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한국인 맞춤형 혈압계 커프 블래더

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Blood Pressure Cuff Bladders Tailored For Koreans

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요 약

고혈압은 임상 현장에서 매우 흔한 질환인데 그 유병률이 국제적으로 상승세를 보이고 있다. 고혈압의 폐해는 너무 많으며 여러 장기들에 영향을 미친다. 필요 시 보통 평생 동안 치료해야 한다. 한국질병관리본부에 따르면 고혈압 유병률이 날로 증가하고 있다. 2011 조사에서 성인 중 28.9%가 고혈압이었으며, 여자 보다 남자가 약간 더 높았다. 환자를 분류하고, 혈압관련 위험을 확인하고 그리고 치료법을 안내하는 데 있어 정확한 혈압 측정은 필수적이다. 혈압계의 정확도에 영향을 미치는 요인 중 블래더 크기의 일탈이 장비 에러의 주된 원인이 된다. 혈압을 정확히 측정하기 위해, 위 팔 중심의 둘레에 따른 올바른 크기의 블래더 사용은 필수적이다.

시중의 혈압계를 조사한 결과, 커프 블래더들이 국제 규격 ISO 81060-1:2007에서 권유된 크기와 다름을 알 수 있었다. 블래더가 클 경우 혈압이 더 낮게 나오고, 더 작을 경우 더 높게 나온다는 것은 잘 알려져 있다. 미)심장협회(AHA)가 권고하는 어른용 블래더의 크기는 17-25cm의 팔 둘레를 가진 작은 어른, 24-32 cm의 팔 둘레를 가진 어른, 32-42cm의 팔 둘레를 가진 대다수 어른, 그리고 42-50cm의 팔 둘레를 가진 비만 어른으로 구분 된다. 반면에 한국 어른의 팔 둘레는 23-31cm에 불과하므로 AHA의 어른용 블래더 한 가지에 해당한다. 23-31cm의 팔 둘레를 가진 한국 어른을 위한 블래더의 종류는 ISO 81060-1을 따를 경우 3 개의 블래더가 필요하다. 병원들은 어른 환자들을 위해 보통 하나 혹은 두 가지 크기의 서양식 커프를 사용한다. 이 때문에 일부 환자들은 정확한 혈압 측정을 기대할 수 없다. 한국인에서 취합한 인체치수 참조 데이터에 기초한 블래더의 크기는 한국에서 가장 정확한 혈압을 측정하는데 도움이 될 것이다.

Key words : arm circumference, blood pressure, hypertension, sphygmomanometer, cuff bladder

ABSTRACT

Hypertension is one of the most common clinical diseases, with an increasing prevalence globally. Hypertension triggers various harmful consequences and affects multiple organs. Life-long care may be required in some cases. According to the Korea Center for Disease Control and Prevention, the prevalence of hypertension is gradually increasing. A 2011 survey revealed that 28.9% of Korean adults had hypertension. The prevalence rates were slightly higher among men than women.

Accurate measurement of blood pressure(BP) is crucial to classify patients, to identify BP-related risks, and to inform correct treatment. For accurate blood pressure measurement, the use of a cuff bladder size appropriate for the mid-upper arm circumference(MUAC) is essential. Incorrect sized cuff bladder is one of the main causes of equipment error affecting sphygmomanometer accuracy. When commercial sphygmomanometers were examined, the

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cuff bladders differed from the dimensions specified in the ISO 81060-1:2007 standards. Undercuffing is responsible for a spurious overestimation of BP in patients with large arms leading to overdiagnosis of hypertension, whereas overcuffing (that is, use of relatively large cuffs with small arms), may be responsible for an opposite problem, leading to erroneous underestimation of BP levels. The cuff bladder sizes recommended by the American Heart Association(AHA) are an arm circumference(AC) of 17-25 cm for small-sized adults, AC of 24-32 cm for adults, AC of 32-42 cm for normal-sized adults, and AC of 42-50 cm for obese adults. In contrast, the AC of Korean adults ranges from 23-31 cm, belonging to a single type of adult bladder. Three types of bladders are necessary for Korean adults with an AC of 23-31cm. Hospitals often use one or two differently-sized Western cuffs for adult patients, which can yield inaccurate BP determinations. Cuff bladders with dimensions based on anthropometric reference data obtained from Koreans will aid hospitals to measure BP more accurately.

Ⅰ. Introduction

The most commonly used technique to measure Blood Pressure(BP) in routine conditions is indirect measurement. The equipment used universally for this purpose is a mercury gravity sphygmomanometer and a stethoscope. The sphygmomanometer comprises a manometer tube (mercury or aneroid) with a calibrated scale for measuring pressure, a mercury reservoir with a valve, and an inflation system. The inflation system consists of an inflatable bladder encased in a non-distensible cuff that can be securely wrapped around the limb, an inflation bulb for manual inflation of the bladder in the cuff, and tubing connecting both the manometer and the inflation bulb to the bladder. This complexity of the equipment is susceptible to error. In the event of less than ideal quality control related to equipment selection, calibration, repair, and production of components, this fairly reliable equipment can produce erroneous results[1].

Mercury sphygmomanometers are supposed to be phased out by 2020[2], which provides a great opportunity for manufacturers to provide a superior device in terms of both safety and quality. The automated BP device is one non-mercury alternative, though it is limited in its formal coverage. The various types of automated BP devices include electronic sphygmomanometers, automated spot-check devices, wrist devices, finger devices, spot-check non-invasive BP monitors, and ambulatory BP monitors.

Various factors and activities can affect the accuracy of a sphygmomanometer, including improper bladder size, cuffs over clothing, an unsupported back or feet, crossed legs, a lack of rest period, patient talking, labored breathing, pain, or improper arm position. Not all of these factors are considered by users. Deviation from the recommended cuff bladder sizes in reference to the AC is a chief source of equipment error.

Ⅱ. Cuff size

The cuff is an inelastic cloth that encircles the arm and encloses an inflatable rubber bladder. The cuff is secured around the arm most often by Velcro on its adjoining surfaces, occasionally by wrapping a tapering end into the encircling cuff, and rarely, by hooks[3]. To achieve identical results with direct and indirect methods, it is essential that the cuff pressures act upon the artery without any interference by tissues [4].

To accurately measure BP, the use of appropriate cuff bladder sizes is essential. The ISO 81060-1:2007 standard considers the optimum bladder size to be a width 40% of the limb circumference(LC) and a length 80% to 100% of the LC at the center of the range for each cuff size. These dimensions are subject to ongoing consideration.

If a bladder does not satisfy the current recommended size standards, the accuracy of the sphygmomanometer might be compromised because the design is inherently defective. The selection of a snug-fitting sphygmomanometer cuff bladder is of critical importance. The MUAC must first be measured, followed by the careful selection of an appropriate cuff.

This study is intended to determine the ideal cuff bladder sizes for Koreans.

2.1. Changes in the BP cuff width

When Riva-Rocci introduced the cuff method of blood pressure measurement in 1896, he used a 50-mm-wide cuff. In 1991, von Recklinghausen showed that the systolic pressures obtained in dogs with Riva-Rocci's method were approximately 10% higher than when the intra-arterial pressure was deter-mined directly. He also showed that in man, when the width of the cuff was increased to 120-140 mm, the pressure readings were unaffected by cuff size, and narrower cuffs gave higher readings[4].

Further studies have extended the conclusions of von Recklinghausen for application to Korotkoff's auscultatory method. Increasing the cuff width beyond 120 mm or 130 mm had practically no influence on either the systolic or diastolic pressure reading. Also, direct intra-arterial pressure measurements in man have been compared with the indirect method. Although occasionally marked differences may occur, readings obtained with the aid of the wide cuffs correspond most closely to the intra-arterial measurements. A conclu-sion may be drawn that cuffs that are too narrow overestimate systolic and diastolic readings, whereas an increase in cuff width does not generally lead to too low readings in adults. Results obtained with cuffs varying in width from 120 mm to 140 mm may be considered comparable[4].

The first recommendation of the American Heart Association in 1939 stated that the appropriate cuff size for BP measurements was a bladder width of 120–130 mm[5].

In 1951, a bladder width 20% larger than the AC was recommended[6]. The last three reports recommend a bladder width of 40% of the upper AC and a length that encircles at least 80% of the AC[7-9]. The latest guidelines and pertinent standards recommend a bladder width and length of 40 and 80% of the AC, respectively[10-12].

2.2. Changes in the BP cuff length

The classic experimental work of King in 1967 used a bladder that was sufficient to completely encircle the arm. In "the third revision of the AHA recommendations" published in 1980, a bladder 120 - 140-mm in wide with a length approximately twice the bladder width was recommended[13].

Geddes found the literature regarding bladder length inconclusive, and stated[4], "As it stands now, there appears to be no general agreement on the optimum length of the pneumatic cuff."The American Society of Hypertension recommended that the bladder length should nearly or completely encircle the arm[14].More recently, a World Health Organization expert recommended a bag long enough to encircle the arm (or leg) where the measurement is made. The internal bladder of the cuff should encircle at least 80% of the arm(but not more than 100%). The size of the subject's arm should be measured with a tape measure and the correct size of cuff selected before a BP reading is taken [15]. The last two reports recommend a bladder width of 40% of the upper AC and a length that encircles at least 80% of the AC[9].

The recommended bladder dimensions of 130 x 240 mm were chosen to give a bladder width that is greater than 40% of the circumference and a bladder length that is greater than 80% of the circumference of most adult arms. Some investigators have favored longer bladders of 350-400 mm. Bladders of this length would fully encircle the arm of 99% of adults and reduce errors in blood pressure measurement. The use of bladders of inadequate dimensions, as in most of the cuffs examined, leads to overestimation of BP with the possibility of mis-diagnosing normotensive patients as hypertensive[16]. In the sizes recommended by the today's standards or international recommendations (e.g. ISO 81060-1:2007, ISO 81060-2:2009, OIML R 16-2 Ed. 2002, the optimum bladder size is a width 40 % of the LC at the midpoint of the cuff application and a length at least 80 % of the LC at the mid-point of cuff application (but preferably 100%). Table 1 lists the changes in cuff size that serve as a background for the establishment of current requirements.

Table 1. Historical changes in cuff size

Year	Literature	Remarks
1896	M. J. Karvonen, M.D., Ph.D., Director of the Physiological Department, Institute of Occupational Health, Helsinki, Finland, Effect of Sphygmomanometer Cuff Size on BP Measurement	A 50-mm-wide cuff was introduced for the 1st time.
1901	M. J. KARVONEN, M.D., Ph.D., Director of the Physiological Department, Institute of Occupational Health, Helsinki, Finl and, Effect of Sphygmomanometer Cuff Size on BP Measurement*	The width of the cuff was increased.
1982	M J Burke, Hellen M Towers, K O'Malley, D J Fitzgerald, E T O'Brien, Sphygmomanometers in hospital and family practice: problems and Recommendations, British Medical Journal Vol. 285, 14 August 1982	The bladder dimension of '40% width and 80 % length' was introduced.
1993	Verschuren W and 6 team-mates. Cardiovascular disease risk factors in the Netherlands. Neth J Cardio l93;6:205-10.	Three(3) cuffs were used.
1993	National Health and Nutrition Examination Survey III, Cycle 2. Pulse and BP procedures for household interviewers.(1993).	Four(4) cuffs were used.
2004	The 4th report on high BP in children & adolescents Available as National Heart, Lung, and Blood Institute Publication No. 56-091N. 2004	Use of seven (7) bladders were recommended
2005	Eoin O'Brien and 14 team-mates. Practice guidelines of the European Society of Hypertension for clinic, ambulatory & self BP measurement	BHS: 3 bladders, AHA: 4 bladders
2007	ISO 81060-1:2007 & ISO 81060-2: 2009	The standard for noninvasive sphygmomanom-eters

Ⅲ. Inspection of sample bladders currently available on the market

Commercial sphygmomanometers generally have three to six bladders. Table 2 shows the BP results of two sphygmomanometers having five and six bladders tested according to ISO 81060-1:2007 standards.

Table 2. Inspection of sample bladders available in the market. Unit: mm

AC Patient	width/ length	Ref. Size IAW ISO 81060*	Actual Size
Sample A (having 5 different bladders)			
140 – 215 Pediatric	width	≥86	80
	length	172 – 140	215
205 – 285 Small adult	width	≥114	106
	length	228 – 205	240
275 – 360 Adult	width	≥144	135
	length	288 – 275	300
350 – 450 Large adult	width	≥180	170
	length	360 – 350	380
440 – 560 Thigh	width	≥224	210
	length	440	480
Sample B (having 6 different bladders)			
100 – 150 Infant	width	≥60	55
	length	150	154
140 – 215 Pediatric	width	≥86	80
	length	140 - 215	215
205 – 280 Small Adult	width	≥112	105
	length	205 - 224	240
270 – 350 Adult	width	≥140	130
	length	270 - 280	280
340 – 430 Large Adult	width	≥172	160
	length	340 – 344	350
420 – 540 Thigh	width	≥216	200
	length	420 - 432	430

* Reference size IAW(in accordance with) ISO 81060-1:2007

All bladders shown in Table 2 did not meet the ISO 81060-1:2007 standards. Sample A was developed for patients with a MUAC range of 140-560 mm. Sample B was for patients with a MUAC range of 100-540 mm. A minimum of 10 bladders were needed to meet the requirements recommended by ISO 81060-1:2007. When bladder size was measured according to the American Heart Association recommendations, five of six cuffs failed the quality test (Table 3).

Table 3. AHA(American Heart Association) recommended Bladder Sizes Unit: mm

Bladder Width	**Bladder Length**	**AC Range Patient**	**Inspection IAW ISO 81060-1: 2007**
30	60	≤ 60 Newborn	Pass
50	150	$60-150^{+}$ Infant	Fail (See note)
80	210	$160-210^{+}$ Child	Fail (See note)
100	240	220-260 Small adult	Fail (See note)
130	300	270-340 Adult	Fail (See note)
160	380	350-440 Large adult	Fail (See note)
200	420	450-520 Adult thigh	Fail (See note)

Note. In case of the cuff for the infant, the 5-cm-bladder is not enough for the AC(Arm Circumference) 15, and some of them is too long e.g. 15-cm-bladder will overlap the AC which is below 15.

Ⅳ. MUAC (Mid-Upper Arm Circumference)

The circumference of the arms should be measured to ensure that the bladder being used is adequate for the patient[17]. The arms of some people are very thin, while others are thick, with most cases being intermediate. The mean MUAC values can differ in different countries or between people. Statistical data was used to compare MUAC variations between Korea and the United States.

The MUAC ranges

0 100 200 300 400 mm

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⇦============⇨

(115 - 355 mm / white Americans)

⇦========⇨

(125 - 308 mm / Koreans)

Fig. 1. The comparison of the MUAC ranges between white Americans and Koreans

Table 4. The MUAC ranges of white Americans and Koreans Unit: mm

Age	MUAC(Mid-Upper Arm Circumference)			
	Korea		U.S.A (White)	
	Femal e	Male	Female	Male
0~3 months	125	132	No data	No data
3~6 months	147	153	136	138
6~9 months	156	152	144	147
9~12 months	154	158	148	152
12~18 months	157	159	159	154
2	158	165	160	161
3	162	165	165	168
4	164	170	173	173
5	170	175	184	180
6	178	182	188	190
7	187	192	199	196
8	196	202	214	208
9	204	213	222	221
10	213	219	234	233
11	218	235	246	249
12	229	238	254	257
13	238	247	265	270
14	245	260	279	278
15	252	268	280	292
16	252	273	280	306
17	254	279	283	315
18	257	287	287	326
19	252	290	293	319
20~24	253	298	317~344	343~352
25~29	263	303	317~341	342~354
30~34	267	305		
35~39	276	308		
40~49	282	307	320~351	349~355
50~59	293	304		
60~69	289	294	316~338	334~339
70이상	279	274		

Source of data: National Center for Standard Reference Data in Korea, and Anthropometric Reference Data for Children and Adults, United States, 2007–2010

Ⅴ. The bladder dimensions for Koreans

Table 5 is made based on the Korean MUAC(mid-upper arm circumferences) data released by the Korea Institute of Standards and Science. Bladder dimensions comply with the requirements of ISO 81060-1:2007. Koreans mostly have a small build and their range of AC is smaller compared to white Americans, as shown in Fig. 1 and Table 4. The majority of people in Korea can be successfully covered by 6 different bladders.

Table 5. Bladder dimensions tailored for Koreans (ranging from children to the obese). Unit: mm

AC Patient	Dimen -sion	Ref. Size IAW ISO 81060	Actual Size	Ver- dict
125 - 155 Pediatric	width	>62	63	Pass
	length	>124	124	Pass
155 - 190 Child	width	>76	77	Pass
	length	>152	152	Pass
190 - 230 Adult, small	width	>92	93	Pass
	length	>184	184	Pass
230 - 285 Adult, medium	width	>114	115	Pass
	length	>228	228	Pass
285 - 330 Adult, large	width	>132	133	Pass
	length	>264	264	Pass
330 - 370 Obese	width	>148	149	Pass
	length	>296	296	Pass

Ⅵ. Discussion

Uncontrolled high BP can lead to heart attack or stroke, aneurysm, heart failure, weakened and narrowed blood vessels in the kidney, thickened, narrowed or torn blood vessels in the eyes, metabolic syndrome, and trouble with memory or understanding. Accurate BP measurement is vital in the prevention and treatment of BP-related diseases. Additionally, in very ill patients, accurate measurement of BP is essential for monitoring cardiovascular homeostasis[18]. A BP determination error ≥3 mmHg can result in clinically significant errors in the detection of hypertensive conditions However, it seems hard to ensure the accuracy with a limited number of bladders. Sphygmomanometer manufacturers may increase the number of bladders. All the bladder sizes should be validated if they are connected to an automated sphygmomanometer. Because of this, manufactures may hesitate to increase the number of bladders.

The number of bladders can be reduced by customizing bladders for specific markets. Only 6 different BP bladders might be enough in most Asian countries where people have a small build like Koreans. This can be verified through further tests and clinical validations.

Ⅶ. Conclusion

The blood pressure bladder should be long enough to encircle at least 80% of the arm and wide enough to encircle 40% of the arm at its midpoint, but finding an acceptable bladder was not easy on the market. Healthcare providers generally insist on the use of the manual mercury sphygmomanometer for accurate diagn osis. The phase- out of the mercury sphygmomanometer has gradually expanded the use of auto-mated oscillomet ric sphygmomanometers, which tend to be less precise than the manual version. The correct cuff bladder size needs to be developed, in addition to the modification of other structural needs. Inherently defective bladders hamper the accurate measurement of BP.

The MUAC of Korean adults ranged between 125 and 308 mm, which is thinner than white Americans (maximum of 47 mm) (Fig. 1, Table 4). Using the cuff tailored to westerners is thus undesirable. For this reason, six bladder dimensions have been developed by considering obese Koreans absent in the MUAC range of 125–308 mm of the National Center for Standard Reference Data in Korea. Those six different bladders have a width of more than 40% and lengths of 80%-100% of MUAC. They fit all Koreans, from children to adults, and meet the latest ISO 81060-1:2007 standards.

In conclusion, the use of cuffs that conform to pertinent standards is one of the prerequisites for accurate BP determination. As shown in Table 5, the dimensions of BP bladders can be tailored to Koreans whose arm circumferences are relatively smaller than white Americans. However, this suggestion can be justified only by successful follow-up clinical validation or calibration processes.

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