis of Systolic Blood Pressure in Mercury, Digital and LED Sphygmomanometer group by one way ANOVA test, it was found that difference of diastolic blood pressure among three groups was extremely significant (P < 0.0001).

Pulse Pressure Difference: On comparison of among same participants' Pulse Pressure recorded by Mercury, Digital and LED Sphygmomanometer by one-way Analysis of Variance (ANOVA), variation among means of three group was statistically significant (P = 0.0002).

Mean Blood Pressure Difference : On analysis of Mean Blood Pressure recorded by Mercury, Digital and LED Sphygmomanometer recorded among same participants' by one-way Analysis of Variance (ANOVA), variation among means of three group was statistically very significant (P = 0.0045).

	159 / 90-99	(2.38%)	(5.95%)	(1.59%)
Stage 2	>160 / >100	2 (0.79%)	2 (0.79%)	2 (0.79%)

On analysis of stage of Hypertension as per JNC 8 Guideline, as shown in **figure 1 & table 3**, total number of participants showing normal, pre-hypertensive, stage 1 and stage 2 hypertension were almost similar but on looking at data there were difference in stage of hypertension measured by different instrument. In general, different participants were labelled normotensive, pre-hypertensive, or hypertensive by mercury, digital or LED sphygmomanometer by different permutation and combination. These findings suggest that there may be error of false hypertensive or normotensive diagnosis by non-mercury equipment.

Similar finding was observed after considering **Indian Hypertension Guideline-II** for staging of hypertension of participants as shown in **figure 2 and table 4**. As per previous studies, records of digital sphygmomanometer were questioned. Sensitivity and specificity of aneroid device and mercury instruments were noted higher as compared to digital device [13].

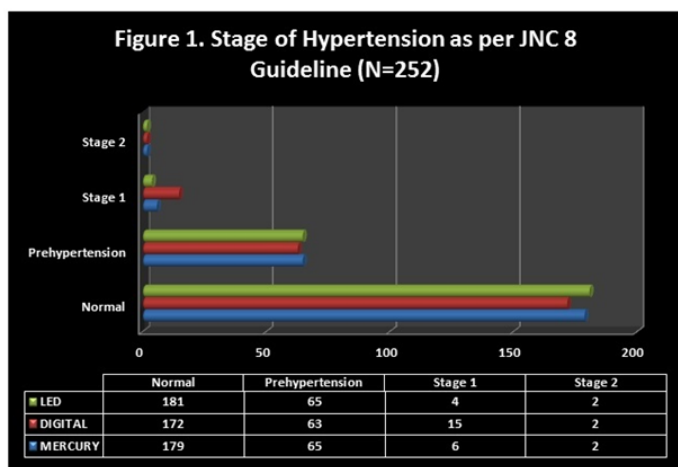


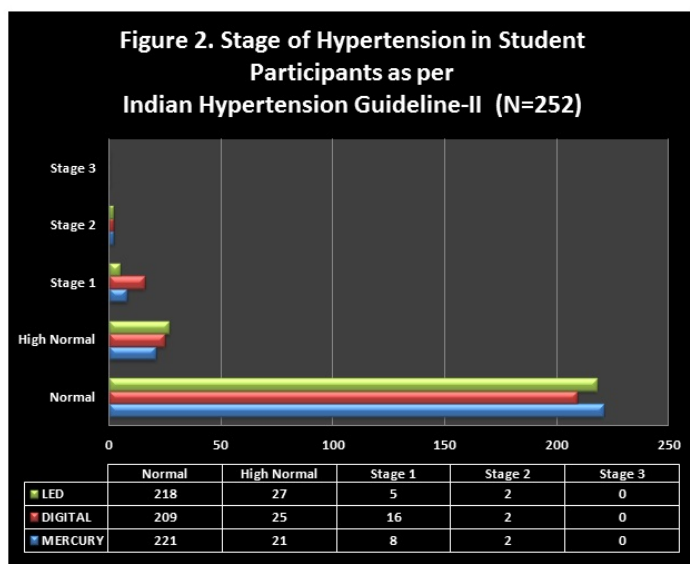
Table 3. Stage of Hypertension in Student Participants as per JNC 8 Guideline by Different Sphygmomanometer

Blood Pressure (mmHg)	Systolic / Diastolic	Mercury (N=252)	Digital (N=252)	LED (N=252)
Normal	<120 / <80	179 (71.03%)	172 (68.25%)	181 (71.83%)
Prehypertension	120-139 / 80-89	65 (25.79%)	63 (25.00%)	65 (25.79%)
Stage 1	140-	6	15	4

Table 4. Stage of Hypertension in Student Participants as per Indian Hypertension Guideline-II

Blood Pressure (mmHg)	Systolic / Diastolic	Mercury (Gold Standard) (N=252)	Digital (N=252)	LED (N=252)
Normal	<130 / <85	221 (87.7%)	209 (82.94%)	218 (86.51%)
High Normal	130-139 / 85-89	21 (8.33%)	25 (9.92%)	27 (10.71%)

Stage 1	140-159 / 90-99	8 (3.17%)	16 (6.35%)	5 (1.98%)
Stage 2	160-179 / 100-109	2 (0.79%)	2 (0.79%)	2 (0.79%)
Stage 3	>180 / >110	0 (0.00%)	0 (0.00%)	0 (0.00%)



During this analytical study, one technical error was identified that's alert sign related to power supply by dry battery (dry cell) weaning effect. After 3-4 days usage of Digital & LED Sphygmomanometer, we had noted gross error in blood pressure like too high or too low measurement as compared to Mercury Sphygmomanometer that got rectified by simply changing dry cells for electric power. It's critical that at time of emergency there is a need to identify right blood pressure. Similar technical variation with digital device was identified in one epidemiological survey for comparison of the accuracy and errors of blood pressure measured by 2 types of non-mercury sphygmomanometers [15].

In this study, as per readings of "Gold Standard" Mercury Sphygmomanometer, total **221 (87.7%)** student participants were **normotensive** as per staging done based

on **Indian Hypertension Guideline-II**. On the contrary, total **179 (71.03%)** participants were identified as **normotensive** as per staging of **JNC VIII** global guideline for hypertension. Such error in staging can lead to false labelling of normotensive person to pre-hypertensive or hypertensive just based on difference in global versus Indian people's cut off for staging of hypertension.

Globally, various guidelines for Hypertension recommend different diagnostic cut off and treatment target. Moreover, majority of the global guidelines had unanimity on the cutoff value (140/90 mmHg, recorded twice) to diagnose hypertension. The Joint National Committee 8 (JNC 8), Japanese Society of hypertension (JSH), Canadian Hypertension Education Program (CHEP), and American Society of Hypertension/International Society of Hypertension (ASH/ISH) guidelines provide a higher BP target for the elderly hypertensive populations, while the National Institute for Health and Care Excellence (NICE) and European Society of Hypertension (ESH) guidelines provided a lower BP target for the elderly patients. However, as per one meta-analysis having a systolic BP target of <130 mmHg can be more beneficial for all patients [16].

In this study, total **10 (3.96%)** participants were diagnosed **hypertensive** as per "Gold Standard" **Mercury Sphygmomanometer** as per **Indian Hypertension Guideline-II**. Among them total 2 (two) participants were reported as having stage 2 hypertension and 8 (eight) were reported as having stage 1 hypertension and they were referred to physician for further evaluation and treatment to rule out secondary hypertension.

As per previous epidemiological studies conducted in India, in the last six decades, an escalating prevalence of hypertension had been noted both in the urban and rural

areas [17]. As per one observational study, the incidence of hypertension in India is between 30% and 40% for adult population [18]. In another study, the totality of evidence reflects the overall incidence of hypertension to be close to 30% in adult population [19]. In this study, total 18 (7.14%) and 7(2.78%) participant were diagnosed as hypertensive as per Digital and LED Sphygmomanometer respectively as per Indian Hypertension Guideline-II. But if we follow revised 2017 guideline of American College of Cardiology/ American Heart Association (ACC/AHA) for classification of Blood Pressure by considering Systolic >130 or Diastolic > 80 mmHg then number of hypertensive will be more and it will increase the number diagnosed with HTN. In one international study, it was identified that a participant may be labelled pre-hypertensive or hypertensive as per ACC/AHA, but they were found asymptomatic, so classification of western guidelines is not applicable as per genetic profile of Asian Population [20]. Finally, it was found that if western or global guideline for diagnosis of Hypertension is applied to South East Asian Region, it will dramatically increase in just number of hypertensive cases who may be falsely labelled as hypertensive. Moreover, similar finding was detected in one research to find Impact of 2017 ACC/AHA guidelines on prevalence of hypertension and eligibility for antihypertensive treatment in United States and China by cross sectional study. Globally, it was concluded that adoption of the new ACC/AHA guidelines of 2017 would be associated with a marked increase in the prevalence of hypertension in the US and China. More than 7 million more US adults would require treatment, but adoption in China would increase the number of patients eligible for treatment by more than 55 million [21].

As per overall summary of this study, differences in blood pressure reading was highly significant ($P < 0.0001$) for diastolic blood pressure on analysis by paired t - test, which suggest that **we can expect -22 to 35 mmHg range of difference while measuring diastolic blood pressure by Digital or LED** as compared to Mercury Sphygmomanometer.

Moreover, difference of Pulse Pressure, Mean Blood Pressure and Diastolic Blood Pressure was identified as highly significant by one way ANOVA test ($P < 0.001$) that is suggestive of possible risk of error on assessment of blood pressure by Digital or LED sphygmomanometer.

Globally, various researchers have raised question on validity, and accuracy of various electronic equipment while measuring blood pressure. Treating normotensive person as hypertensive arises undue anxiety and adverse drug reaction.

On the other hand, if hypertensive patient is labelled normotensive, she/he will be deprived from standard treatment and eventually it will lead to early end organ damage. Therefore, in spite of global movement to replace mercury sphygmomanometer, in absence of suitable alternative it will be the only option to measure accurate blood pressure after regular standardization of equipment. On the contrary to this movement, overall comparison of the accuracy and errors of blood pressure measured by 2 types of non-mercury sphygmomanometers in an epidemiological survey identified that record of different digital device was significantly different based on different manufacturer also [15].

As per findings of one meta-analysis, ability to detect correct biological parameter by digital or power based equipment remained uncertain as current protocols for validating sphygmomanometer devices give no guarantee of accuracy in clinical practice. Due to paucity of

evidence available, it was concluded that performance of such equipment in clinical practice will be even worse than under protocol testing [22].

Globally, only a fraction of the BP measurement devices available those are independently validated. Among them only five of the hundreds of devices available were found to be validated using the two standard protocols, of which only two met the criteria for recommendation of European Society of Hypertension [23].

Overall, difference of recording of Blood Pressure can lead to false positive hypertension diagnosis and irrational treatment, or false negative i.e. normotensive diagnosis which may be left untreated till end organ damage. Considering significant range of difference in recording of comparative Mercury, Digital and LED sphygmomanometer, there is a need of study on larger population to confirm validity of newer Blood Pressure measurement equipment.

Monitoring of response to anti-hypertensive drug by measuring with different types of Sphygmomanometer can be misleading. If different equipment is showing different reading then prospective monitoring of blood pressure by different sphygmomanometer can lead to false high or low blood pressure which can affect further treatment and outcome towards end organ damage prevention goal.

Finally, properly designed meta-analysis of similar study on large group of people can help to decide clinicians and researchers to decide whether shifting to modern sphygmomanometer can be more fruitful to patients or not.

Conclusions: Indian people need to be diagnosed normotensive or hypertensive based on Indian Guideline to prevent false diagnosis that can increase in cases of

hypertension by following guidelines of other region. Moreover, stage of hypertension varies based on changes of equipment type that is an alert signal for clinicians to be considered for diagnosis and follow up for patient.

After all Mercury sphygmomanometer is still considered “Gold Standard”, while lack of proper protocol at manufacturing level for Digital & LED sphygmomanometer, validity of non-mercury equipment still remains questionable that may be solved by meta-analysis of large scale comparative research studies.

Abbreviations

BP	Blood Pressure
HTN	Hypertension
mmHg	millimeters of mercury
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
JNC 8	Joint National Committee VIII
ACC/AHA	American College of Cardiology/ American Heart Association
JSH	Japanese Society of hypertension
CHEP	Canadian Hypertension Education Program
ASH/ISH	American Society of Hypertension/International Society of Hypertension
NICE	National Institute for Health and Care Excellence
ESH	European Society of Hypertension
ANOVA	Analysis of variance
Df	Degree of freedom
BMI	Body Mass Index

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