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Article

Quality Analysis of Pressure Measurement Automatic Sphygmomanometer and Non-automatic Sphygmomanometer

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Abstract. Hypertension is the fifth leading cause of death in Indonesia. Hypertension occurs because the blood vessels are continuously experiencing high pressure. Medical device that supports doctors and other health workers in diagnosing hypertension is sphygmomanometer. Sphygmomanometer is an instrument for measuring blood pressure. Accuracy of blood pressure measurement is very important in diagnosing hypertension. An Error in measuring blood pressure will be fatal for patients, health workers, and health facilities. So that this study aims to analyze the quality of automatic and non-automatic sphygmomanometer. This research method is in form of quantitative research based on experiments. The data was taken by using direct measurements. Measurements were carried out by using the 2018 Ministry of Health work method. Quality assessment of the sphygmomanometer was taken based on the results of sphygmomanometer calibration analysis. Automatic sphygmomanometer with the OMRON brand got score 95 and the non-automatic sphygmomanometer with the ABN brand got score 97.3. The results of the analysis showed that both tools had high accuracy of pressure measurement and were within tolerance limits. So it can be concluded that both tools are feasible to use.

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1. Introduction

Hypertension is the fifth leading cause of death in Indonesia [1]. Hypertension occurs because the blood vessels are continuously experiencing high pressure [2] on the arterial walls [3]. Many cases of hypertension are found in pregnant women who have history of hypertension, a lot of exposure to cigarette smoke, obesity [4], pregnancy stress and parity [5]. Hypertension and obesity can cause heart disease [6], preeclampsia which is the most common cause of death in pregnant women [7] and also in some cases cause stroke in young adults [8] . The difficulty of measuring oscilometric blood pressure [9] and specialist doctors is a factor in the increase in hypertension with preeclampsia [10].

The medical device that supports doctors and other health workers in diagnosing hypertension is sphygmomanometer. Sphygmomanometer is an instrument for measuring blood pressure. Accurate blood pressure measurement is the key in overcoming hypertension treatment [11]. In general, this tool consists of two types, automatic sphygmomanometer and non-automatic sphygmomanometer. Non-automatic sphygmomanometers are such as mercury and aneroid. Meanwhile, automatic sphygmomanometer is often called digital sphygmomanometer. The working principle of the aneroid sphygmomanometer uses an air pump and round frame to determine blood pressure, while the digital sphygmomanometer uses sensors to determine blood pressure [12]. Automatic sphygmomanometer such as the Omron Hem 9210T had been validated and was good for controlling blood pressure in pregnant women [13].

Accuracy of blood pressure measurement is very important in diagnosing patients with hypertension and preeclampsia [14]. The correct pressure measurement is influenced by several factors like measuring instrument, measurement method, interpretation of results based on age, gender, and height [15]. Error in measuring the patient's blood pressure will be fatal for the patient, health workers and health facilities. Because of this reason, it is very important for health workers and health facility management to ensure that sphygmomanometer used has the quality that meets standards and accurate in measurement. A way to maintain the precision and accuracy of the tool is to carry out calibration activities [16]. In addition, in the regulation of the ministry of health number 54 [17], medical devices must be calibrated periodically.

Based on the study of blood pressure measuring devices in the past and present, there is no international standard that regulates the calibration of blood pressure measuring devices [18]. In addition, there are differences in measurement results from automatic and non-automatic measurement tools [19]. Therefore, it is important for health workers to be informed about the accuracy of both types of devices [20] [21]. Furthermore, the result of the study from 213 patients who had age range 23-93 years on the use of Non-Invasive Blood Pressure (NIBP), there was a momentary change in the SPO2 value of ±17% [22]. The use of automatic blood pressure measuring devices (Microlife VSA, Uscom BP+ and Tensiomed Arteriograph) and non-automated aneroid type for antenatal patients in Australia resulted that automatic measuring devices other than the tensiomed arteriograph could be used [23].

Today medical devices containing mercury such as a mercury sphygmomanometer are no longer allowed to be used in hospitals [24]. This is because the mercury sphymomanometer often leaks, such as what happened at the Cairo General Hospital, Egypt, of the 465 calibrated instruments, 34.8% of the equipment leaked [25]. Likewise, the measurement accuracy of the automatic sphygmomanometer is higher than the mercury one [26]. Besides that the cuff material used in measuring the pressure of the sphygmomanometer also contributes to the uncertainty of blood pressure measurement by 12% [27] and also the use of this cuff makes the patient uncomfortable [28] as well as intermittent measurements [29]. Therefore, based on some of the problems above, this study aims to analyze the quality of automatic sphygmomanometer and non-automatic aneroid sphygmomanometer blood pressure measurements.

2. Experimental Section

Research method is divided into 3 stages:

2.1. Pre Research

In pre-research stage, the author conducted literature study about state of the art from research on sphygmomanometer calibration. Then, a review of calibration method was carried out. The calibration method used in this study was working method of the Ministry of Health in 2018 [30]. Working method reviewed was studied in detail and reduced into several documents needed during the research. These documents were work instructions, worksheets, and data processing techniques created on google spreadsheets to calculate the value of the measurement uncertainty. Documents which had been made were validated by the quality team of PT NIQ Teknik Indonesia. After did the validation process, the next step was preparation of measurement tools and sphygmomanometer tools to be tested.

(a) (b)

Figure1. Calibration Measuring Instrument (a) NIBP Analyzer, (b) Thermohygrometer

2.2. Research Implementation

This research was started with data administration collection of all measuring instruments and tools to be tested and calibrated. The data collection was conducted by writing brand, type and serial number of each measuring instrument and also sphygmomanometer would be tested. The data collection environmental conditions were measured too, such as the temperature and humidity of the room. Measurement of room temperature and humidity was carried out at the beginning and at the end of calibration activities. The results of the measurement of room temperature and humidity were written on the prepared worksheet.

Furthermore, physical examination and the function of the tool were conducted by following the parameters that had been prepared in the work instructions. Physical inspection and function of the tool were carried out to observe whether the tool was functioning properly. If the tool was not functioning properly then the test and calibration could not be continued.

Testing the performance of the tool was the last stage of this research. Performance test of non-automated sphygmomanometers included leak test, rapid pressure discharge rate test, and pressure gauge test. Meanwhile, in performance test of automatic sphygmomanometer, pressure test was carried out on Systol, Dyastol and MAP. All measurement results obtained are written on a worksheet.

(a) (b)

Figure 2. Sphygmomanometer (a) Non Automatic, (b) Automatic

2.3. Research Data Processing

The results of all measurements in the worksheet were inputted into the prepared google spreadsheet. Data processing was carried out by calculating the average value, standard deviation, correction value, uncertainty in measurement (KTPS) and tolerance limits that had been set in the work method. For non-automated sphygmomanometers, the performance measurement parameters included physical and tool function checks, leak tests, rapid exhaust rate test and pressure test, while for the automatic ones, performance testing included physical and function checks and pressure test. The decision making category of sphygmomanometer was suitable or not based on the total value of various performance tests. If the total value of the performance test of each tool is 70 then the tool is declared fit for use.

Uncertainty calculation analysis was carried out by taking into account the sources of measurement uncertainty from type A & type B. Type A included repeated observations of spectral irradiance by standard, with the sensitivity coefficient value being 1 (one) and the degree of freedom for 5 measurements 4. Meanwhile for type B the value of standard uncertainty based on the calibration certificate of the calibrator, UUT resolution, and Standard Drift value. Furthermore, the sources of uncertainty obtained were calculated with combining uncertainty using the Uncertainty Budget table [31]. The flow chart of the research process can be seen in Figure 3.

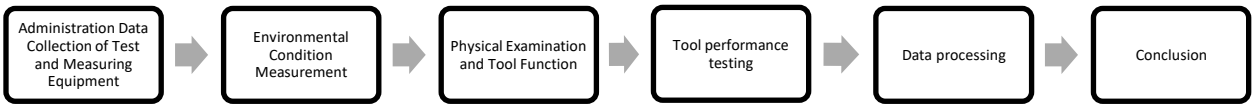

Figure 3. Flowchart of the Sphygmomanometer Calibration Process

3. Results and Discussion

The results of administrative data collection for Automatic and Non-automatic Sphygmomanometers can be seen in Table 1. Where the digital Sphygmomanometer is with the Omron brand and the non-automatic ABN brand. The measuring instruments used in this calibration process were Non Invasive Blood Pressure (NIBP) and Thermohygrometer for measuring room temperature and humidity. The NIBP brand used was the Fluke Type cufflink output with the 2185412 series while the room temperature and humidity measuring device was the thermohygrometer brand and the DM-303 type. Furthermore, measurements of environmental conditions were carried out, the results of which can be seen in Table 2. Measurement of environmental conditions was done at the beginning of calibration

and at the end of calibration activities. There was a decreasing in room temperature by 1°C with an average measurement of 25.6°C. After analyzing the measurement uncertainty (KTPS) by entering the correction of the measuring instrument certificate, the temperature measurement KTPS value was 0.2. This value had met the standard set in the 2018 Ministry of Health Work Method, which was 25°C ± 5°C. For room humidity, the value of 46% RH with KTPS 2.2 was obtained, this value also met the requirements set in the measurement standard, namely 55% RH ± 20% RH.

Table 3. Represents the results of the physical examination and the function of the instrument for both types of sphygmomanometer. Physical examination was done by observing 6 parameters as shown in Table 3. The results of observations made on all parameters got a good score with a score of 100. Physical examination and the function of this tool are important because it is necessary to ensure that the tool functions work properly before calibration is carried out. If the tool function is not work properly then the calibration process cannot be carried out until the tool is in good condition.

Table 1. The Data Collection Tool Administration

No	Specification	Digital Sphygmomanometer	Non-automatic sphygmomanometer	NIBP Analyzer	Thermo hygrometer
1	Merk	Omron	ABN	Fluke	Thermo Hygrometer
2	Type	HEM-7130	Regal Clock Aneroid	Cufflink	DM-303
3	Seri	20181001714VG	258409	2185412	N/A

Table 2. Measurement of Environmental Conditions Pressure Measurement (a) Automatic Sphygmomanometer and (b) Non-automatic Sphygmomanometer

No	Parameter	Measured						Mean	Corrected Average	Certificate Correction	KTPS
1	Room Temperature (a)	Beginning	:	26.1	End	:	25.1 °C	25.6	25.6500249	-0.05002489	0.2
2	Room Temperature (b)	Beginning		27.2	End		26.3 °C	26.75	26.7	0.028319	0.2
3	Room Humidity (a)	Beginning	:	46	End	:	46 %	46	49.40302403	-3.403024033	2.2
4	Room Humidity (b)	Beginning		61	End		57 %	59	61.9	-2.894945	2.2

Table 3 is the result of the pressure measurement test from the automatic sphygmomanometer. Tests were done on the systole, dyastole and MAP parameters. For the measurement of systolic pressure, setting of the tool started from 60, 80, 100, 120, 150, 200 mmHg. The measurement of dyastolic pressure started from 30, 50, 65, 80, 100, 150 mmHg while the measurement range for MAP started from 40-166 mmHg. Measurements were repeated 5 times for each tool setting. After the data were obtained, data processing was carried out by taking into account the tolerance value of 5 mmHg and the uncertainty in measurement (KTPS). The results of data processing for all device settings were below tolerance and were categorized as passing the performance test except for the 80 mmHg systolic pressure setting which was declared failed because it exceeded the tolerance limit. Table 3.b shows the results of a technical review of the automatic sphygmomanometer calibration based on physical parameters, function and blood pressure. The results of the technical review indicated that the equipment was within tolerance limits and functioning properly. This tool was declared suitable for

use because the value obtained was 95, which exceeds the standard set by the 2018 Ministry of Health Work Method, which is 70.

Table 3. Results of Physical Examination and Device Functions (a) Automatic Sphygmomanometer and (b) Non-Automatic Sphygmomanometer

No.	Parameter	Observation Result			
		(a) Digital Sphygmomanometer	Score	(b) Non-automatic sphygmomanometer	Score
1	Body and surface	Good	100	Good	100
2	Toolbox Contact	Good		Good	
3	Main supply cable	Good		Good	
4	Safety Fuse	Good		Good	
5	Knob	Good		Good	
6	Display and Indicator	Good		Good	
7	Zero pressure setting	Good		Good	

Table 4.a Performance Measurement of Non-Automatic Sphygmomanometer Leak Test

Setting (mmHg)	Pressure Leak After 5 minutes (mmHg)					Total Leak in 5 minutes	Threshold (mmHg/min)	Result	Score
	1 menit (1)	1 menit (2)	1 menit (3)	1 menit (4)	1 menit (5)				
50	0.75	0.75	0.75	0.50	0.50	**3.25**	**4**	worthy	100
100	0.75	0.75	0.75	0.50	0.50	**0.65**	**4**	worthy	
150	1.25	0.75	0.75	0.50	0.50	**0.75**	**4**	worthy	
200	1.00	1.00	0.75	0.50	0.50	**0.75**	**4**	worthy	
250	1.00	1.00	0.75	0.75	0.50	**0.80**	**4**	worthy	

Table 4.b Performance Measurement of Non-Automatic Sphygmomanometer Fast Exhaust

Setting (mmHg)	Pressure reduction from 260 mmHg to 15 mmHg	Threshold (Second)	Result	Score
Pressure reduction time	2	10	worthy	100

Table 4.c Measurement of Non-Automatic Sphygmomanometer Performance Pressure Test

Tool Appointmen (mmHg)	Standard Designation (mmHg)			Mean	Correction (Average+correction-Standard Setting)	KTPS	Correction +KTPS	Tolerance (mmHg)	R	Score
	1.00	2.00	3.00							
0.00	0.00	0.00	0.00	**0.00**	0.00	0.26	0.26	3.00	W	
50.00	48.0	48.0	48.0	**48.0**	-1.75	0.26	2.01	3.00	W	
100.00	99.0	99.0	98.7	**98.9**	-0.83	0.32	1.15	3.00	W	
150.00	148.0	148.0	147.7	**147.9**	-1.83	0.32	2.15	3.00	W	
200.00	199.0	199.0	19.00	**139.0**	-60.50	258.1	318.66	3.00	NW	
250.00	248.0	248.0	248.0	**248.0**	-1.50	0.26	1.76	3.00	W	**90.91**
200.00	199.5	199.5	199.5	**199.5**	0.00	0.26	0.26	3.00	W	
150.00	149.2	149.2	149.2	**149.2**	-0.50	0.26	0.76	3.00	W	
100.00	100.5	100.5	100.5	**100.50**	0.75	0.26	1.01	3.00	W	
50.00	49.50	49.50	49.50	**49.50**	-0.25	0.26	0.51	3.00	W	
0.00	0.00	0.00	0.00	**0.00**	0.00	0.26	0.26	3.00	W	

Tabel 4.d Technical review for Non-automatic Sphygmomanometer Calibration Result

No	Parameter	Score	% Bobot	Bobot	Result	Tool function	Technical Review	Conclusion
1	Physical examination and function	100	10	10.0	**97.3**	**Good**	**Within Tolerance Limit**	**Worthy** **Perform repairs and recalibration**
2	Leak Test	100	90	87.27				
3	Fast Exhaust Rate	100						
4	Pressure Accuracy	90.9						

Table 4 shows the results of performance measurements from non-automatic sphygmomanometers. Before performing a pressure performance test on the device, it is necessary to test the leak test parameters in Table 4a and the rapid exhaust rate in Table 4b. The results of the leak test at all pressure settings of 50, 100, 150, 200, 250 mmHg passed the leak test with a tolerance limit of 4 mmHg/minute. Then for the measurement of the rapid exhaust rate, it occured for 2 seconds from a pressure setting of 260 mmHg - 15 mmHg. The value of this fast exhaust rate was also within the tolerance limit of 10 seconds, so that the rapid exhaust rate pressure test was declared to have passed the test. Then, the pressure test was carried out starting from 0-250 mmHg and 250-0mmHg. The results of the pressure test measurements can be seen in Table 4c. Where all tests were categorized as passed except for the pressure setting of 200 mmHg which was declared not to pass because it was far exceeding the tolerance limit that had been set or the setting pressure of 200 mmHg, in the future

an in-depth analysis can be carried out using the regression method [32]. If a technical study is carried out from this non-automatic sphygmomanometer calibration, the result is 97.3 where the tool functions properly and within tolerance limits, so that the non-automatic sphygmomanometer of the ABN brand is declared fit for use.

4. Conclusion

If we examine the results of the calibration of the Omron brand automatic sphygmomanometer with value of 95 and the ABN brand non-automatic sphygmomanometer with value of 97.3, it can be concluded that both tools have high pressure measurement accuracy and suitable to use. There is no significant difference in the pressure measurement calibration results from the two tools, both are still within the tolerance limits..

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