

The Development of a Cuff for the Accuracy Enhancement of the Sphygmomanometer

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The purpose of this study is to develop a new cuff to improve the accuracy of blood pressure measurement, and to evaluate the performance of the developed system. We added a small bladder to the normal cuff, which we refer to as the double bladder system. The system that we developed for blood pressure measurement was based on the oscillometric method using a double bladder. This system was developed in order to reduce the oscillation noise and to amplify the signal of pure blood pressure. An oscillometric signal database based on the developed system was evaluated according to the ANSI/AAMI/SP10-1992 standard. The correlation coefficients between the cuff of the double bladder and the normal cuff were 0.98 for systolic pressure and 0.94 for diastolic pressure. The mean differences and the standard deviations between the average blood pressure obtained from a mercury manometer and that obtained from an automated sphygmomanometer were -0.7mmHg and 4.9mmHg for systolic, and -1.4mmHg and 5.4mmHg for diastolic pressure. We conclude that the proposed double bladder-based cuff system improves the accuracy of oscillometric blood pressure measurement. The developed system reduces the range of error by about 44~62% for systolic pressure and about 6~21% for diastolic pressure compared to the most recently developed, commercially available sphygmomanometers.

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1. Introduction

The pressure of the blood which circulates within an artery is divided between systolic and diastolic pressures, which are determined by cardiac output and periphery resistance. The types of blood pressure measurements include an invasive method and a non-invasive method. In the invasive method, a catheter is inserted into the artery and monitoring is performed. Non-invasive methods include the Korotkoff sound auscultation method, the oscillometric method, and a method which uses supersonic waves.¹

Through continuous measurement, invasive measurement is able to observe variations in seriously low blood pressure. In this situation, measurement using the indirect method is difficult. Arterial blood extraction can be easily performed, but may be complicated by issues such as pain, arterial damage, hematoma, infection, thrombus, and embolism. Therefore, non-invasive and continuous blood pressure measurements have been studied.^{2,3}

In 1905, Korotkoff introduced the auscultatory method for non-invasive blood pressure measurement using a mercury manometer. Employing a Rava Rocci cuff and a child's stethoscope, Korotkoff described the sequence of sounds that occurred during cuff deflation from above systolic to zero pressure. The first sound signaled the systolic pressure, and the point of disappearance of sound identified the diastolic pressure.¹ This method has been used extensively because it has effectively reduced both the cost and ease of use. Interpretation may result in errors or biased results. Additionally, even though blood the pressure is usually normal, meeting with doctors sometimes results in the "white coat effect," which increases the blood pressure in the presence of the physician. In order to eliminate the bias of the subject or the clinician, a number of measurements

should be taken.⁴⁻⁶

In 1876, Marey blocked the arterial blood flow by applying pressure to the cuff and introduced the oscillometric method, which calculates the blood pressure according to the variation of the oscillometric pressure of the blood vessel. Since 1984, most sphygmomanometers have been based on the oscillometric method.⁷ This method provides an alternative to the mercury manometer, which has potential for latent exclusions and misreading. Sphygmomanometers can be applied on adults, children, and animals without noise influence. The oscillometric method can also be used for magnetic resonance or X-ray (CT) image photography. Notably, shivering has a bad influence on the accuracy of blood pressure measurement.⁸

Non-invasive measurement, which uses a mercury manometer and a sphygmomanometer, adopts a cuff method that delivers a repulsive power to the sphygmomanometer when arterial blood flow is disturbed as the bladder expands. The sphygmomanometer is less accurate when detecting the diastolic blood pressure signal than it is when detecting the systolic blood pressure signal.

A sphygmomanometer determines the blood pressure of a subject and displays the results on a liquid crystal display, and consists of a pressure sensor, a cuff, and a body. Any study designed to improve the accuracy of the sphygmomanometer must incorporate a thorough study of the cuff, pressure sensor, and blood pressure decision algorithm.

In terms of the pressure sensor and algorithm, new forms of pressure sensors and algorithms that adopt fuzzy logic and use statistical methods have been developed. In terms of the pressure sensor resistor-type sensor, piezoelectric film, miniature fiber optic pressure sensors, and sensors that utilize applied the MEMS

technique have been studied.⁹⁻¹¹ In order to develop a new algorithm, Moraes¹² considered the correlations among comparative blood pressure measurement, the blood pressure decision constant, age, weight, height, and arm circumference. Lin¹³ decreased noise in the amplitude of oscillometric pressure by using a recursive weighted regression algorithm.

The cuff is the location at which repulsive power is received when pressure is added to the arteries. The cuff is the most important component of the sphygmomanometer. Cuff length is defined by the length of the entire cuff when it is stretched and laid out, and cuff width is the measurement of the cuff in the reverse direction. In 1901, the first study of the cuff was executed by Von Recklinghausen in order to determine a suitable cuff width for adult arms. This study determined that 10–12cm is the most effective cuff width for delivering blood pressure signals. In 1967, Bordley concluded that effective cuff width should be approximately 20% of the circumference of the arm. In 1980, Kirkendall mentioned that the cuff width should be 0.4 times the circumference of the arm. Because the general circumference of the adult arm is about 30cm, the most suitable cuff width considered to be 12cm. Additionally, in 1980, the American Heart Association (AHA) accepted 12cm as a suitable cuff width. The AHA conducted a study of both cuff width and length, and determined the most appropriate width and length to be 12cm and 23cm, respectively.¹

The sphygmomanometer is less accurate than the mercury manometer. Therefore, this study assumed that when a small volume bladder is added, an amplified blood pressure signal can be better detected. Through the application of Boyle's law, which stated that regular air volume and pressure (P) are inversely proportional at regular temperatures, it was determined that the blood pressure signal (P) from the bladder is inversely proportional to the volume of the bladder. As a result, a new form of cuff was manufactured with a small bladder positioned in the distal portion of the cuff, and when the cuff pressure is higher than the arterial blood pressure, the noise signal from the artery to the cuff is decreased.

The previous explanation of the sphygmomanometer cuff played an important role in the development of blood pressure measurement technology. However, even though it has been studied for 100 years, from the early 20th century to the late 20th century, the study of the cuff has been limited by its reliance on arm circumference in determining the dimensions of the cuff. Therefore, the purpose of this paper was to describe the development of a newly-developed cuff that performs as a physical amplifier or eliminates the noise signal, and to evaluate its precision through clinical application.

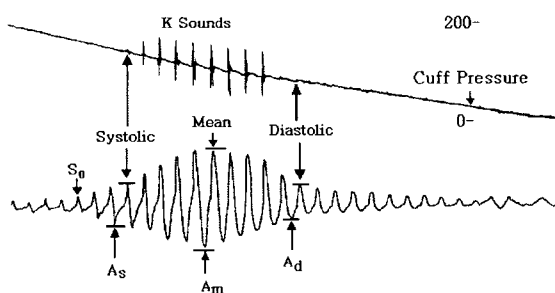


Fig. 1 Cuff pressure with superimposed Korotkoff sounds and amplified cuff pressure oscillations¹

2. Experimental methods

2.1 Blood pressure measurement theory: oscillometric method

Using the oscillometric method, systolic and diastolic pressures are calculated by the proportional method, as illustrated in Fig.1. Cuff

pressure for systolic oscillometric pressure (S_0), as signaled by the sudden increase in cuff pressure oscillations, was slightly above the cuff pressure using the first Korotkoff sound, which identifies the auscultatory systolic pressure that is known to be slightly below the intra-arterial systolic pressure. The amplitude of cuff-pressure oscillations (A_S) that corresponded to the auscultatory systolic pressure was measured and expressed as a ratio of the maximum amplitude (A_m), which occurs at the mean pressure. The ratio of A_S/A_m decreased from 0.57 to 0.45 over the systolic pressure range of 100 to 190mmHg. At normal systolic pressure (120mmHg), the ratio was 0.55. The oscillation amplitude (A_d) corresponding to the auscultatory diastolic pressure was measured and expressed as a ratio of the maximum amplitude (A_m), which occurs at the mean pressure. The ratio of A_d/A_m decreased from 0.82 to 0.74 over the diastolic pressure range of 55 to 115 mmHg. At normal diastolic pressure (80mmHg), the ratio was 0.82.¹

The systolic pressure is determined by $A_S = \text{constant} \times A_m$, where blood pressure is decided after the A_S/A_m ratio is determined using a regular constant. Similarly, using the equation, $A_d = \text{constant} \times A_m$, diastolic pressure is decided after the A_d/A_m ratio is determined using a regular constant.

2.2 Development of the cuff with a double bladder

According to Boyle's law ($P \propto 1/V$), the blood pressure signal, $P(t)$, the pressure variation of the inner bladder, can be represented by the following relationship with the volume (V_{bladder}) of the inner bladder.

$$p(t) \propto \frac{1}{V_{\text{bladder}}} \quad (1)$$

Consequently, the measured blood pressure signal, $P_{Lb}(t)$, from the original bladder plus the generated blood pressure signal, $P_{Sb}(t)$, from the small bladder plays the role of a physical amplifier, as in Eq. (2).

$$P(t) = P_{Lb}(t) + P_{Sb}(t) \quad (2)$$

Fig. 2 illustrates the hardware of the sphygmomanometer that we have developed. A is the envelope of the cuff, B is the original bladder, and C is the added bladder. The dimensions of the pressure device used in this experiment are 480mm × 150mm, the original bladder is 230mm × 120mm, and the smaller added bladder is 127mm × 25mm.

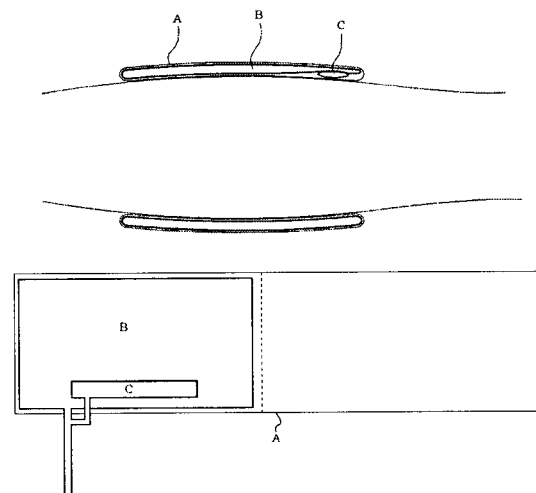


Fig. 2 Schematic view of the cuff

The dimensions of the added bladder were decided according to experimental suitability. Additionally, when the arm was used as a standard, the added bladder was located in a distal position from the body, and the oscillometric pressure of the blood vessel along the line of the heartbeat was transmitted to the bladder. This reduced the

pressure when the blood flow was impeded, as the pressure of the inner bladder is greater than the maximum blood pressure.

The double bladder that we have developed is shown in Fig. 3. B is the original bladder and C is the added bladder.

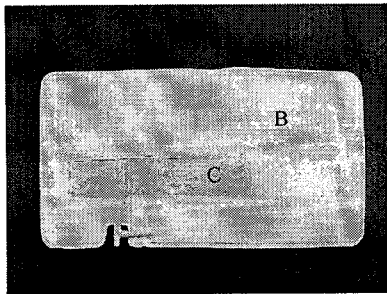


Fig. 3 The double-bladdered cuff

2.3 Subjects

This study was conducted with data from Chung-ang University Hospital obtained from 2003. 8. 24 to 2003. 8. 29. Blood pressure values were acquired from 38 male and 47 female subjects with no known cardiovascular disease. The age range for the subjects was 15 to 80, and the characteristics of the subjects are presented in Table 1.

Table 1 The characteristics of the patients

	Age (S.D) [years]	Height (S.D) [cm]	Mass (S.D) [kg]	Arm circumference size(S.D) [cm]
Men	41.61(18.91)	170.79(5.41)	68.84(9.98)	28.61(2.57)
Women	56.43(14.94)	157.23(4.01)	54.96(7.23)	25.77(2.27)

2.4 Experimental method and measurement items

2.4.1 Measurement of blood pressure signal

A sphygmomanometer (SE-7070, Sein electronics Co. Ltd. Korea) was used for the purpose of blood pressure measurement. An ASCII file data acquisition board (USB Data Acquisition Function Module, Data Translation, Inc., USA) was used to transform the blood pressure signal of the sphygmomanometer. In order to verify the equality between the sphygmomanometer and mercury manometer prior to the experiment, we checked the static calibration of the unit under the testing conditions by connecting a T-typed pipe. To measure the difference in blood pressure signals between a single-bladdered cuff and double-bladdered cuff, which was first developed and introduced in this study, the blood pressure signal of the subject was measured after the sphygmomanometer was connected to a single-bladder cuff. After completion of the blood pressure measurement, the single-bladder cuff was eliminated and the blood pressure signal was again measured after the double-bladdered cuff was connected. The same sphygmomanometer was used throughout the experiment.

2.4.2 Measurement of blood pressure

Measurement of blood pressure through the Korotkoff sound method is likely to provide inaccurate results due to external noise, so blood pressure measurement was conducted in a specific area of the hospital in which external noises could not be heard. All subjects were given enough time to rest in order to maintain a stable blood pressure. Because conversation and movement of the subject have an effect on the process of blood pressure measurement, conversation was not allowed and the movement of the subject was carefully controlled. To verify the results of the sphygmomanometer, the cuff was connected to a T-typed pipe for the purpose of concurrent blood pressure measurement. This verification was in accordance with the recommendation of the ANSI/AAMI SP10-1992, which has been adopted by the AAMI (American Association for the Advancement of Medical Instrumentation).¹⁴ The cuff was located at the same height

as the heart. Blood pressure was measured 3 times using the AAMI standard, and 255 readings were acquired.¹⁴

2.4.3 Verification of Accuracy

For statistical analysis of data, the SAS program was used. Pearson's correlation analysis was carried out to determine the correlation between the sphygmomanometer and the mercury manometer. To statistically verify whether a difference existed between the two averages measured by the sphygmomanometer and the mercury manometer, a paired t-test was carried out at a 5% significance level. At this time, we established the null hypothesis (H_0), that the population average blood pressures determined by the mercury manometer and the sphygmomanometer are the same, and the opposition hypothesis (H_1), that the population average blood pressures determined by the mercury manometer and the sphygmomanometer are not the same.

$$H_0 : \mu_1 = \mu_2$$

$$H_1 : \mu_1 \neq \mu_2$$

μ_1 : the average of the mercury manometer,

μ_2 : the average of the sphygmomanometer

The efficiency of the blood pressure measurement was evaluated according to the ANSI/AAMI SP10-1992 standard, which requires that the mean difference and standard deviation of the systolic and diastolic pressures are within 5mmHg and 8.0mmHg, respectively, when compared to blood pressure measurements by the mercury manometer, as shown in Table 2. Average values were judged to be different if measurement of the two sphygmomanometers was in concordance with the Bland-Altman¹⁵ diagram. The results are represented as mean difference \pm standard deviation.

Table 2 ANSI/AAMI SP10-1992 Protocol

ANSI/AAMI SP10

Pass : mean difference \leq 5mmHg, plus SD \leq 8.0 mmHg for both SBP and DBP

Fail : mean difference $>$ 5mmHg or SD $>$ 8.0 mmHg for both SBP and DBP

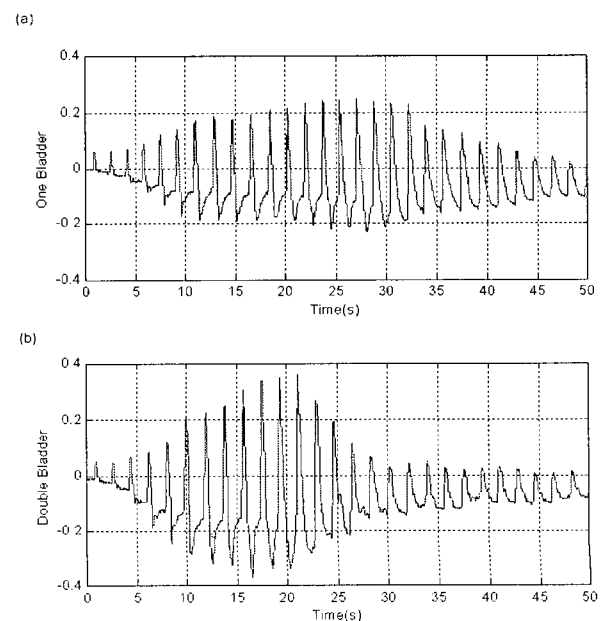


Fig. 4 Oscillometric signal of the cuff sphygmomanometer: (a) Single bladder (b) Double bladder

3. Results

3.1 Comparison of blood pressure signals

Blood pressure signals measured by both the single- and double-bladdered sphygmomanometers are shown in Fig. 4: (a) is the blood pressure signal using a single bladder and (b) is the value using a double bladder. The mean value of the single-bladdered sphygmomanometer was 0.2490 and A_m was -0.2295, as seen in Fig. 4 (a). The mean value of the double-bladdered sphygmomanometer was 0.3161 and A_m was -0.3711. This shows increases of 45.1% and 61.7%, respectively. According to the standard of mean values, the deflection of the single-bladdered sphygmomanometer was 0.0092, and that of the double-bladdered sphygmomanometer was 0.0168.

When the constant (A_s/A_m) that determined the systolic pressure using a single bladder was set to 0.55, A_s was represented by $-0.2295 \times 0.95 = -0.1262$, and when the constant (A_d/A_m) that determined the diastolic pressure was set to 0.82, A_d was represented by $-0.2295 \times 0.82 = -0.1882$. On the other hand, when the constant (A_s/A_m) that determined the systolic blood pressure using a double bladder was set to 0.55, A_s was represented by $-0.3711 \times 0.55 = -0.2041$, and when the constant (A_d/A_m) that determined the diastolic blood pressure was set to 0.82, A_d was represented by $-0.3711 \times 0.82 = -0.3043$.

Table 3 Range of systolic and diastolic blood pressures

Range of systolic blood pressure		
range of systolic	requirement	result
Less than 100mmHg	$\leq 10\%$	27/255(10.6%)
Greater than 180mmHg	$\geq 10\%$	28/255(11.0%)
Range of diastolic blood pressure		
range of diastolic	requirement	result
Less than 60mmHg	$\leq 10\%$	27/225(10.6%)
Greater than 100mmHg	$\geq 10\%$	37/255(14.5%)

3.2 Measurement of blood pressure

Table 3 presents the permissible range of systolic and diastolic blood pressures. In terms of the systolic pressure, readings of less than 100mmHg blood pressure should represent $\leq 10\%$ in the overall trials. The result was 10.6% (27/255), exceeding the AAMI standard by 0.6%. Blood pressure readings greater than 180mmHg should represent $\geq 10\%$. Twenty-eight of the 255 readings were found to be greater than 180mmHg, representing 11% in the overall trials. This satisfied the AAMI standard. In terms of the diastolic pressure, readings of less than 60mmHg blood pressure should represent $\leq 10\%$ in the overall trials. The result was 10.6% (27/255), exceeding the AAMI standard by 0.6%. Blood pressure readings greater than 100mmHg should represent $\geq 10\%$. Thirty-seven of 255 readings were found to be greater than 100mmHg, representing 14.5% in the overall trials. This satisfied the AAMI standard.

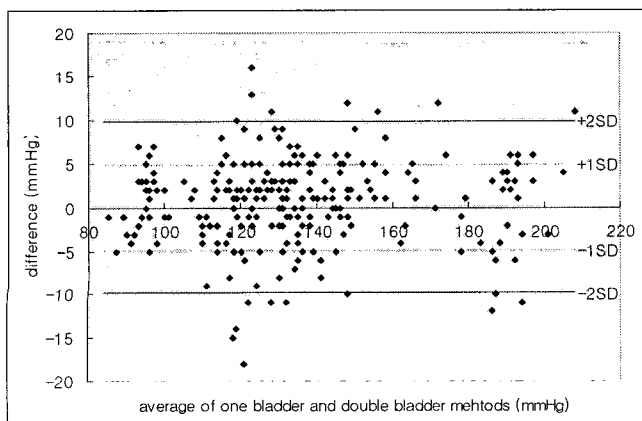


Fig. 5 Agreement between the systolic pressures measures by the single-bladdered and double-bladdered sphygmomanometers (n=255)

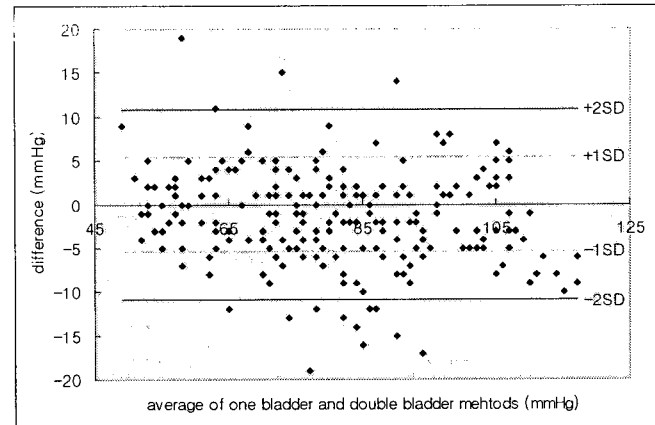


Fig. 6 Agreement between the diastolic pressures measured by the single-bladdered and double-bladdered sphygmomanometers (n=255)

3.3 Verification of accuracy

When the sphygmomanometer was compared to the mercury manometer, high correlations ($r=0.98$, $r=0.94$) were seen with both the systolic and diastolic pressures. At a significance level of 5%, a paired t-test showed that the systolic blood pressure, as measured by a sphygmomanometer and a mercury manometer, were statistically significantly different ($p=0.0211$). A statistically significant difference was also found for the diastolic blood pressure ($p<0.0001$).

The differences between the two sphygmomanometers are presented in Bland-Altman diagrams¹⁵ in Fig 5. and 6. Fig. 5 presents the difference in the averages of the systolic blood pressure as measured by sphygmomanometers using a single bladder and a double bladder. Fig. 6 presents the same comparison with respect to the diastolic blood pressure.

Using the Bland-Altman diagram, the difference in the mean blood pressure values of the mercury manometer and the double-bladdered sphygmomanometer was distributed at 93.4%; in the cases of the systolic blood pressure and the diastolic blood pressure, the distribution was 94.2% within $\pm 2SD$.

Table 4 The mean differences \pm standard deviation between the observers and the device (n=255, unit: mmHg)

	A company ¹⁶	B company ¹⁷	This study
Systolic	-0.13 \pm 7.51	-1.6 \pm 7.7	-0.7 \pm 4.9
Diastolic	2.54 \pm 5.21	-2.1 \pm 6.3	-1.4 \pm 5.4

When compared to the mean value (within ± 5.00 mmHg) and standard deviation (within 8.00mmHg) of the ANSI/AAMI SPI0 standard, the cuff which was developed for this study had a difference of mean systolic blood pressure value of -0.7mmHg, and a difference of mean diastolic blood pressure value of -1.4mmHg. The standard deviation was 4.9mmHg in the case of the systolic blood pressure, and 5.4mmHg in the case of the diastolic blood pressure. Table 4 presents those results.

To verify the improvement in accuracy of the sphygmomanometer using the cuff that we have developed, the humeral blood pressure was measured as described above, and was compared to the products of another company, which used the oscillometric method. Company 'A' acquired 545 blood pressure values from 109 subjects and compared the values to those of a mercury manometer. Company 'B' practiced a limited experiment, which showed a lower systolic blood pressure, except for one patient whose difference of blood pressure was greater than 15mmHg. The blood pressure values acquired by Company 'B' were also compared to those of a mercury manometer.

The difference in the mean values of the systolic pressure in the case of company 'A' was -0.13mmHg, and the standard deviation was

7.51mmHg. The error obtained by the standard deviation was $\pm 7.51\text{mmHg}$. The range of error was 15.02mmHg, 2 times the standard deviation. When the error of average deviation was added, the error increased to 15.15mmHg. Additionally, the average deviation of the diastolic pressure was 2.54mmHg, and the standard deviation was 5.21mmHg. Therefore, the error was 10.42 mmHg, and the added error of the average deviation increased the error to 12.96mmHg.

The difference in the mean values of the systolic pressure in the case of company 'B' was -1.6mmHg, and the standard deviation was 7.7mmHg. The error obtained by the standard deviation was $\pm 7.7\text{mmHg}$. The range of error was 15.4mmHg, 2 times the standard deviation. When the error of average deviation was added, the error increased to 17mmHg. Additionally, the average deviation of the diastolic pressure was -2.1mmHg, and the standard deviation was 6.3mmHg. Therefore, the error was 12.6mmHg, and the added error of the average deviation increased the error to 14.7mmHg.

The average deviation of the systolic blood pressure using the blood pressure cuff was -0.7mmHg, and the standard deviation was $\pm 4.9\text{mmHg}$. The error obtained by the standard deviation was 9.8mmHg. When the error of average deviation was added, the error increased to 10.5mmHg. Additionally, the average deviation of the diastolic pressure was -1.4mmHg, and standard deviation was 5.4mmHg. Therefore, the error from the standard deviation was 10.8mmHg, and the added error of the average deviation increased the error to 12.2mmHg.

Using the cuff that was developed in this study, the error in the measurement of the systolic blood pressure was decreased to 44.28% and 61.90%, when applying the standards of two companies, 'A' (15.15mmHg) and 'B' (17mmHg), respectively. The error in the measurement of the diastolic blood pressure was decreased to 6.23% and 20.49%, when applying the standards of two companies, 'A' (12.96mmHg) and 'B' (14.7mmHg), respectively.

4. Conclusions

Measurement of blood pressure by the invasive method is more accurate than non-invasive methods, but it also involves side effects, such as pain, arterial damage, infection, etc. To avoid these side effects, methods by which blood pressure can be measured in a non-invasive manner have been studied. However, because the sphygmomanometer, which uses non-invasive methods to measure blood pressure, is less accurate than the invasive method, the proficiency of the person performing the measurements should be verified at the time of measurement. To reduce differences in blood pressure measurements according to the proficiency of the performer, and because they make the measurement more convenient, sphygmomanometers have been widely distributed. However, the accuracy of this instrument is lower than that of the mercury manometer using the Korotkoff sound method.

To improve the accuracy of the sphygmomanometer, a number of trials have been conducted, but the resulting improvements have been insufficient, as they did not provide a cuff which generated a blood pressure signal as a result of direct contact with a subject. Therefore, the blood pressure signal itself inevitably contained error and the improvement of its accuracy was limited.

Oscillations occur when a blood pressure signal enters through the bladder, which is located at the inner part of the cuff, and amplified blood pressure is acquired when the volume is reduced according to Boyle's law, which states that the volume of a regular gas is inversely proportional to the pressure at a regular temperature. Variations of cuff pressure are equal to blood pressure variations. Therefore, under the assumption that an amplified blood pressure signal would be acquired, we developed a cuff with an additional, small bladder.

The double-bladdered cuff that was developed in this study increased the value of A_m to 61.7%, a standard for determining blood

pressure. The double-bladdered cuff is more efficient than the cuff with a single bladder and is better correlated (systolic pressure: $r=0.98$ and diastolic pressure: $r=0.94$) with the mercury manometer. The result of a paired t-test showed that there was a highly significant difference ($p=0.0211$, $p<0.0001$) in terms of correlation with the mercury manometer. In conclusion, the sphygmomanometer with the double-bladdered cuff which was used in this study passed the AAMI regulation related to verification of the sphygmomanometer. Compared to a sphygmomanometer using oscillometric methods, the error was decreased and the accuracy was increased using the double-bladdered cuff developed in this study.

The double-bladdered sphygmomanometer decreased measurement error and allowed the detection of amplified blood pressure signals. This study is limited by the fact that the pulse of arterial blood contains noise which oscillates the cuff when the pressure of the cuff is higher than the pressure of the arterial blood because the blood pressure signal ingredient, $P_{Lb}(t)$, of the original single bladder remained. In the future, we will attempt to develop a cuff which minimizes error by excluding the $P_{Lb}(t)$ component.

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