ORIGINAL ARTICLE

INACCURACY OF NONINVASIVE BLOOD PRESSURE MONITOR DEVICES, DO WE HAVE AN ALTERNATIVE?

Aisha Khan Jadoon[1], Fasiha Sohail[1], Arzu Jadoon[1], Sumera Nawaz Qabulio[1]
[1]Department of Medicine, Ziauddin Medical University, Karachi

ABSTRACT

Background: Blood pressure (BP) is obligatorily measured each time a patient visits Emergency room (ER) or is admitted in ICU/CCU. Accuracy of blood pressure measurement in clinical settings is the key to appropriate diagnosis of hypertension in a patient. It remains elusive, however, whether oscillatory automated BP measurement yields lower values than auscultatory manual methods. It has been witnessed that both the devices give different readings of the same patient at one point in time. This study helped to determine the accurate or more reliable of the two devices.

Methods: A double-blind randomized clinical cross over trial was carried out at Ziauddin University Hospital from February 2018 to June 2018. Sample of 100 was taken through random sampling. The device used in this study was the Dinamap Procare 100. SPSS 20 was used for data entry and analysis.

Results: The mean of difference in systolic manual Blood Pressure (sMBP) and systolic automated Blood Pressure (sABP) was estimated to be 15.62 with a standard deviation of ± 8.57, while the mean of difference in diastolic MBP and ABP was 12.6 with a standard deviation of ± 24.7. Both systolic and diastolic readings were far low by automated devices in comparison to Manual devices.

Conclusion: The results of this study suggested that automated method in measurement of BP frequently shows lower BP. This can influence diagnosis of hypertension and management of certain medical conditions.

KEYWORDS: Blood Pressure Calibration; Hypertension; Intensive care Unit; Emergency room.

Corresponding Author
Dr. Aisha Khan Jadoon
House number 120, street 29,
Khayaban-e-Rahat, phase 6,
DHA, Karachi, Pakistan
Email: aishajadoon@hotmail.com

INTRODUCTION

Hypertension is known as a silent killer and affects more than 1 billion people worldwide.[1]

It has a negative impact on various body organs. It speeds up the process of arterial stiffness and atherosclerosis resulting in cerebrovascular disease, myocardial infarction, congestive heart failure, stroke, ischemic cardiac and end-stage renal disease as well as dementia.[2]

Antihypertensive drugs seem to be one of the most frequently prescribed medications worldwide.

Hypertension can rupture tiny and delicate blood vessels of the kidneys and eyes. In order to avoid these complications, caused independently by hypertension, it is mandatory to monitor blood pressure continuously so that early diagnosis is made and prompt treatment is initiated.

The high prevalence of hypertension in both developed and developing countries makes it a signifi-

cant factor for mortality and morbidity. Almost 18.9% Pakistanis aged >=15 years were hypertensive according to the National Health Survey of Pakistan (NHSP). [3]

An accurate measurement of BP is a defining point in providing appropriate treatment for chest pain and altered mental status. If BP is over estimated it can compel the patient to take unnecessary treatment and dietary restrictions. This puts additional burden of medical costs and exposure to adverse effects of antihypertensive drugs. While underestimation can put the patient at a risk of HTN related diseases. Cardiovascular diseases cost the lives of 790,000 people per year in the United States and are known to be the leading cause of mortality among both men and women. [4] Hence, an accurate reading is important so that diagnosis is done on time.

There is a variety of methods for BP calibration: Invasive (direct) or Non- invasive (indirect) methods. Invasive methods include arterial line transducer pressure sensing, used in intensive care units or in surgical settings due to their high degree of accuracy and continuous monitoring. This has certain disadvantages, one that it is very expensive and needs an expert supervision and second that it can increase the risk of infection and patient discomfort,[5] thus it cannot be used in clinics or at homes. There are two non invasive methods; Auscultatory and Oscillometric methods. Throughout the world the commonly used modalities at a hospital or clinic settings are manual mercury sphygmomanometer, aneroid meter and the automated oscillometric device. These are relatively risk free.

The manual mercury sphygmomanometer is considered to be the gold standard.[6] Counter pressure is read in an artery using a mercury manometer, a stethoscope, an inflating cuff and by hearing to the heart sounds, called Korotkoff's sounds, but it requires a trained person and considerable time to acquire the desired readings. In the past ten to fifteen years automated oscillometric BP devices have replaced manual auscultatory mercury sphygmomanometers. Automated BP monitors are easy to use and are less time consuming, although studies have doubted their accuracy.[7] Whether auscultatory BP devices should be replaced with the automated oscillometric devices or not is still under debate.

Accurate manual blood pressure measurements are at the stake of certain factors such as the site and size of the cuff, stethoscope type, patient's age, pregnancy, exercise, arrhythmias, white coat response and above all following the proper protocol.[8] Readings can also vary depending on the attention diversion of the BP taker and background noise or silence.[4] All these factors have a potential for inaccurate BP measurements and hence misdiagnosis.

Emotions, tobacco, alcohol, temperature, pain, bladder distension, respiration and exercise all influence BP readings in general.[9] But as compared to manual BP devices, Automated Oscillometric devices are seen to be less affected by these factors particularly the white coat response [10]

This study was conducted at a tertiary care hospital in Karachi, Pakistan, to estimate the difference between ABP measurements as compared to the manual BP measurements.

METHODS

The study was conducted at Ziauddin University Hospital, Keamari campus that is a 100 bedded tertiary care facility located in Keamari. It caters to middle and lower socio-economic strata. The hospital is equipped with ABP monitors, Dinamap Procare 100 and manual mercury sphygmomanometers. ER is the busiest department in any hospital and similar is the case at Ziauddin Keamari Campus. Almost 500 patients visit the ER on a daily basis that indicates the number of BP calibrations in a day at this department. Patients that are admitted in the ICU/CCU need extra care and monitoring due to their critical condition. There is a single large ICU cum CCU that is a 12 bedded facility, accommodating Medical, Surgical and Obstetrical/gynaecological patients. A Littman classic II stethoscope was used each time for BP calibration.

It was a double-blind randomized clinical cross over trial. BP was checked by putting all patients in a supine position. Each patient was assigned two staff nurses who used both automated oscillometric blood pressure device and a manual mercury sphygmomanometer for checking BP of the same patient. The device and nurses were randomly determined. Both the nurses remained blind of the readings they recorded.

100 patients were included in the study that fulfilled the inclusion criteria; this was done by random sampling technique. The study was done from February 2018 to June 2018.

Adult age group that is above 14 years was included. BMI was calculated as weight in kilograms divided by height in meters squared.

As per National Institute of Health (NIH) BMI categories are:
Underweight = <18.5
Normal weight = 18.5–24.9
Overweight = 25–29.9
Obesity = BMI of 30 or greater

ER and ICU both are the most crucial places in a hospital where swift and accurate working techniques have to be adopted so that prompt diagnosis can be grafted. These tactics become the basis of low mortality affiliated to a hospital.

Patients with the complaints of altered mental status and chest pain were excluded because it was not appropriate to subject them to double BP calibrations due to either critical condition or non-cooperation. In addition to this patients who had history of smoking were not included in the study because they have a good chance of variability in the readings.

Data was analyzed by version 20 of SPSS. Test of significance was T test and p value <0.05 was taken as significant.

The Performa that was filled by staff nurses comprised of questions like, name of the device, presenting complaint, history of smoking or any co morbid. Randomization was done by sealing patients envelop with filled performas. The crossover was performed by taking manual then automated or automated and then manual measurements.

RESULTS

Mean age of participants was 44.17 with a standard deviation of ±13.6. There were 53 male subjects and 47 female. 31 samples were obtained from ER where as 69 from the ICU. Thorough history and examination was carried out. 22 patients out of the total 100 had diagnosed hypertension. Majority of the patients (41%) had cardiac issues followed by other diseases (36%), surgical (14%) and lastly obstetric/gynaecological (9%). This is further elaborated in Figure 1.

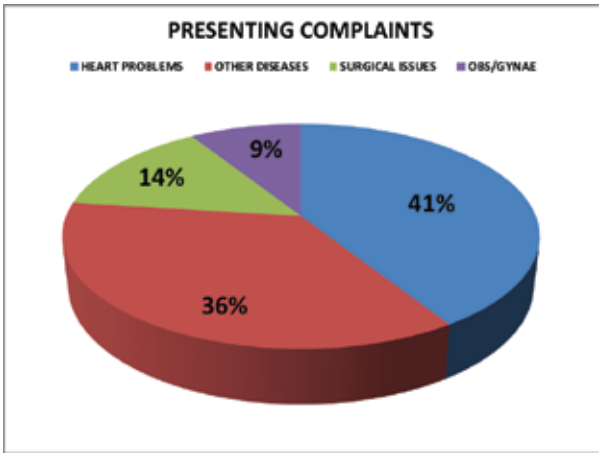

Figure 1: Presenting complaints in ER and ICU/CCU

Sixty-two patients had normal GCS (14), 11 were found to have a minor drop in GCS level (≤13), 20 had a moderate GCS (9-12) where as 7 had severely low GCS levels (≤8) as shown in Figure 2.

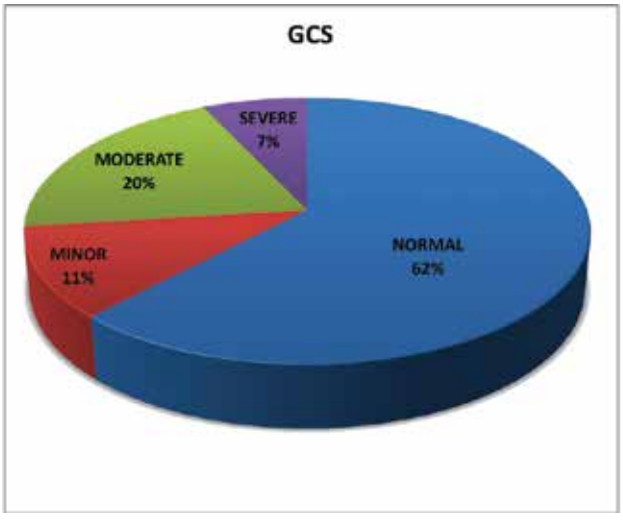

Figure 2: GCS level of patients received in the emergency room and ICU/CCU

68% had normal BMI, 20% were overweight, 8% were obese however only a small percentage were underweight (4%) as illustrated in Figure 3.

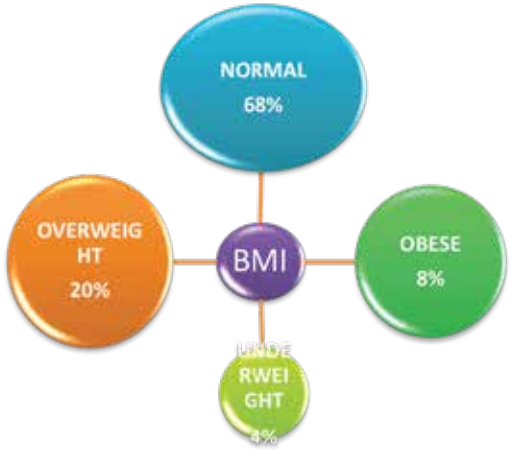

Figure 3: BMI of the participants

Fig 1 and Fig 2 show graphically the combined sensitivity of all Gm +ve organisms and all Gm –ve organisms against applied antimicrobials. Higher sensitivity of gram +ve organisms against Linezolid (100%), Vancomycin (92%) and Teicoplannin (91%) can be observed. While gram-ve organisms has shown a superior sensitivity against Amikacin (82%), Meropenem (73%) and Cefaerazone/Sulbactum (67%).

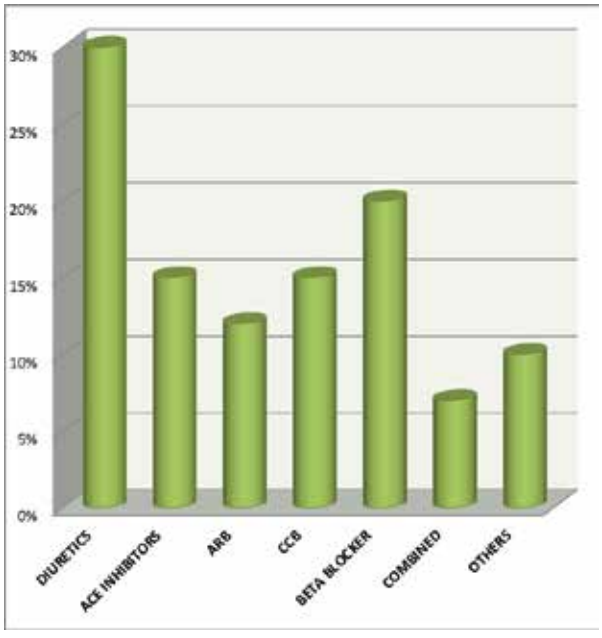

Figure 4: Antihypertensives given to patients with abnormal blood pressure

The mean of difference in systolic MBP and ABP was estimated to be 15.62 with a standard deviation of ± 8.57, while the mean of difference in diastolic MBP and ABP was 12.6 with a standard deviation of ± 24.7. The values for individual means, standard error and significance can be seen in Table 1a and 1b. The range of difference between systolic taken by the two methods was 90 to 100, while that of diastolic blood pressure was 70 to 80. The 95% CI for systolic blood pressure lies in the range of 13.9 to 17.3. The 95% CI for diastolic blood pressure lies in between 7.68 to 17.5.

Table 1a: MEANS, SD, SE obtained by Dinamap Procare 100 and manual mercury

Blood Pressure Reading	Mean	Standard deviation (SD)	Standard error (SE)
Systolic MBP	138.12	26.96	2.69
Systolic ABP	122.5	27.57	2.75
Diastolic MBP	86	16.63	1.66
Diastolic ABP	73.4	18.13	1.81

SD: standard deviation, SE: standard error

Table 1b: MEANS, SD, SE and significance level obtained by Dinamap Procare 100 and manual mercury

Blood Pressure Reading	Mean	Standard deviation (SD)	Standard error (SE)	pValue
Difference between Systolic ABP and MBP	15.62	8.57	0.85	0.000
Difference between Diastolic ABP and MBP	12.6	24.7	2.47	0.000

SD: standard deviation, SE: standard error

DISCUSSION

Emergency Department and ICU/CCU are the most vital departments in a hospital. Diagnosis made in the ED design the rest of management for the patient and the treatment carried out in critical care units help save lives. These two departments all over the world receive a diverse array of ill patients with a variety of deteriorating clinical conditions.

Accurate blood pressure measurements lay the basis for management of a patient. Care must be taken in using automated or manual BP readings in important clinical scenarios. Heinemann et al.[11] compared the mean values of the two methods and mentioned that automated device underestimated SBP and DBP.

Skirton et al suggested that replacing automated oscillometric machines with auscultatory devices could cause negative affects in many ways; for instance cases of trauma or an unstable patient, hypertensive patients or patients with arrhythmias should be monitored with manual meters as opposed to automated.[12]

Suokhrie et al.[13] revealed that automated readings averaged 3.9 points higher that is a significant difference between manual and automatic SBP readings.

Automated Oscillometric devices are gaining fame and are gradually replacing auscultatory (mercury or aneroid) devices [14] because they are less time consuming, do not require a skilled or trained person and overcome white collar hypertension bias. They are perfect for BP recording at home. Myers et al.[15] demonstrated that ABP measurement significantly reduces the white coat hypertension in comparison with its counterparts.

The British Hypertension Society (BHS) and the US Association for the Advancement of Medical Instrumentation (AAMI) have compiled a list of devices that are approved for home as well as clinical use.

They have devised protocols for validating BP monitors sadly; these two protocols are not followed strictly. Different types of oscillometric devices are available in the market without validation. [16]

Oscillometric devices can be influenced by Diabetes, pregnancy, arrhythmias and age of patients. Multiple readings should be taken at regular intervals to ensure accuracy. Many studies have suggested that Oscillometric devices overstate blood pressure and at times understate blood pressure this can influence management. [17] The inaccuracy of automated over manual monitoring has been reported with regards to the failure of automated monitoring to reliably detect orthostatic hypotension in patients at the ER in triage. [18]

On the other hand the manual BP measurement, especially with mercury sphygmomanometer has been used for more than 100 years and considered as a gold standard for BP calibration. They require a skilled staff, a good stethoscope and also dependent upon environmental conditions. BP is detected higher when taken by physicians instead of staff nurses, in treatment settings in comparison to non-treatment settings and at office instead of home.[15]

Mercury can act as a potent neurotoxin and cause serious harm even at very low levels. The WHO considers Mercury sphygmomanometers a major occupational hazard, as it may result in dangerous exposures to patients and health care staff and is working towards the removal of Mercury from hospitals and other health care settings.[19] Many countries have already eradicated mercury sphygmomanometers and have adopted other alternative devices[20]. Mercury sphygmomanometer remains available as a reference standard until an alternative device will be recognized as much. [21]

While some studies suggest that auscultatory measurements are comparatively more accurate others clearly favour oscillometric devices. [22, 23] Accurate BP measurements can be attained if patients are asked to rest for a few minutes before BP calibration along with selection of a validated automated device and multiple recordings are taken. In routine clinics ABP may be 15-18 mmHg lower than the manual method.[14] An automated device is only recommended if AAMI criteria are fulfilled; that is both systolic and diastolic measurements should not have a mean difference > 5 mmHg or a standard deviation > 8 mmHg. The British Hypertensive Society denotes a grade of A or B if a device is approved.[24, 25]

In the current study, out of the sample of 100 patients, 22 had diagnosed hypertension. Diuretics were widely prescribed antihypertensive drugs followed by beta blockers, ACE inhibitors, ARBs, Calcium channel blockers. Combined therapy was also used in such patients with blood pressure anomalies. Mean age of participants was 44.17; majority was males. Most of the samples were obtained from the ICU. Thorough history and examination was carried out. GCS levels were assessed and BMI was calculated for each patient. 62% patients had normal GCS however only 7% were assessed to have severely low GCS levels (≤8). In addition to this, majority had a healthy BMI whereas almost 30% had abnormal levels.

The mean of difference of systolic blood pressure was 15.62 with a standard deviation of ± 8.57 (p-value 0.000), while the mean of difference of diastolic blood pressure was 12.6 with a standard deviation of ± 24.7 (p-value 0.000). Both systolic and diastolic readings were understated by automated devices majority of the times in comparison to Manual devices.

The device used in this study was the Dinamap Procare 100, which has been validated and approved by the British Hypertension Society26. Figure 5 shows the photographs of automated and manual devices used in the ICU and ER. BHS has labeled 28 devices to be reliable.

Figure 5: Automated and manual devices used in the ICU and ER

The average price is PKR 201,973/. The cost is significantly high for developing countries like Pakistan. Cheaper and accurate alternatives of mercury sphygmomanometers are a requirement of a poverty stricken country, in order to diagnose hypertension.

CONCLUSION

Manual blood pressure measuring devices that is aneroid and mercury sphygmomanometer are the

most accurate and reliable but depend on trained staff and environment. Automated blood pressure monitors are safe, faster and easier to use but are expensive and also underestimate the readings. More efforts need to be put in for the development of accurate ABP devices so that mercury sphygmomanometers can be smoothly banned.

REFERENCES

1. Cappuccio FP, Miller MA. Cardiovascular disease and hypertension in sub-Saharan Africa: burden, risk and interventions, Intern Emerg Med 2016; 11: 299–305.
2. A global brief on hypertension: Silent killer, global public health crisis. World Health Organization; 2016.
3. NHSP. Pakistan medical Research Council, Pakistan National Health Survey.1990-1994. Pakistan Medical Research Council publication ISBN 969-499-000. Islamabad, Pakistan 1990–1994.
4. Jafri MO, Baig S, Siraj S. Role of vitamins in cardiovascular system –a review. Pak J Med Dent 2018; 7(1): 50-4.
5. Johnson C, Kerr J. Automatic blood pressure monitors. A clinical evaluation of five models in adults. Anaesthesia 1985; 40(5):471–8.
6. Ogedegbe G, Pickering T. Principles and techniques of blood pressure measurement. Cardiol Clin 2010; 28(4): 571–86.
7. Fuentes R, Banuelos M. Digital blood pressure monitor. J Appl Res Technol 2004; 2(03):224-9
8. O'Brien E, Asmar R, Beilin L, Imai Y, Mallion J-M, Mancia G, et al. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. J Hypertens 2003; 21:821–48.
9. Parati G, Ulian L, Santucciu C, Omboni S, Mancia G. Blood pressure variability, cardiovascular risk and antihypertensive treatment. J Hypertens Suppl 1995;13(4): S27–S34.
10. Myers MG, Valdivieso M, Kiss A. Use of automated office blood pressure measurement to reduce the white coat response. J Hypertens 2009; 27:280–6.
11. Heinemann M, Sellick K, Rickard C, Reynolds P, McGrail M. Automated versus manual blood pressure measurement: A randomized crossover trial. Int J Nurs Pract 2008; 14(4): 296-302.
12. Skirton H, Chamberlain W, Lawson C, Ryan H, Young E. A systematic review of variability and reliability of manual and automated blood pressure readings. J Clin Nurs 2011; 20: 602–14.
13. Suokhrie LN, Reed CR, Emory C, White R, Moriarity CT, Mayberry J. Differences in automated and manual blood pressure measurement in hospitalized psychiatric patients. J Psychosoc Nurs Ment Health Serv 2013; 51(3): 32-7.
14. Kallioinen N, Hill A, Horswill M, Ward HE, Watson MO. Sources of inaccuracy in the measurement of adult patients' resting blood pressure in clinical settings: a systematic review. J Hypertens 2017; 35(3): 421–41.
15. Myers MG, Valdivieso MA. Use of an automated blood pressure recording device, the BpTRU, to reduce the "white coat effect" in routine practice. Am J Hypertens 2003; 16(6): 494-7.
16. Cao X, Song C, Guo L, Yang J, Deng S, Xu Y, et al. Quality Control and Validation of Oscillometric Blood Pressure Measurements Taken During an Epidemiological Investigation. Medicine (Baltimore) 2015; 94(37): e1475.
17. Rose KM, Arnett DK, Ellison RC, Heiss G. Skip patterns in DINAMAP measured blood pressure in 3 epidemiological studies. Hypertension 2000;35:1032–6.
18. van Popele NM, Bos WJ, de Beer NA, van Der Kuip DA, Hofman A, Grobbee DE, Witteman JC. Arterial stiffness as underlying mechanism of disagreement between an oscillometric blood pressure monitor and a sphygmomanometer. Hypertension 2000;36(4):484-8.
19. World Health Organization. Department of Protection of the Human Environment Water, Sanitation and Health. Mercury in Health Care. August 2005.
20. Health Care Without Harm. End of An Era. The phase-out of mercury-based blood pressure measurement devices in the United States and its implications for Europe and the rest of the world. 2008. http://noharm.org/lib/downloads/mercury/End_of_an_Era_Mercury.pdf
21. Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR. Mercury sphygmomanometers in healthcare and the feasibility of alternatives [Online]. [cited 2009]; Available from: URL: http://ec.europa.eu/health/ph_risk/ committees/04_scenihr/docs/scenihr_o_025.pdf
22. Myers, M. G. Why Automated Office Blood Pressure Should Now Replace the Mercury Sphygmomanometer. J Clin Hypertension 2010;12: 478–80.
23. Myers MG, Godwin M, Dawes M, Kiss A, Tobe SW, Curry F, et al. Conventional versus automated measurement of blood pressure in primary care patients with systolic hypertension: randomised parallel design controlled trial. BMJ 2011; 342.
24. Association for the Advancement of Medical Instrumentation. American National Standard. Manual, electronic or automated sphygmomanometers ANSI/AAMI SP10-2002/A1. Arlington, VA 22201-4598, USA: AAMI, 2003.
25. O'Brien E, Atkins N. A comparison of the British Hypertension Society and Association for the Advancement of Medical Instrumentation protocols for validating blood pressure measuring devices: can the two be reconciled? J Hypertens 1994; 12(9):1089-94.
26. British Hypertension Society http://www.bhsoc.org/bp-monitors/bp-monitors/