UNIVERSITÀ DEGLI STUDI DI PADOVA

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EFFECT OF THE ANTHROPOMETRIC CHARACTERISTICS OF THE ARM ON BLOOD PRESSURE MEASUREMENT IN THE OBESE

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ABSTRACT

BACKGROUND

The type of cuff that should be used for blood pressure measurement in the obese is still the subject of debate. The problem is even more controversial in people with morbid obesity due to the pronounced tronco-conical shape of the upper arm.

OBJECTIVES

In this study we investigated the effect of the shape of the cuff on blood pressure measurement in obese subjects with arm circumference > 42 cm by comparing the blood pressure readings obtained with a cylindrical and a tronco-conical cuff with the same width.

MATERIAL AND METHODOS

We enrolled 33 obese subjects (mean BMI, 45 ± 5 kg/m^2) with arm circumference between 42 and 50 cm (mean 44.8 ± 2.7 cm). In each subject, body weight and height, upper arm length, proximal, medial and distal circumference, biceps and triceps skinfold, and blood pressure at enrolment were measured. From the proximal and distal arm circumference and the arm length the slant angle (in degrees) of the truncated cone was calculated. Two cuffs and bladders of different shape (cylindrical and conical) of proper fit were built following the recommendations of the American Heart Association. The tronco-conical cuff had a 85.5° slant angle (bladder had proximal and distal length, respectively, of 45 and 35 cm). Sequential same-arm measurements were performed in triplicate by two observers using the two cuffs in a random order. The obese subjects (group 2) were compared with a group of individuals with normal upper arm circumference (< 32 cm, group 1). In group 2, the pressure transmitted to the arm surface under the centre of the two cuffs was also measured using a paper thin sensor.

RESULTS

The blood pressure differences between the two cuffs were negligible in group 1. In contrast, in the obese subjects of Group 2 the systolic blood pressure (SBP) and diastolic blood pressure (DBP) differences were 4.8±4.0 and 3.0±4.3 mmHg, respectively, and were significantly greater than in the control group (SBP, p< 0.001 and DBP, p=0.01, after adjustment for age an sex). These differences remained significant also after adjustment for BP at enrolment (p< 0.001/0.01). Among the obese participants, in a multivariable linear regression that included sex, age, height, upper arm length and systolic blood pressure, upper arm slant angle was an independent predictor of the between-cuff SBP difference (p=0.003). A close correlation was found between SBP at enrolment and the measurement error with the cylindrical cuff (r=0.55, p<0.001). In the subjects of the top SBP quintile (SBP≥150 mmHg), the between-cuff SBP difference was particularly elevated, being 9.1±5.1 mmHg.

Measurement of BP under the cuffs with the pressure sensor revealed that there was a loss of pressure under the cylindrical cuff which was proportional to the BP applied, with a mean difference of -10.2 ± 5.2 mmHg.

CONCLUSIONS

In people with morbid obesity, the upper arm has a pronunced tronco-conical shape and cylindrical cuffs may overestimate the true pressure especially in people with high SBP. Tronco-conical cuffs should be used for blood pressure measurement in individuals with very large arms.

INTRODUCTION

Arterial hypertension is widely recognized as one of the major cardiovascular risk factors in the western population.

Socially, hypertension can be defined the disease of the century, because it is increasingly recognized in a large number of populations scattered throughout most of the globe. From the scientific point of view, research on arterial hypertension can be summarized not so much as to exemplify the study of a morbid condition, though widespread and important, but to illustrate an area of study that provided us a broader and more detailed, integrated and analytical picture of the various control systems involved in blood circulation regulation. In medical terms, the control of arterial hypertension is a success that the medical science of our century can be proud, in a set of successes and failures, of certainties and doubts.

Over the last 40 years - from 1975 to 2015 - the number of people with arterial hypertension in the world has almost doubled, reaching 1.13 billion. The increase in the spread of this risk factor for many diseases (including stroke) occurred in low and middle income countries, while in high-income countries blood pressure values have generally declined. In 2015, 258 million (23 percent) of the 1.13 billion adults with hypertension lived in southern Asia (200 million in India) and others 235 million (21 percent) in East Asia (226 million in China). In the developed countries there has been a reduction in the prevalence of the disorder, a factor attributable to an improvement in overall health, increased consumption of fruit and vegetables, and a more frequent and earlier diagnosis associated with the availability of drugs for its control (1). The trend also affects Italy, where the prevalence of hypertension ranged from about 40 percent to about 30 percent in males and about 30 percent to less than 20 percent in women. In the North-East of Italy 37% of men and 29% of women have arterial hypertension. In Veneto the hypertensive people are: 33% of men and 28% of women. In the South of Italy and in the Islands 33% of men and 34% of women, in the North West 33% of men and 29% of women and in the Center 31% of men and 29% women are hypertensive (2).

The prevalence of arterial hypertension increases with age and part of this increase can be explained by the increasing trend of overweight-obesity (3). Hippocrates wrote "Corpulence is not only a disease itself, but the harbinger of others", recognising that obesity is a medical disorder that also leads to many comorbidities. This association is profoundly important for the affected individuals, but the associated morbidity is also economically damaging for society (4).

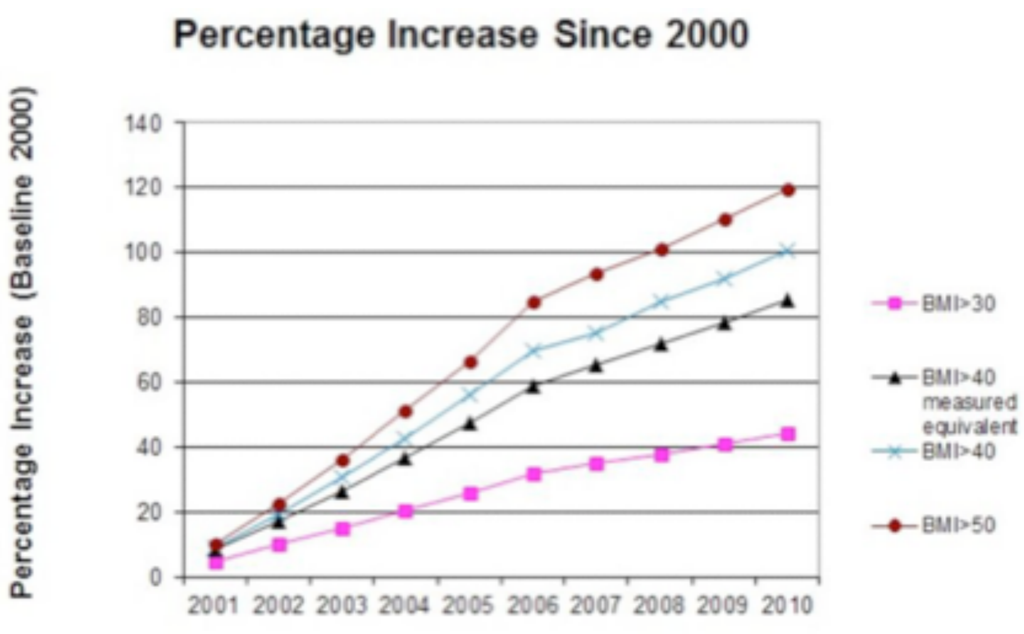
There are three measures of obesity often used in epidemiological studies: body mass index (BMI), waist circumference (WC) and waist to hip circumference ratio (WHR). The most commonly used is BMI which equals the ratio of weight in kilograms divided by height in meters squared (kg/m2). The classes of BMI reported by the WHO and CDC (Centers for Disease Control and Prevention) are, 18.5–24.9 kg/m2 for normal, 25.0–29.9 kg/m2 for overweight and ≥30 kg/m2 for obesity (Tab. 1) (5-10).

Table 1. Classification of overweight and obesity by BMI (Body Mass Index)

Classification	**BMI (Kg/m^2)**
Underweight	<18.5
Normal	18.5-24.9
Overweight	25.0-29.9
Obesity	≥30.0
-Class I	30.0-34.9
-Class II	35.0-39.9
-Class III ("extreme" or morbid obesity)	≥40.0

Between 1975 and 2016 the worldwide prevalence of obesity nearly tripled. In 2016, more than 1.9 billion adults aged 18 years and older were overweight; of these over 650 million adults (39%) were obese. Overall, about 13% of the world's adult population (11% of men and 15% of women) were obese in 2016. The prevalence of overweight and obesity among children and adolescents aged 5-19 has risen dramatically from just 4% in 1975 to just over 18% in 2016. The rise has occurred similarly among both boys and girls: in 2016 18% of girls and 19% of boys were overweight (11). According to the "Osservasalute 2016 report", which refers to the findings of the Multiscope Survey of Istat "Aspects of Daily Life", it emerges that in Italy, in 2015, more than one-third of the adult population (35.3%) is overweight, while one in ten is obese (9.8%); overall, 45.1% of subjects age ≥18 years are overweight. As in previous years, differences in the area confirm a North-South gap in which the southern regions have the highest prevalence of obese people (Molise 14.1%, Abruzzo 12.7% and Puglia 12.3%) and overweight (Basilicata 39.9%, Campania 39.3% and Sicily 38.7%) than the northern ones (obese: Bolzano PA 7.8% and Lombardy 8.7%, overweight: Trento PA 27.1% and Valle d'Aosta 30.4%).

Figure 1. Prevalence growth by severity of obesity



In particular, class III or extreme obesity (BMI ≥40.0 kg/m^2) (13) is emerging as a major public health problem in several developed countries (14–16), most notably in the US, where BMI ≥ 30, 40, or 50 kg/m^2 among adults has increased more than 2-, 4-, and 10-fold, respectively, since the mid-1980s (17) (Fig. 1). Subjects with BMI in the class III obesity range (40.0–59.9 kg/m^2) experienced substantially higher rates of death compared with those in the normal BMI range

(18.5–24.9 kg/m^2), with most of the excess due to deaths from heart disease, cancer, and diabetes. These higher rates appear to be largely attributable to metabolic abnormalities associated with excess adiposity, including diabetes and hypertension.

The association between obesity and hypertension is well documented at the epidemiological level and in NHANES studies there appears to be a linear relationship between blood pressure and body weight, even in normal subjects, although with a different degree in different ethnicities.

Accurate blood pressure measurement is a prerequisite for proper management of hypertension, with regard to both the ability of the physician and the choice of reliable and suitable equipment.

HISTORICAL NOTES ON BLOOD PRESSURE MEASUREMENT

Before the appearance of specific tools the doctor had only one way to evaluate blood pressure of a patient: to press a finger on the radial artery and judge empirically if the systolic peak was strong or weak. The first experimental measurements were attempted by Hales in 1773: applying to the artery of a horse a glass tube he was able to measure the height and the oscillation of the column of blood, later the tube was replaced with a simpler mercury manometer; the measurements were always cruel, dangerous and very rough, so they could not find a practical application in humans. Poiseuille, in 1828, improved the experiment using a mercury manometer and filling with potassium carbonate the connection with the artery to prevent the coagulation. With this tool, called "hemodynometer", he showed that the blood pressure increases and decreases with expiration and inspiration. In 1857 it was designed an interesting mechanical device called "sphygmograph": attached to the wrist gave a graphic registration of pressure curve.

Around the second half of 1800 the idea of applying an inflatable cuff to a mercury manometer allowed to obtain more reliable measurement but these tools because of their complexity and fragility were relegated to laboratories (Fig. 2). Is due to Von Basch, Potain and subsequently to Scipione Riva-Rocci (1863-1937) the merit of having them processed into manageable units and affordable for all; the current mercury sphygmomanometers are very similar at least in principle to those of Riva-Rocci (Fig. 3).

Figure 2 – Sphygmograph (1857)

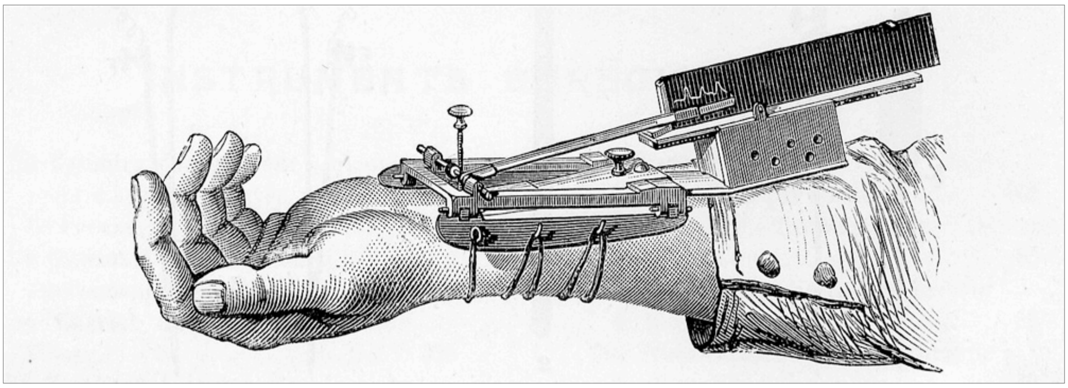


Figure 3 – Riva-Rocci sphygmomanometer (1896)

Even before the end of the 19th century there were descriptions of the clinical condition known since 1911 as essential hypertension but these were based on anatomic-pathological material rather than measuring blood pressure. Schaarschmidt and Nicolai (1752) talk about patients with spastic constriction of vascular bed and whose bloodstream was characterized by a state of "vehement agitation" which can cause vascular and bleeding conditions.

In 1836, Bright showed the frequency with which cardiac hypertrophy occurred in patients with albuminuria; he advanced the hypothesis that an alteration of small vessels and capillaries required greater cardiac activity to force the blood through distant districts of the vascular system; an affirmation that, translated in mechanical terms, was equivalent to recognizing that an increase in blood pressure would have to occur.

GUIDELINES AND GENERAL ASPECTS OF BLOOD PRESSURE MEASUREMENT

The correct blood pressure (BP) measurement is a problem still discussed by researchers around the world. Blood pressure is a hemodynamic parameter subject to extreme physical and environmental variability and influenced by many factors.

That's why we enforce guidelines codified and accepted unanimously.

Before measuring the blood pressure you must allow the patient to remain at rest for a short time (5 min) in a quiet and comfortable environment. Also you must advise the patient not to speak before the measurement and not to cross the legs. It is necessary to perform multiple measurements, one next to the other, until you get a medium pressure constant (18), because only the application of the cuff can cause a transient increase in blood pressure.

Whatever the position of the patient, but mostly upright, it is important that the subject's arm is supported by the observer at the level of the elbow; this procedure avoids the patient to perform an isometric exercise that can induce a increased blood pressure and heart rate (19).

Support the arm at heart level is also important for measurement accuracy; if the arm is below heart level there is a overestimate of systolic and diastolic blood pressure, while there is a blood pressure underestimate if the arm is kept above (20).

Even with the patient in the supine position, if it is not observed this rule, you may encounter an error up to 5 mmHg for diastolic pressure. Using computed tomography it is seen that, with patient in supine position, the right atrium is located about halfway between the surface of the bed and the breastbone; for this reason it is necessary to place a support under the arm and pulling up to the desired level (21).

The arm should be totally free from clothes, with the palm of the hand facing up.

The measurement should not be done hastily, the doctor should not swell and deflate the cuff too quickly, since this maneuver can lead to underestimating the systolic pressure and overestimating diastolic blood pressure.

Once the position and the appropriate conditions have been reached, the cuff should have a lower margin of 2-3 cm above the point where brachial artery pulse is sought (22-23).

The cuff contains the bladder which, when inflated, causes the occlusion of the brachial artery; because the pressure applied on the vessel is homogeneous it is necessary that the bladder is centered on the artery. The stethoscope should be placed over the brachial artery without exerting excessive pressure with the diaphragm, to avoid producing sounds that can distort the artery and alter the procedures.

The results of auscultatory observation largely depend on the accurately identified and interpreted Korotkoff tones.

Errors in measurement can occur at different times, but the weak link remains the human component, that is, the observer. The most common errors associated with the observer are: the systematic inability to perform correct measurements, the "digit preference" (preference for a digit and rounding) and prejudice or preconceptions linked to the observer about how "should" be the blood pressure.

In the blood pressure measurement the cuff should be inflated 30 mmHg over the pressure at which the radial pulse is no longer palpable and deflated constantly with speed not exceeding 2-3 mmHg/sec.

For the correct determination of systolic blood pressure phase I has been chosen by Korotkoff (onset of sounds).

For the correct determination of diastolic blood pressure was chosen the phase V of Korotkoff (disappearance of tones).

After the disappearance of the tones the cuff should be deflated quickly and completely to prevent venous congestion in the arm before you repeat a measurement. (table 2).

Table 2. Korotkoff sounds

Phase I	The first appearance of faint, repetitive, clear tapping sounds which gradually increase in intensity for at least two consecutive beats is the systolic blood pressure.
Phase II	A brief period may follow during which the sounds soften and acquire a swishing quality
Auscultating gap	In some patients the sounds can disappear for a short time
Phase III	The return of sharper sounds, which become crisper to regain,

	or even exceed, the intensity of phase I sounds. The clinical significance of phases II and III has not been defined.
Phase IV	The distinct abrupt muffling of sounds, which become soft and blowing in quality.
Phase V	The point at which all sounds finally disappear completely is the diastolic pressure.

CHARACTERISTICS OF CUFF AND BLADDER

Blood pressure measurement is based on the occlusion of the brachial artery through of a bladder contained in a cuff attached to a sphygmomanometer. The bladder, which is the key element for blood pressure measurement, is made of rubber and is contained in anelastic "shirt", the cuff, whose length should extend beyond the end of bladder itself. While the size of the bladder has always been a point of discussion, there is no indication of the length/width of the cuff that holds it.

Incorrect use of the cuff/bladder can lead to inaccurate blood pressure measurements; a cuff with a bladder of inadequate size compared to the patient's arm represents an important factor of error. This is a problem that is usually neglected in clinical practice, but is a source of errors and confusion.

It has been demonstrated by more than a century (24) that an inappropriate size bladder respect to the patient's arm will cause a systematic error in measuring blood pressure; if the bladder is too wide the pressure will be underestimated, if the bladder is too narrow the pressure will be overestimated; This last mistake can lead to a false diagnosis of hypertension and occurs especially when using a standard cuff for adults on obese individuals, or in general with large arms (25). From the observation of this phenomenon, in 1960 the term "cuff hypertension" was coined (26).

In 1978, Geddes agreed with the recommendations of the American Heart Association, which indicated the use of bladder with width equal to arm diameter increased by 20%. Since it was easier to measure the circumference of the arm rather than deriving the diameter measurement, he simplified this indication suggesting that the bladder should be wide about 40% of the circumference of the arm (27). Regarding the length of the bladder, Geddes did not make any indications, but confirmed that if it was too short, it determined an overestimation of the pressure values and, if it was too long, led to an underestimation (28).

In 1982 Maxwell conducted a study on 1240 obese patients: obtained a correction formula for different bladder measurements applied to arms of different sizes and calculated precise correction factors for each bladder. While the American Heart Association advised using Maxwell's correction boards, the British Hypertension Society suggested using a single cuff containing a 12.5x35 cm bladder (for very obese patients, it suggested also a bladder lenght of 42 cm); bladders with a width of 15 cm were also not recommended because they were not practical especially in patients with short arms. In the 80's and 90's, clinical trials were mainly aimed at assessing the width/length ratio of the bladder; the best value deducted was 0.4.

In 1993, the American Heart Association, influenced by Ratsam's studies, recommended that the bladder have the following dimensions: 40% of the length that should be at least 80% of the arm circumference in adults (100% in children).

According to recent data, the use of a too narrow or short bladder leads to an overhang of the blood pressure with a 3.2/2.4-12/8 mmHg error range (up to 30 mmHg) in obese subjects (29); the use of an over-long or long bladder results in underestimation of pressure values with a range of 10-30 mmHg. The most common mistake is the first, that is, the use of underdimensional cuff with the risk of diagnosing as hypertensive subjects who are actually normotensive (30).

BLADDER

The dimensions of each bladder must be clearly indicated on the outside of the cuff on which there is normally a colored marker indicating the center of the bladder.

The bladder LENGTH is a key point in the pressure area applied to the brachial artery; if the bladder is too short the blood pressure will be overestimated since the pressure will not be fully transmitted to the artery.

As mentioned earlier, some authors reported that with 35 cm long bladder, or long enough to completely wrap the subject's arm, measurements were better correlated with direct intra-arterial recordings and reduced intersubjective variation (31). Subsequent studies have not always confirmed these conclusions (32) and have pointed out that with the use of standard bladder (12x23 cm) and obesity cuff (with bladder 15x39 cm) there was an underestimation of systolic blood pressure compared to intrarterial direct measurement (measured in femoral artery); considering the diastolic blood pressure, however, there was no significant difference between direct and indirect measurement with wide cuff although with the increase in arm circumference there was a small overestimation with the latter method. With the use of a standard bladder on obese patients, the diastolic blood pressure was significantly higher than intrarterial measurement and error increased proportionally to arm size (33).

There is a common agreement on the importance of the use of cuff with adequate size even if uniformity has not been achieved over the years in the measurements of the bladder contained in the cuff. For the moment it is recommended that the bladder length is at least 80% of the arm circumference. Despite these recommendations, most of the cuff on the market have a bladder that measures only 23 cm in length and would only be adequate when the arm circumference is within 28 cm; if you do not have cuff with larger bladder, it is recommended at least that the central part of the bladder (usually marked by a colored mark on the bracelet) is positioned directly above the artery. (34).

The WIDTH of the bladder determines the length of the artery segment that is occluded during the measurement. The use of a too narrow bladder produces an overestimation of blood pressure, but it is calculated that the error is not as significant as that resulting from the use of a too short bladder. In 1986, the British Hypertension Society confirmed that the width of the bladder should be 40% of the circumference of the upper arm (between 12 and 15 cm depending on whether the arm was normal or large). In 2004 this indication was revised by fixing the width of the bladder to 12 cm regardless of the arm size.

The British Hypertension Society guidelines (BHS IV) recommend the use of:

• a standard cuff with a bladder measuring 12x26 cm for adults (maximum arm circumference 33 cm);

• a cuff with a bladder measuring 12x40 cm for obese (maximum arm circumference 50 cm);

• a small cuff with 12x18 cm bladder for thin adults and children (maximum arm circumference 26 cm). (35) (Tab. 3)

Table 3 - Guidelines BHS IV Cuff size, O'Brien et al, 1997

Cuff	**Bladder**	**Arm circumference**
"Small"	12x18 cm	up to 26 cm
"Standard"	12x26 cm	up to 33 cm
"Big"	12x40 cm	up to 50 cm

The American Heart Association (AHA) recommends 4 cuff (Tab.4) (36):

• a small adult cuff with a 12x22 cm bladder for upper arms with a circumference between 22 and 26 cm;

• a standard adult cuff with a 16x30 cm bladder for upper arms with a circumference between 27 and 34 cm;

• a big adult cuff with a 16x36 cm bladder for upper arms with a circumference between 35 and 44 cm;

• a very big adult cuff with a 20x42 cm bladder for upper arms with a circumference between 45 and 52 cm.

Table 4 - Guidelines AHA Cuff size, Pickering et al., 2005 (36)

Cuff	**Bladder**	**Arm circumference**
"Small"	12x22 cm	22-26 cm
"Standard"	16x30 cm	27-34 cm
"Big"	16x36 cm	35-44 cm
"Very big"	20x42 cm	45-52 cm

Subsequently interchangeable cuff (Tricuff, 9x26 cm, 12x37 cm, 15x46 cm) were constructed, depending on the arm size, that can provide good performance in patients with a larger arm (37). Compared with intra-arterial measurement, Tricuff tended to underestimate of 3/5 mmHg systolic blood pressure in subjects with 30-31 cm upper arm circumference and of 8/10 mmHg in subjects with upper arm circumference > 36 cm (38). The application of this product did not find widespread use because of rigid conformation of the cuff and its high cost.

SHAPE BLADDER

Cuff and bladder for the measurement of blood pressure are characteristically rectangular. The observartion of morphology arm, which, especially in obese subjects, has a more noticeable tronco-conical shape, led Steinfeld to propose a trapezoidal bladder that best suited to the shape of the arm (39). Based on this, Huige created a cuff with tronco-conical bladder that proved most accurate in measuring the blood pressure in obese people compared to invasive measurement

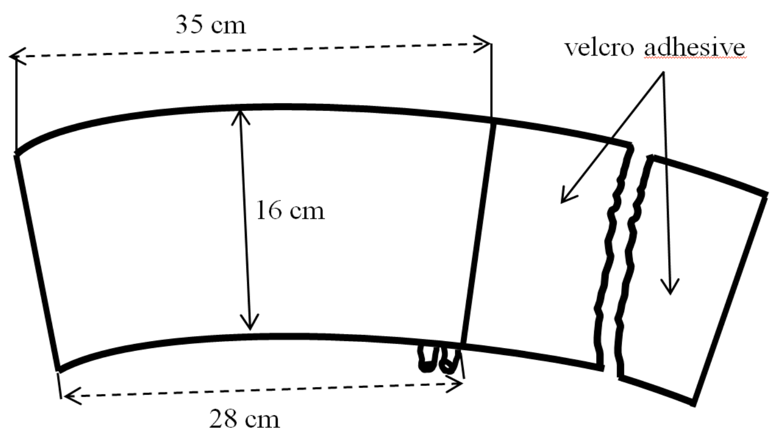
(40). Maxwell confronted Huige's cuff (Fig. 4) with two rectangular-shaped cuffs (12x32 cm and 15x32 cm bladder) with the purpose of evaluating its application in a wide range of upper arm circumference, to propose the use of this cuff in the general population. The large rectangular cuff has been used on patients with arm circumference > 34 cm; in 589 subjects, with a wide range of arm circumference, 2 blood pressure measurements were performed with each cuff (rectangular and tronco-conical) alternating the order in the different subjects. After the analysis of systolic blood pressure differences, four categories of subjects were identified: I category in which the tronco-conical cuff measured higher values than the appropriate rectangular cuff (12,7%), II category in which identical values were obtained with the two cuffs (13.4%), III category in which lower measurements were obtained with the experimental cuff (73.9%), IV category in which the measurements obtained with the tronco-conical cuff were less than 10 mmHg or more than the traditional cuff (22,2%). The same classification was also performed for diastolic blood pressure (I cat 10.9%, II cat 14.8%, III cat 74.4%, IV cat 18.2%). On average, the measurements obtained with tronco-conical cuff were lower than 4.5 mmHg for systolic blood pressure and 4.2 mmHg for diastolic blood pressure; no correlation was found between these blood pressure differences and the arm circumference.

Despite these results, the use of tronco-conical cuff raised practical problems when applied to small and medium-sized arms (upper arm circumference < 30 cm) in which it was often too wide in the proximal part of the arm and too adherent in the distal part (due to the predominantly cylindrical shape of this type of arm). In larger arms (circumference > 34.5 cm), more frequently with tronco-conical shape, the problem was the poor adherence of the rectangular cuff to the distal part of the arm that was partially solved by crossing the two flaps of the cuff diagonally.

The fact that with the tronco-conical cuff there would be lower pressure values, regardless of the circumference of the arm, was enigmatic; probably this was due to the fact that, on small arms, the cuff was disproportionate because it was too large ("wide cuff effect") and there was a scatter of energy compressing the artery. The poor adherence of the rectangular cuff to individuals with large arms could explain higher measurements in these subjects.

In conclusion, despite the result obtained in this study, the use of the tronco-conical cuff was proposed only in subjects with large arms, in which the arm conformation improved the adherence of the bladder (41). The figure 4 shows Huige's cuff, also used by Maxwell, where the bladder measures 35x28x16 cm.

Figure 4 - Huige's cuff



In a subsequent study (42), intra-arterial pressure was compared with the pressure obtained using cuffs of various sizes (bladder: 12x23 cm, 12x30cm, 14x30cm, 14x38cm, tronco-conical 16x35 [proximal] 28 [distal] cm) in order to assess whether one of these was effective in all adults irrespective of the size of the arm. 37 subjects with wide range of arm circumference (23-48cm) and enrolled blood pressure values (46-122 / 109-222 mmHg) were subjected to direct measurement in left brachial artery and 3 measurements with each type of cuff in random order. As the size of the bladder increased, there was reduction of auscultated blood pressure values than those obtained with intra-arterial measurement. This effect was most noticeable in subjects with larger arms, in which using the two smaller cuffs, an overshoot of the blood pressure values was obtained (12x23cm cuff 10[SD 8-1]mmHg; 12x30cm cuff 7[SD6-9]mmHg). This study showed that the blood pressure differences between auscultatory and intra-arterial method in obese subjects are acceptable only when using appropriate cuff and that these differences cannot be estimated in advance based on the size of the arm. In subjects with normal sized arms measurements, obtained with standard cuff, proved accurate.

The tronco-conical cuff, however, showed some problems of adherence to the arm being too broad on many subjects, for which it was considered impractical.

Among the cuffs used, the cuff with 14x38cm bladder had shown better accuracy in all subjects; in this study, it was concluded that the sizes of the bladder were less significant than usually deemed and it was claimed the use of only cuff (with 14x38 cm bladder) in common clinical practice.

BLOOD PRESSURE MEASUREMENT IN OBESE PEOPLE

Conditions for optimal blood pressure measurement include (43-44):

- full explanation of the procedure and proper patient's education
- correct attitude of patient and observer
- correct posture of the patient
- arm support
- arm position at heart level
- proper arm selection
- selection of cuff and bladder of adequate size.

Obesity is an emerging problem in developed countries and may result in inaccurate blood pressure measurements (45-46). Choice of an appropriate cuff and bladder size is an essential prerequisite for accurate blood pressure assessment. Use of cuffs containing bladders of inappropriate dimension is the source of measurement errors, which may lead to misclassification of patients' blood pressure levels in clinical practice (29). Undercuffing is responsible for a spurious overestimation of blood pressure in patients with large arms leading to overdiagnosis of hypertension, whereas overcuffing may be responsible for an opposite problem, leading to erroneous underestimation of blood pressure levels. Also for obese people, the cuff should be tailored according to the arm circumference and patients with severe obesity will often require the use of extralarge sized cuff. The appropriate cuff size in obese individuals depends not only on the arm circumference but also on its shape. A conical shaped arm, common in obese individuals, makes it difficult to fit the cuff to the arm, increasing the likelihood of inaccurate blood pressure measurements (43). According to results from Bonso et al (47), the shape of the upper arm is tronco-conical in virtually all individuals. The difference between the proximal and the distal upper arm circumferences ranged from 1 to 20 cm, with an average value of 8.7cm. The conical shape of the arm may vary according to gender, degree of obesity, and arm circumference. When the arm circumference near the shoulder is much greater than the arm circumference near the elbow, a preshaped cylindrical cuff may provide inaccurate blood pressure measurements. In this condition, the elbow end of the cuff will remain loose and will expand irregularly over the lower part of the arm and the use of a cylindrical cuff may cause an overestimation of the true blood pressure. This phenomenon is more likely to occur in people with large upper arm and when cuffs made of semi-rigid material are used. If a semi-rigid cylindrical cuff is used in large-size conical arms may provide inaccurate readings because the distal part of the cuff will remain loose and will transmit a lower pressure to the subcutaneous tissue overlying the artery. In a study of our group, when a semi-rigid cylindrical cuff was used in combination with an automatic oscillometric device, it clearly overestimated systolic blood pressure in a group of subjects with mid arm circumference >30cm. In contrast, when the conical cuff was used the device provided accurate readings, with similar device-observer differences in the group with standard arm and the group with large arm, according to Maxwell study. Furthermore in a group of 30 subjects with arm circumference 37.5–42cm, we showed that a soft cylindrical cuff overestimated blood pressure measured with a tronco-conical cuff by 2.4/1.8 mmHg indicating that the choice of the appropriate shape for the bladder may be a key element for obtaining an accurate auscultatory blood pressure measurement even when cuffs are made of a soft material.

In patients with morbid obesity, very large arm circumferences may be found in combination with short upper arm length. In these patients measurement with a cuff of the appropriate size is often difficult in the presence of a short humerus lenght because the elbow end of a large cuff may extend past the elbow by several centimeteres. According to the AHA recommendations (36), for arm circumferences ranging from 35 to 44 cm a bladder measuring 16 cm in width should be used. For circumferences from 45 to 52 the bladder width should be 20 cm (48), but in patients with short upper arm length, a 16 cm wide cuff should better be used (36). Results from our laboratory obtained in 349 subjects indicate that these bladders are not suitable for many individuals. According to our data, arm length was <20cm in 22% of the subjects and <16 cm in 0.6% of the subjects (44). Thus, a large arm often cannot be correctly cuffed. The practical consequence is that special cuffs that can accommodate large and very large arm sizes are needed.

OBJECTIVES OF THE STUDY

The literature shows that our knowledge of the optimal dimensions of the cuff and bladder used for auscultatory blood pressure measurement is still very limited. One aspect that has often been neglected is that of the optimal shape of the cuff in large arms, as the literature data is very scarce and partially controversial. In recent decades, despite the great advances in technology in the field of automatic equipment, little attention has been paid to the problems associated with the performance of cuffs in the obese. When the arm circumference near the shoulder is much larger than the circumference of the arm near the elbow, a cylindrical (rectangular) cuff will expand irregularly on the lower arm making it difficult to perform a reliable measurement. Conical arms may be commonly encountered in obese patients, and may be a major source of inaccurate blood pressure measurements. Recent epidemiological data document a greater prevalence of obesity among US adults, resulting in a significant increase in the population of the mean arm circumference. The results of a previous study have shown that in patients with large arm circumference (up to 42.5 cm) the use of a cylindrical cuff, even of adequate size, can lead to imprecise pressure measurement (49). The problem is even more controversial in people with morbid obesity due to the pronounced troncoconical shape of the upper arm. In this study we investigated the effect of the shape of the cuff on blood pressure measurement in obese subjects with arm circumference > 42 cm by comparing the blood pressure readings obtained with a cylindrical and a tronco-conical cuff with the same width.

MATERIAL AND METHODS

We enrolled for this study 33 individuals that met the following criteria: age of at least 18 years old and upper arm circumference between 42 and 50 cm (group 2). These subjects (group 2) were compared with a group of 33 individuals with normal upper arm circumference (< 32 cm, group 1). We have recruited patients attending general medical outpatient clinics at the Padova University Hospital. All individuals agreed to partecipate in the protocol and gave informed consent. The study was approved by the Ethics Committee.

Sample size calculation

On the basis of our previous work (49), considering an alpha level set at P= 0.05 and a required power set at 0.8, we calculated that 26 subjects per group would allow us to detect a mean between-cuff SBP difference of 4.0 mmHg (comparing the 2 groups), assuming a standard deviation of 5.0 mmHg. Seven more subjects per group were enrolled to account for possible measurement failures or missing data in final analysis**.**

Measurements

Body weight and height, arm length, proximal, medial and distal circumference of upper arm, biceps and triceps skinfold, and office blood pressure were measured.

For measurement of arm dimensions, partecipants were placed in the supine position with arms resting comfortably at the sides with forearms in the pronated position. Upper arm lenght was measured from the axilla to the antecubital fossa; arm proximal circumference was measured just below the axilla eand distal circumference just above the antecubital fossa to the nearest 0.5 cm with a measuring tape. Upper arm middle circumference was measured at the midpoint from the acromion to the olecranon.

The circumference of the extremity at the proximal and distal limits of the segment, together with the lenght between them, was used to calculate the slant angle (in degrees) using the formula:

slant angle=arccosine $[(C_1-C_2)/(2\pi \times L)] \times (360/2\pi)$

in which "C_1" is the arm proximal circumference, "C_2" is the arm distal circumference and "L" is the arm lenght. Skinfold thickness was measured in triplicate at the triceps and biceps with a manual caliper; the average of the six measurements was defined as skinfold thickness. Blood pressure was measured with a mercury sphygmomanometer in the sitting position. BMI was calculated as body weight divided by height squared.

Cuffs

Two different cuffs (cylindrical and tronco-conical) with adequate bladders were constructed (El. Med Garda S.r.l, Costermano, Italy) following the recommendations of the American Heart Association (AHA) for arm circumeferences ranging from 42 to 50 cm. Both tronco-conical and cylindrical bladders had a lenght that was 80% and a width that was at least 40% of arm circumference at the midpoint (respectively, 40 x 20 cm on the center).

The tronco-conical cuff had a 85.5° slant angle (its bladder had proximal and distal length, respectively, of 45 and 35 cm).

The cuffs were formed of two layers of soft, pliable, polymer that was strong enought for repeated inflations.

Procedures

The procedure followed were in accordance with institutional guidelines. We compared systolic and diastolic blood pressure, measured with a conical and cylindrical cuffs connected to a mercury sphygmomanometer. Each participant served as his/her own control with blood pressure measured with both cuffs. The primary dependent variables were the difference in systolic and diastolic blood pressure measurements between the two cuffs. Blood pressure measurements were performed by two persons experienced in device validation using similar procedures to those recommended by the 2010 European Society of Hypertension (ESH) guidelines for validation of blood pressure measuring devices (50). The two observers used for the present study (E.B. and C.F.) participated in previous published validation studies (51-57). Blood pressure was measured simultaneously by the 2 experienced observers using a binaural stethoscope. Before starting the study, the two observers did a period of training to check their concordance in blood pressure measurement. The 2 observers were blinded to the measurement values of each other and took blood pressure measurement with a mercury sphygmomanometer. For analysis, the results of the two observers were combined. The deflated cuffs were snugly applied to the upper arm with the centre of the bladder over the medial surface of the arm. Three pairs of measurements were performed with the cylindrical and conical cuff, in alternating order. All readings were taken using diastolic phase V. The difference between systolic and diastolic blood pressures in the 3 pairs of measurement were then calculated. The patient was kept in the sitting position and relaxed for at least 5 minutes to reduce as far as possible the factors that may increase blood pressure variability (anxiety, white coat effect).

In the participants of group 2, the pressure present in the inflated cuffs was measured on the arm surface under the cuff at five different pressure levels (60, 90, 120, 150 and 180 mmHg). The pressure on the arm surface was measured using a paper-thin pressure sensor attached to the central point of the cuffs and connected to a pressure transducer (Microlab, Padua, Italy). At each pressure level, three readings were collected and averaged with both the cylindrical and the tronco-conical cuffs using the same sequence employed for blood pressure measurements.

Statistical analysis

Data are presented as mean ± SD unless specified. For comparisons between groups an ANCOVA test was used adjusting for age and sex. Relations between continuous variables were assessed using Pearson's correlation. Predictors of between cuff pressure discrepancies were included in multivariable linear regression analyses. A P value of 0.05 or less was considered as statistically significant.

RESULTS

Subjects' characteristics

We compared two groups of people: group 1 with middle upper arm circumference < 32 cm (control group) and group 2 with upper arm circumference >42 cm.

Group 2 (obese subjects). Obese participants' mean ± SD age was 51 ± 12 years, systolic blood pressure was 127 ± 21 mmHg, diastolic blood pressure was 78 ± 13 mmHg and BMI was 45 ± 5 kg/m^2. Mean upper arm proximal, middle and distal circumferences were 48.4 ± 4.0, 44.8 ± 2.7 and 34.0 ± 2.8 cm, respectively. Arm length was 22.1 ± 2.0 cm. Upper arm shape was tronco-conical in all of the participants with slant angles ranging from 80.4 to 87.6° (mean 84.1 ± 1.4°) and middle angle from 86.1 to 89.4° (mean 88.1 ± 0.8°) (Tab.5). Thus, the circumference near the shoulder was always greater than the circumference near the elbow. These data indicate that in the obese, the upper arm shape is actually represented by the sum of two truncated cones with different slant angles having the lower frustum a sharper angle than the upper one (Fig. 5). The 60% of the group takes on antihypertensive treatment and all patients are followed with regular outpatient follow-up for obesity.

Group 1 (control group). The control group had a similar age and systolic blood pressure (132 ± 22 mmHg) and diastolic blood pressure (77 ± 12 mmHg). The number of males and females was the same in the 2 groups (16 males, 17 females). BMI was 24.2 ± 4.5 kg/m^2. Mean upper arm proximal, middle and distal circumferences were 30.2 ± 3.4, 26.9 ± 2.9 and 24.3 ± 2.7 cm, respectively. Arm length was 20.6 ± 1.3 cm. Upper arm shape was tronco-conical in all but the slant angle was greater than in group 2 ranging from 85.9 to 89.2° (mean 87.4 ± 0.8°) and the middle angle had a similar width to the upper one ranging from 85.5 to 89.2° (mean 87.7 ± 0.9°). Thus, the two truncated cones in these leaner subjects had a similar shape (Tab. 6).

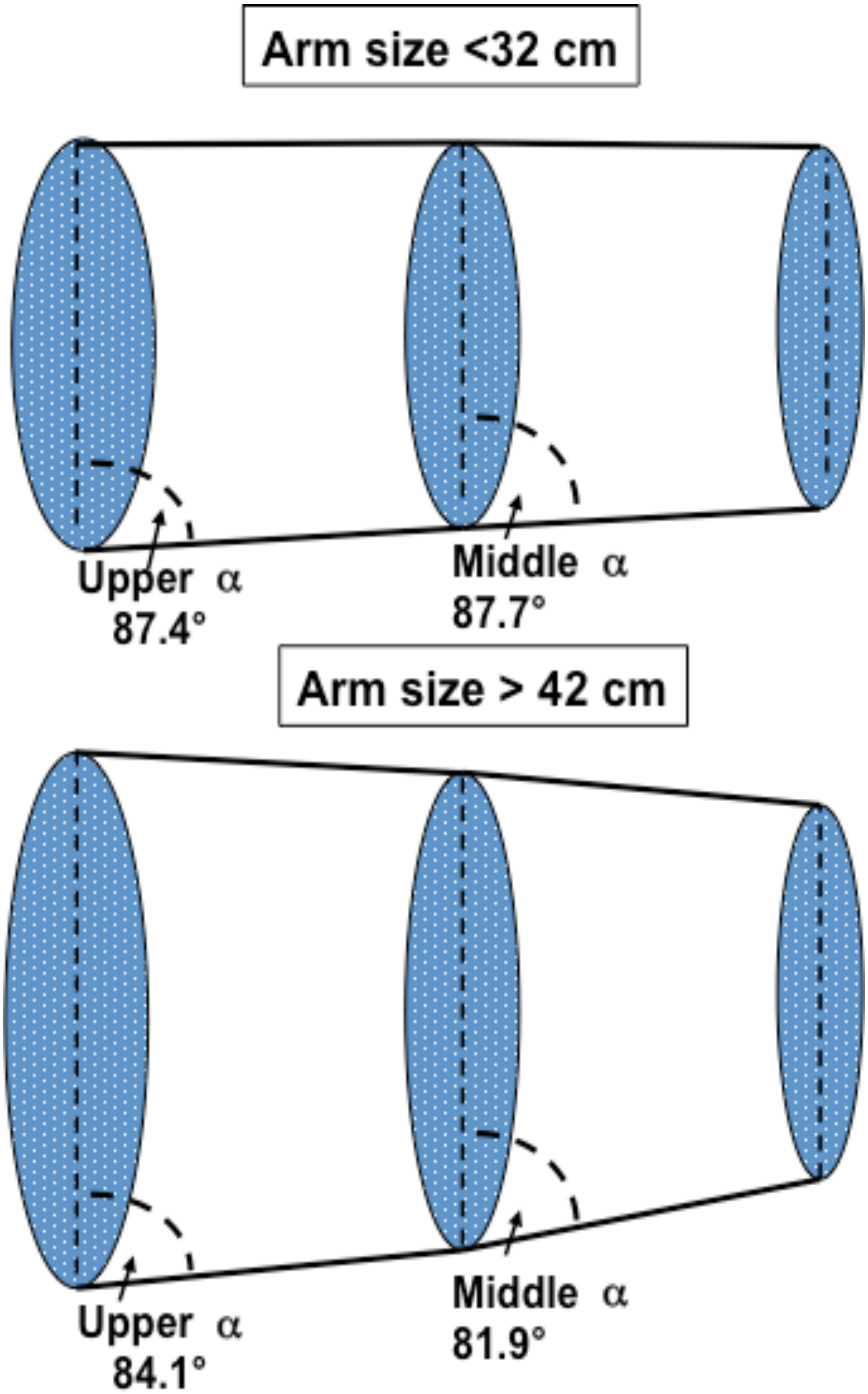
Table 5. Group 2 (obese subjects) characteristics

Variable	**N of Cases 33 (16 males)**	
	Mean	**S.D.**
Age (years)	51.30	12.22
Weight (Kg)	126.33	35.59
BMI (Kg/m^2)	45.04	4.66
Upper arm length (cm)	22.14	2.07
Upper arm proximal circumference (cm)	48.44	4.04
Upper arm middle circumference (cm)	44.80	2.73
Upper arm distal circumference (cm)	34.06	2.84
Skinfold thickness (cm)	2.90	0.46
Upper arm slant angle (°)	84.08	1.44
Upper arm middle slant angle (°)	88.14	0.76
SBP (mmHg)	127.12	20.65
DBP (mmHg)	77.88	13.14
SBP difference between conical and cylindrical cuff	-4.83	4.05
DBP difference between conical and cylindrical cuff	-2.96	4.27

Table 6. Group 1 (control group) characteristics

Variable	**N of Cases 33 (16 males)**	
	Mean	**S.D.**
Age (years)	51.33	18.84
Weight (Kg)	66.46	14.53
BMI (Kg/m^2)	24.24	4.50
Upper arm lenght (cm)	20.64	1.28
Upper arm proximal circumference (cm)	30.21	3.39
Upper arm middle circumference (cm)	26.97	2.92
Upper arm distal circumference (cm)	24.33	2.69
Skinfold thickness (cm)	1.13	0.45
Upper arm slant angle (°)	87.43	0.76
Upper arm middle slant angle (°)	87.70	0.99
SBP (mmHg)	132.61	22.60
DBP (mmHg)	77.21	11.76
SBP difference between conical and cylindrical cuff	-0.92	3.29
DBP difference between conical and cylindrical cuff	-0.65	2.65

Figure 5. Upper arm shape in group 1 and in group 2



Cylindrical versus conical cuff

Systolic and diastolic blood pressure differences (SBP and DBP) between the pressures obtained with the two cuffs in the two groups are presented in Fig. 6.

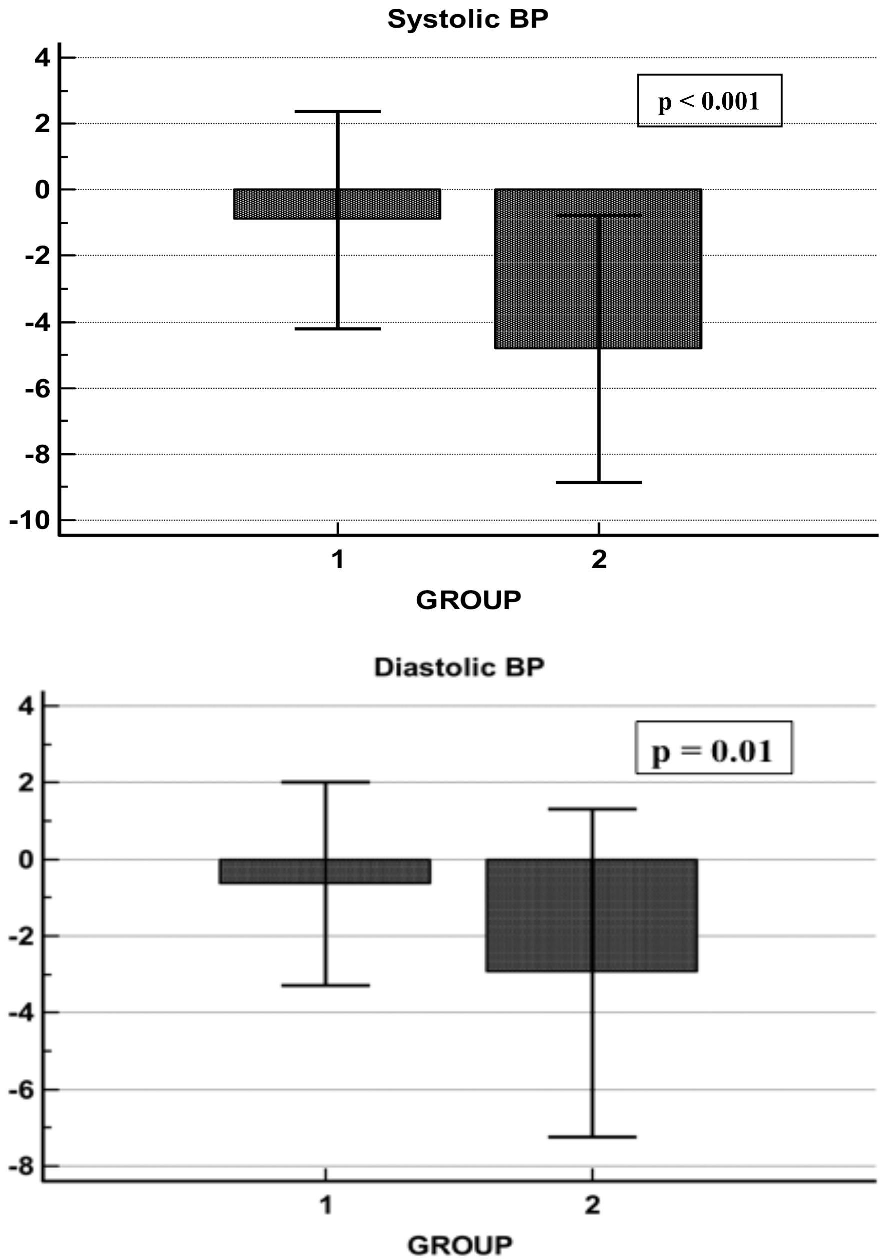


Figure 6. Systolic and diastolic blood pressure (BP) discrepancies between the tronco-conical and the cylindrical cuff in the two groups. Data are mean ± SEM and are adjusted for age and sex. Results of ANCOVA: SBP, group 2 $p < 0.001$ versus group 1; DBP,group 2 p=0.01 versus group 1.

A negative value indicates that cylindrical cuff blood pressure measurement is greater than the tronco-conical cuff measurement. Blood pressure differences were negligible in group 1. In contrast, in the obese Group the SBP and DBP differences were -4.8 ± 4.0 and -3.0 ± 4.3 mmHg and were significantly greater than in the control group (SBP, $p < 0.001$ and DBP, $p=0.01$, after adjustment for age an sex). These differences remained significant also after adjustment for blood pressure at enrolment ($p < 0.001/0.01$). Thus, the cylindrical cuff overestimated both SBP and DBP measured with the tronco-conical cuff.

Among the obese participants, in a multivariable linear regression that included sex, age, height, upper arm length and enrolled systolic blood pressure, upper arm slant angle was an independent predictor of the between cuff systolic blood pressure difference ($p=0.003$) (Tab. 7); the level of statistical significance was reduced after skinfold thickness was included in the model ($p=0.027$). The association between the SBP difference and the slant angle remained significant in both men ($p=0.039$) and women ($p=0.032$) considered separately. The variance inflation factor was < 3 in all models. When the upper slant angle was excluded from the regression model, other independent predictors of the blood pressure difference were lower truncated cone slant angle ($p=0.056$), skinfold thickness ($p=0.046$) and upper arm middle circumference ($p=0.039$) (Tab. 8-9-10). In contrast, in the control group no variable showed a significant association with the between-cuff SBP differences (Tab. 11). For diastolic blood pressure differences, no association was found with any variable in either group.

Table 7. Multivariable linear regression analysis using the between-cuff difference as the dependent variable (Group2)

	SBP difference between conical and cylindrical cuff					
	Coefficient	**STD Er**	**STD Coef**	**Tolerance**	**T**	**p-value**
Costant	-76.818	29.757	0.000		-2.581	0.016
Conic angle[a]	**1.197**	**0.367**	**0.425**	**0.786**	**3.265**	**0.003**
Age	-0.086	0.043	-0.260	0.805	-2.016	0.054
Sex	2.078	1.297	0.261	0.504	1.602	0.121
Height	-0.114	0.067	-0.335	0.341	-1.693	0.103
Arm lenght	0.131	0.314	0.067	0.519	0.418	0.680
*SBP**	-0.087	0.030	-0.444	0.568	-2.900	0.007
*= Systolic Blood Pressure [a]=Upper arm slant angle						

Table 8. Multivariable linear regression analysis using the between-cuff difference as the dependent variable (Group2)

	SBP difference between conical and cylindrical cuff					
	Coefficient	**STD Err**	**STD Coef**	**Tolerance**	**T**	**p-value**
Costant	-22,7034	21,7901	0,0000	.	-1,0419	0,3070
Sex	2,6520	1,4124	0,3327	0,5198	1,8777	0,0717
Age	-0,0894	0,0471	-0,2702	0,8047	-1,8974	0,0689
Height	-0,1171	0,0744	-0,3450	0,3395	-1,5733	0,1277
Arm length	0,1233	0,3481	0,0631	0,5144	0,3544	0,7259
*SBP**	-0,0638	0,0315	-0,3254	0,6328	-2,0265	0,0531
Middleangl[a]	**0,5323**	**0,2671**	**0,2801**	**0,8267**	**1,9934**	**0,0568**
*= Systolic Blood Pressure [a] = Lower truncated cone slant angle						

Table 9. Multivariable linear regression analysis using the between-cuff difference as the dependent variable (Group2)

	SBP difference between conical and cylindrical cuff					
	Coefficient	**STD Err**	**STD Coef**	**Tolerance**	**t**	**p-value**
Costant	29.629	13.528	0.000		2.190	0.038
Skinfold thickness	**-2.597**	**1.242**	**-0.295**	**0.812**	**-2.092**	**0.046**
Age	-0.082	0.047	-0.247	0.803	-1.747	0.093
Sex	2.633	1.403	0.330	0.520	1.876	0.072
Height	-0.133	0.075	-0.391	0.331	-1.773	0.088
Arm lenght	0.156	0.344	0.080	0.519	0.454	0.654
SBP	-0.061	0.031	-0.310	0.651	-1.971	0.059
*= Systolic Blood Pressure						

Table 10. Multivariable linear regression analysis using the between-cuff difference as the dependent variable (Group2)

	SBP difference between conical and cylindrical cuff					
	Coefficient	**STD Err**	**STD Coef**	**Tolerance**	**T**	**p-value**
Costant	41.623	16.902	0.000		2.463	0.021
Arm middle circumf.	**-0.449**	**0.206**	**-0.303**	**0.820**	**-2.176**	**0.039**
Age	-0.081	0.047	-0.244	0.803	-1.731	0.095
Sex	1.718	1.492	0.216	0.454	1.151	0.260
Height	-0.120	0.074	-0.354	0.339	-1.635	0.114
Arm lenght	0.175	0.342	0.089	0.520	0.511	0.614
SBP	-0.069	0.032	-0.352	0.612	-2.182	0.05938
*= Systolic Blood Pressure						

Table 11. Multivariable linear regression analysis using the between-cuff difference as the dependent variable (Group1)

	SBP difference between conical and cylindrical cuff					
	Coefficient	**STD Err**	**STD Coef**	**Tolerance**	**T**	**p-value**
Costant	-61.468	89.565	0.000		-0.686	0.499
Conic angle[a]	0.644	0.991	0.151	0.642	0.651	0.521
Age	0.037	0.045	0.212	0.506	0.814	0.423
Sex	1.887	1.878	0.291	0.412	1.005	0.324
Height	0.046	0.108	0.109	0.520	0.422	0.676
Arm lenght	-0.551	0.526	-0.217	0.806	-1.048	0.304
SBP	0.025	0.032	0.173	0.695	0.779	0.443
*= Systolic Blood Pressure [a]=Upper arm slant angle						

Effect of subjects' SBP on the between-cuff SBP difference

Subject's SBP was a significant predictor of the between-cuff SBP difference ($p<0.001$).

A close correlation was found between SBP at enrolment and the measurement error with the cylindrical cuff (Fig. 7). This indicates that the higher the pressure of an individual the greater the chance of having SBP overestimated by the cylindrical cuff. In the subjects of the top SBP quintile (SBP≥150 mmHg), the between-cuff SBP difference was particularly elevated, being 9.1±5.1 mmHg.

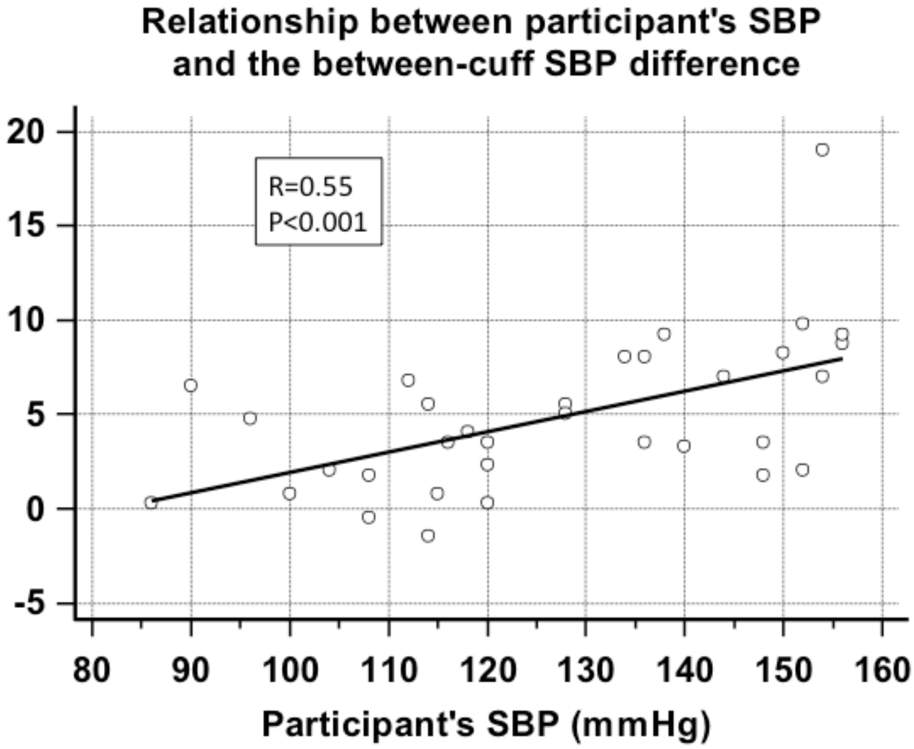


Figure 7. Participant's systolic blood pressure as univariate predictor of the between-cuff systolic blood pressure difference

<u>Differences between the pressure in the cuffs and the pressure measured under the cuffs with a sensor at different pressure levels</u>

Figure 8 shows the differences between the pressures recorded in the two cuffs and the sensor at different pressure levels. Except for the first level (60 mmHg), a higher pressure was found for the cylindrical cuff compared to the conical cuff at any pressure level with a mean difference of -10.2 ± 5.2 and 0.4 ± 5.3 mmHg, respectively. In the cylindrical cuff, this difference progressively increased with increasing level of the pressure inflated in the cuffs.

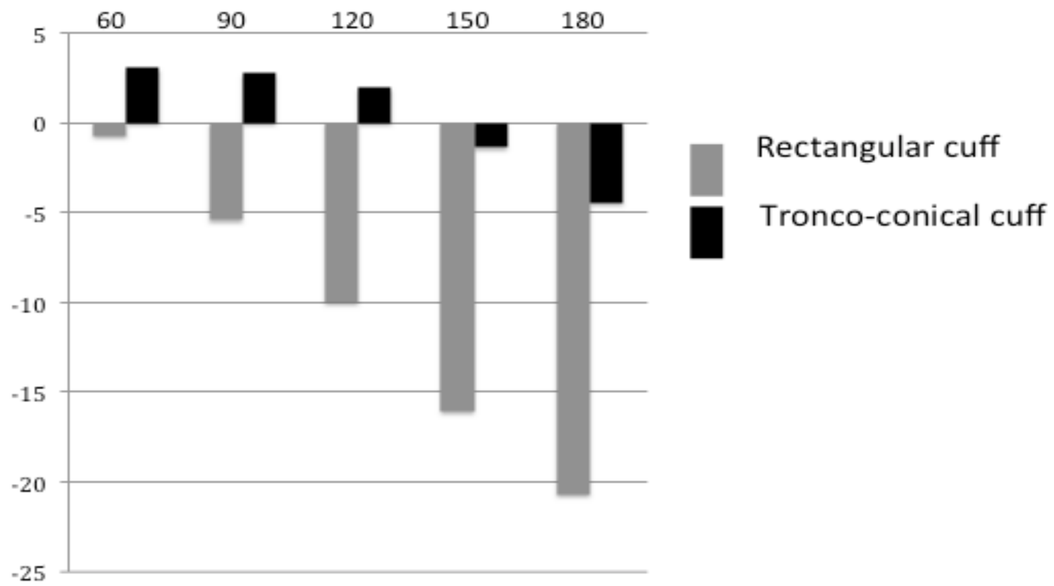


Figure 8. Difference between the pressure in the cuff and the pressure detected by the sensor using the rectangular (cylindrical) and the tronco-conical cuffs. The procedure was repeated 5 times at incremental pressure levels. In x-axis: five pressure levels (in mmHg), in y-axis: difference between the pressure in the cuff and the pressure detected by the sensor (in mmHg).

The discrepancies between the pressures measured with the sensor under the two cuffs at different pressure levels were highly correlated with each other, indicating consistency of the pressure gap within each individual across the pressure range (Tab. 12).

Table 12. Correlations of the differences between the pressures measured with the sensor under the two cuffs at the different pressure levels

Pearson Correlation Matrix							
		DIFSEN 60	DIFSEN 90	DIFSEN 120	DIFSEN 150	DIFSEN 180	DIFSEN Mean
DIFSEN60		1,0000					
DIFSEN90		0,8146	1,0000				
DIFSEN120		0,6759	0,8186	1,0000			
DIFSEN150		0,7973	0,9329	0,8713	1,0000		
DIFSEN180		0,8072	0,8975	0,8087	0,9016	1,0000	
DIFSENTOT		0,8507	0,9542	0,9031	0,9716	0,9617	1,0000

Matrix of Probabilities							
		DIFSEN 60	DIFSEN 90	DIFSEN 120	DIFSEN 150	DIFSEN 180	DIFSEN Mean
DIFSEN60		0,0000					
DIFSEN90		0,0000	0,0000				
DIFSEN120		0,0000	0,0000	0,0000			
DIFSEN150		0,0000	0,0000	0,0000	0,0000		
DIFSEN180		0,0000	0,0000	0,0000	0,0000	0,0000	
DIFSENTOT		0,0000	0,0000	0,0000	0,0000	0,0000	0,0000

DIFSEN=DIFference between the pressures measured with the SENsor under the two cuffs at the different pressure levels (60-90-120-150-180 mmHg)

DISCUSSION

The ability to measure blood pressure accurately may be influenced by the size and shape of the upper arm. Using too narrow or too short bladders and cuffs in people with large arms can lead to an overestimation of blood pressure, a problem often overlooked by doctors when measuring blood pressure in obese subjects.

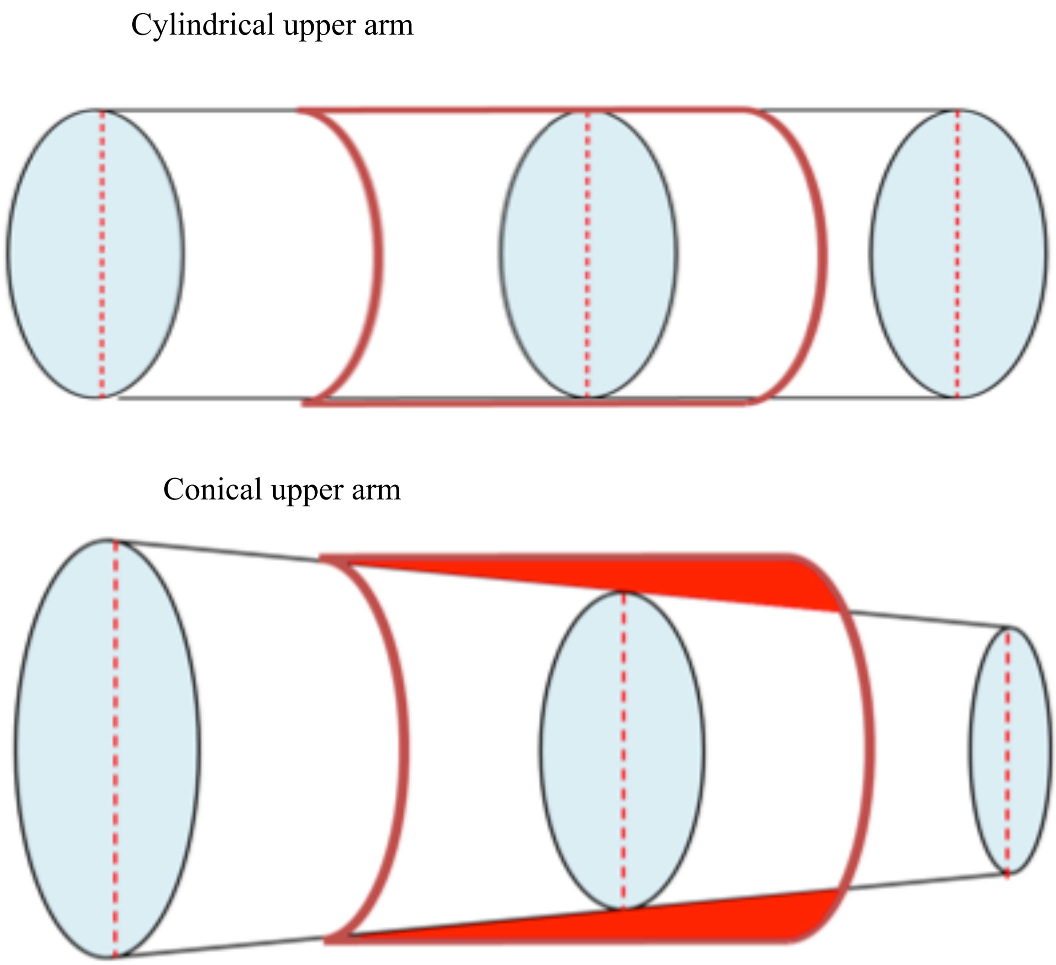
Obesity is an emerging problem in developed countries and can cause imprecise blood pressure measurements in a sizable number of subjects. The size of the standard adult cuff is too small for individuals with an arm circumference of 32 cm or greater and therefore overweight and obese patients often require the use of large cuffs. In patients with morbid obesity, very large arm circumferences will be encountered that can be accompanied by a reduced arm length. In these patients, measurement with a cuff of a theoretically appropriate size is often difficult because the lower edge of a large cuff can extend beyond the elbow of the subject. According to AHA recommendations, for arms circumference ranging from 35 to 44 cm a bladder with a width of 16 cm should be used. For arm circumferences ranging between 45-52 cm the width of the bladder should be 20 cm. However, these bladder are not suitable for all individuals because arm length is <20 cm in many subjects. Previous data from our laboratory obtained in 349 patients with arm circumference ranging from 20 to 49 cm, confirm that those bladders are not suitable for many individulas : arm length was less than 20 cm and less than 16 cm in 22% and 0.6% of the subjects, respectively.

The choice of the appropriate cuff in obese subjects depends not only on the circumference of the arm but also on its shape. According to the results by Bonso et al (47), the shape of the upper arm is tronco-conical in virtually all individuals. The difference between the circumference near the shoulder and the circumference near the elbow was found to range from 1 to 20 cm, with an average value of 8.7 cm. In a previous study, we divided the subjects according to upper middle arm circumference and in the group with arm size 37.5-42.5 cm the difference between the proximal and distal arm circumference ranged from 5 to 15 cm, with an average value of 10.3 cm (49). In the present study of subjects with middle upper arm circumference > 42 cm the difference between proximal and distal circumference ranged from 6 to 22 cm, with an average value of 14.4 cm which attests to a pronounced troncoconical shape of the limb. The conical shape of the arm may vary according to sex, degree of obesity and arm circumference (47-58). In a multiple linear regression in which all anthropometric variables were included, arm circumference explaines most of the variance in the conicity index (47). When the arm circumference near the shoulder is much greater than the arm circumference near the elbow, a pre-shaped cylindrical cuff may provide inaccurate blood pressure measurements. This has been demonstrated in a recent study where the use of a cylindrical (rectangular) cuff greatly overestimated the blood pressure measurements obtained with a tronco-conical cuff in subjects with middle circumference >32 cm (49). The observed measurement errors were greater in subjects with arm circumference 37.5-42.5 cm (mean=2.0/1.8 mmHg) and were found to be proportional to the conical shape of the arm, with differences of up to 10 mmHg in arms with a slant angle <83°.

The present data obtained in subjects with morbid obesity, show that the measurement error with the cylindrical cuff is much greater in people with upper arm middle circumference >42 cm being on average 5 mmHg for SBP and 3 mmHg for DBP. As hypothesized, the truncated cone slant angle was an independent predictor of the between-cuff SBP difference indicating that the measurement error was proportional to the conical shape of the arm. The strength of the association was attenuated by introducing skinfold thickness in the regression model suggesting that both variables concur to determine the measurement error. However, arm circumference appeared to be the driving factor indicating that the measurement error with cylindrical cuffs may occur not only in obese individuals but also in people with muscular arms. The upper arm slant angle was not uniform across the arm length as it became sharper in the distal part. However, the slant angle of the lower frustum was only a bordeline predictor of the measurement error. When a large-sized cylindrical cuff is used in conical arms the elbow end of the cuff will remain loose and will expand irregularly over the lower part of the arm. In this situation a cylindrical cuff may cause an overestimation of the true blood pressure.

The present results are consistent with previous findings obtained long ago by Maxwell et al. in a general population (41). Using a tronco-conical cuff Maxwell et al. obtained lower blood pressure readings compared to those obtained with a cylindrical cuff in obese individuals. Using a single 16 cm-wide conical cuff with a slant angle of 86°, previously worked out by Huige (40, 59), these authors obtained 4 mmHg lower systolic and diastolic blood pressure readings compared with those obtained with cylindrical cuffs, a difference that was unrelated to arm circumference. A limitation of Maxwell et al. study was that the same large-sized conical cuff was used across a wide range of arm circumferences (<30 cm in 51.1%), whereas for the cylindrical cuff a standard cuff (12x23 cm) and a larger cuff (15x32cm) were used according to arm size. As the authors themselves admitted the lower readings obtained with the conical cuff in small and average-sized arms were likely to be due to the so-called "wide cuff effect" caused by an inappropriately large conical cuff. In the article by Maxwell et al., no information was available as to the material used for cuffs. The magnitude of the blood pressure discrepancies may also depend on the characteristics of the sleeve and are likely to be greater with cuffs made of rigid or semi-rigid material as suggested by our previous results obtained with an oscillometric device (47). To obtain accurate blood pressure measurements, the cuff is assumed to perfectly adhere to the arm and to apply uniform pressure on the arm surface. A cylindrical cuff cannot exert a uniform pressure on a conical arm because the distal part will remain loose and expand irregularly, thereby transmitting a lower pressure to the subcutaneous tissue overlying the artery. A tronco-conical cuff can fit better on large upper arms than the cylindrical cuff ensuring proper and consistent cuff placement.

Figure 9. Cylindrical and conical upper arm



In a study published in 2011 Lan H. Et al. (60) showed that the artery experiences extravascular pressure close to cuff pressure under the centre of the cuff, whereas the pressure transmission ratio (pressure in the tissue divided by pressure on the surface) drops gradually down to 30% at the edge of the cuff. This drop in pressure will be clearly greater and unpredictable under the distal part of a cylindrical cuff applied on a conical arm because of the air gap between the elbow end of the cuff and the distal upper arm circumference and can be an important source of error measurement. To confirm this assumption, in the present study we measured the pressure applied on the surface of the arm at the center of the cuff with the use of a pressure sensor and recorded the pressures at different pressure levels. A higher pressure was recorded in the cylindrical cuff at all pressure levels compared with the conical cuff, with mean differences of -10.2 ± 5.2 and 0.4 ± 5.3 mmHg, respectively. In a previous study we showed that to obtain the same pressure on the surface of the upper arm under the cuff, a higher pressure must be pumped into the cylindrical bladder compared with the conical bladder, a difference that roughly corresponded to the systolic and diastolic discrepancies obtained with the two cuff (49). These differences could be even greater if blood pressure is measured with the oscillometric method in which measured cuff pressure oscillations are a reflection of the entire artery volume change under the cuff rather than that of the central section. However, the blood pressure overestimation of the cylindrical cuff with oscillometric measurement will have to be evaluated in an "ad hoc" study. The present results apply only to the traditional auscultatory technique and not to blood pressure measurement performed with oscillometric devices.

Another interesting finding of the present study is that the measurement error was proportional to the SBP level of the subjects. In subjects with SBP equal to or greater than 150 mmHg, the mean between-cuff SBP discrepancy was 9 mmHg. Blood pressure recorded with the sensor at different blood pressure levels confirmed that the pressure gap between the two cuffs was proportional to the pressure pumped into the cuffs. This has important clinical implications because our data suggest that SBP overestimation with the cylindrical cuff may be more pronounced in patients with hypertension thereby exposing the patient to the potential harms related to overtreatment of hypertension.

Limitations

A limitation of the present study is that it was impossible to obtain "blinded" readings, because the observers knew the type of cuff that was being used. On the other hand, for the reasons mentioned above oscillometric blood pressure devices can only be used with the cuff(s) employed for their validation and are not suitable for testing different cuffs. Another limitation may be the lack of a true gold-standard measurement to refer to and we can not thus prove that it was the conical cuff that provided more accurate measurements. However, the results obtained with the pressure sensor put under the cuffs actually demonstrated that there was a loss of pressure under the central part of the cylindrical cuff which increased with increasing level of the pressure applied. Finally, blood pressure measurement with a cuff of appropriate size is impossible in obese subjects with short humerus length who had to be excluded.

CONCLUSIONS

The shape of the arm is not taken into account by current international guidelines for blood pressure measurement. However, in very obese people, the upper arm always has a pronounced tronco-conical shape, which may be the cause of inaccurate blood pressure readings if blood pressure is measured with cylindrical cuffs. This study's findings show that in patients with upper arm circumference > 42 cm the use of a cylindrical cuff even of appropriate size consistently overestimates BP chiefly in people with high BP. This may lead clinicians to incorrectly identify hypertension in normotensive subjects and to overtreat patients with hypertension. Given the increasing number of subjects with these characteristics, manufacturers of blood pressure devices need to develop appropriately shaped cuffs for this population. Tronco-conical cuffs with slant angles of 84-86° are likely to be appropriate for BP measurement in patients with morbid obesity.

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