GE Healthcare

The first clinically validated NIBP cuff for providing accurate measurements from the forearm of obese patients

Connecting intelligence and care.

Introduction

Obese patients are at risk for many conditions, notably cardiovascular[1] and renovascular disease. Failure to identify hypertension in these patients can translate to poorer clinical outcomes and increased cost of care. Until now it has been difficult to obtain accurate noninvasive blood pressure (NIBP) measurements on these patients because it was not possible to select a properly sized BP cuff. As a consequence, clinicians have used upper arm cuffs to measure NIBP from the forearm, an application for which such cuffs are not clinically validated. Use of upper arm cuffs in this manner has been shown to underestimate systolic blood pressure by as much as 10 mmHg.[2]

GE Healthcare has designed the CRITIKON* RADIAL-CUF for use on the adult forearm. Its accuracy was validated in a clinical study[+] using a radial intra-arterial reference. It is the first clinically validated cuff designed for use on the forearm of obese patients. It is validated to be used to accurately estimate radial arterial pressure using the oscillometric method.

[+]GE Healthcare sponsored and compensated Clinimark, LLC for managing and executing the clinical portions of this study. (March 2008/Dec 2011)

OBESITY AND BP CUFF SIZING

Recent data from the National Health and Nutrition Examination Survey shows that more than one-third of U.S. adults were obese in 2009-10.[24]

The epidemic of obesity has driven a need for larger NIBP cuffs in adult[10, 11] populations. It has also increased opportunities for blood pressure measurement (BPM) error caused by the use of improperly sized cuffs. Numerous authors have discussed the impact of obesity on the accuracy of BPM and have concluded that improper cuff size has resulted in significant overestimation of BP in epidemiologic studies.[12, 13, 14, 15]

NIBP measurements on the upper arm require cuffs sized to the patient's arm circumference – proper sizing is a key to BPM accuracy in both automated and manual methods.[2, 3, 4] Numerous studies have evaluated the proper cuff size required for accurate BPM in the upper arm.[5, 6] Current standards recommend that the cuff bladder width be 40% of the patient's arm circumference (W/C) and that the bladder length be 80% of the arm circumference (L/C).[7]

A cuff with a bladder that is too large relative to the patient's arm circumference will result in underestimation of the patient's BP, while a cuff that is too small will cause an overestimation. The error has been reported to be as high as -5 mmHg for overcuffing and +8 mmHg for undercuffing.[8, 9]

Two basic problems affect the ability to measure blood pressure accurately on the upper arms of obese patients. First, as arm circumference increases, the length and width of the cuff bladder must also increase. Therefore, in obese patients, the required bladder width can be greater than the length of the upper arm, causing an overlap at the elbow. Second, the upper arm in obese patients takes on a conical shape, making it difficult for a cylindrical cuff to be properly wrapped on the arm.[12,16] (These same fit problems may also occur in patients with overly muscular biceps).

GE Healthcare's largest adult cuff size is designed to fit a maximum arm circumference of 40 cm, based on a bladder length of 33 cm and a bladder width of 17.2 cm. However, many patients have arm circumferences greater than that value.[17] The GE Healthcare thigh cuff is designed for a circumference of up to 50 cm and has a bladder width of 20 cm. In many individuals, the length of the upper arm is less than 20 cm, which means this cuff would not properly fit the upper arm.

PREVIOUS SOLUTIONS

One solution that has been investigated is to take obese patients' BPM from the forearm[2, 18, 19] or wrist.[20] The advantage of this approach is that even in obese patients, the forearm circumference does not increase significantly. However, these studies found that the BPMs on the forearm and wrist did not accurately reflect the upper arm BPMs.

The studies on forearm cuffs used existing upper arm cylindrical cuffs sized to the forearm. However, the data used to determine the proper ratios for W/C (40%) and L/C (80%) was based on studies done on the upper arm. There is no evidence to support the clinical accuracy of using an upper arm cuff on the forearm.[16, 18]

GE HEALTHCARE SOLUTION

GE Healthcare embarked on a development program to determine the proper size and shape for a NIBP cuff for forearm use. Anthropometric studies on the target patient population demonstrated a significantly conical shape in the forearm. They also determined that over a wide range of upper arm circumference (27-62 cm), the patients' forearm circumference remained within relatively narrow limits (23-37 cm).[21]

Since the appropriate values for the W/C and L/C ratios have not been determined for a forearm cuff, the GE Healthcare study needed to determine proper forearm cuff sizing. All subjects had their blood pressure measured with four different cuff sizes in order to determine the proper cuff bladder width and length. An intra-arterial reference was used to determine the subjects' true blood pressure.

WHY USE RADIAL PRESSURE?

In all patients, BP changes when moving from the aorta to the peripheral arteries.[22, 23] This is due to the branching and reduction in diameter that occurs in the arterial system. In most patients, the systolic pressure increases and the diastolic pressure decreases in the peripheral arteries. However, the amount of the difference varies with patient age, size and arterial compliance. Therefore, it is not possible to develop a simple transfer function relating radial and central pressures.[23] *Figure 1* below illustrates the change in pressure moving from the aorta to the periphery.

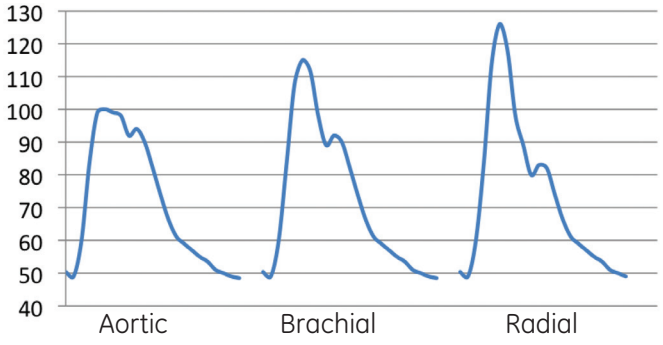

Figure 1. Change in BP moving from the aorta to the periphery.

Parameter	Mean Error (mmHg)	SD (mmHg)	Count	% with error ≤ 5 mmHg	% with error ≤ 10 mmHg	% with error ≤ 15 mmHg
Systolic	-0.12	6.62	446	66.6%	88.3%	95.5%
Diastolic	0.9	3.75	446	83.6%	96.9%	99.6%
MAP	1.66	3.94	446	84.1%	95.5%	98.2%

Table 1. Clinical validation of the CRITIKON RADIAL-CUF BP cuff using a radial intra-arterial reference.

Parameter	Mean Error (mmHg)	SD (mmHg)	Count	% with error ≤ 5 mmHg	% with error ≤ 10 mmHg	% with error ≤ 15 mmHg
Systolic	-9.85	6.85	223	26.5%	53.8%	74.0%
Diastolic	-0.98	5.47	223	78.5%	95.5%	99.6%
MAP	-1.66	3.74	223	84.3%	98.7%	99.6%

Table 2. Clinical validation of the CRITIKON upper arm BP cuff using a radial intra-arterial reference.

BP determined noninvasively from cuff-based measurements is a reflection of the pressure in the artery underneath the cuff. Since the CRITIKON RADIAL-CUF BP cuff is designed for use on the forearm, it was appropriate to evaluate its accuracy compared to a radial artery reference.

STUDY RESULTS

The CRITIKON RADIAL-CUF BP cuff was clinically validated to the AAMI/ANSI/ ISO 81060-2 (2009) standard for NIBP accuracy using a radial intra-arterial reference.[25] It is intended for adults with a forearm circumference range of 26-36 cm and who cannot be properly fitted with an upper arm cuff. This includes patients having an upper arm circumference >40 cm, patients on whom the upper arm is conical, patients where the cuff has a gap near the bottom edge, and/or patients where the upper arm cuff is too long, causing it to overlap the elbow. The forearm cuff is conical to properly fit the shape of the forearm.

Figure 2. CRITIKON RADIAL-CUF BP cuff with DINACLICK* connector

The data in *Table 1* summarizes the clinical validation of the CRITIKON RADIAL-CUF and demonstrates that this cuff designed specifically for the forearm is more accurate than from cuffs used on the forearm that are not designed for the forearm.

The study found a clinically significant difference in the accuracy of NIBP measurements between the CRITIKON RADIAL-CUF and the conventional upper arm cuff when both were used on the forearm. As shown in *Table 2*, the upper arm cuff underestimated systolic blood pressure by almost 10 mmHg (mean error = -9.85 mmHg) compared to the value for the RADIAL_CUF (mean error= -0.12 mmHg) in *Table 1*.

Another measure of the accuracy of the cuff is the percentages of readings that are within 10 mmHg of the reference value. With the CRITIKON RADIAL-CUF, almost 90% of the systolic readings met that criteria *(Table 1)*, with the upper arm cuff only slightly more than half of the readings were within 10 mmHg *(Table 2)*.

HUMAN FACTORS

There was minimal reported cuff slippage with use of the forearm cuff and there was negligible impact to caregivers' existing workflow. From a comfort standpoint, the forearm cuff was preferred to the upper arm cuff by 77% of patients when cuff was applied to the forearm.

CONCLUSION

The CRITIKON RADIAL-CUF bladder width and length to circumference ratios are approximately 30% and 73%, compared to 50% and 100% for a CRITIKON adult cuff. This demonstrated that the correct ratios of width and length to circumference are different for the forearm. The required criteria of the 81060-2 standard, which are absolute mean errors ≤ 5 mmHg and standard deviations of error ≤ 8 mmHg, were met. Based upon these statistical results, this study demonstrates that the CRITIKON RADIAL-CUF can be used to accurately estimate radial arterial pressure using the oscillometric method. This new forearm cuff is an important improvement which should provide convenience for the clinician and better treatment for the obese patient since the radial blood pressure will be accurately estimated.

REFERENCES

1. Hubert, H.B. *et al*. Obesity as an independent risk factor for cardiovascular disease: a 26-year follow-up of participants of the Framingham Heart Study. *Circulation* **67**, 968–977 (1983).
2. Pickering, T.G. *et al*. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the subcommittee of professional and public education of the American Heart Association Council on High Blood Pressure Research. *Hypertension* **25**, 142–161 (2005).
3. Kirkendall, W.M. *et al*. Recommendations for human blood pressure determination by sphygmomanometers. Subcommittee of the AHA Postgraduate Education Committee. Circulation **62**, 1146A–1155A (1980).
4. Perloff, D. *et al*. Human blood pressure determination by sphygmomanometry. *Circulation* **88**, 2460 –2470 (1993).
5. Rastam, I. *et al*. Ratio of cuff width/arm circumference as a determinant of arterial blood pressure measurements in adults. *J Intern Med*. **227(4)**, 225-32 (1990).
6. Geddes, L.A. *et al*. The importance of cuff width in measurement of blood pressure indirectly. Cardiovasc Res Cent Bull. **14(3)**, 69-79 (1976).
7. ANSI/AAMI/ISO 81060-1:2007 Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type
8. Manning, D.M. Miscuffing: inappropriate blood pressure cuff application *Circulation* **68(4)**, 763-6 (1983).
9. Sprafka, J.M. The effect of cuff size on blood pressure measurement in adults. *Epidemiology* **2(3)**, 214-7 (1991).
10. Ostchega, Y. US demographic trends in mid-arm circumference and recommended blood pressure cuffs: 1988–2002; *Journal of Human Hypertension*, 1–7 (2005).
11. Graves, J.W. *et al*. The changing prevalence of arm circumferences in NHANES III and NHANES 2000 and its impact on the utility of the "standard adult" blood pressure cuff. *Blood Press Monit*. **8**, 223–227 (2003).
12. Prineas, R.J. Measurement of blood pressure in the obese. *Ann Epidemiol* **1**, 321–336 (1991).
13. Huige, M.C. Reliability of blood pressure measurement on fat upper arms. *Ther Umsch* **39(2)**, 87-91 (1982).
14. Maxwell, M.H. *et al*. Error in blood-pressure measurement due to incorrect cuff size in obese patients. *Lancet* **2**, 33–36 (1982).
15. Nielsen, P.E. *et al*. Accuracy of auscultatory blood pressure measurements in hypertensive and obese subjects. *Hypertension* **5**, 122–127 (1985).
16. Palatini, P. *et al*. Rectangular cuffs may overestimate blood pressure in individuals with large conical arms, *Journal of Hypertension* **30**, 530–536 (2012).
17. Fonseca-Reyes, S. *et al*. Effect of standard cuff on blood pressure readings in patients with obese arms. How frequent are arms of a 'large circumference'? *Blood Pressure Monitoring* **8(3)**, 101-106, (June 2003).
18. Pierin, A.M.G. *et al*. Blood pressure measurement in obese patients: comparison between upper arm and forearm measurements *Blood Press. Monit*. **9**, 101–105 (2004).
19. Schell, K. A. *et al*. The effects of anatomical structures on adult forearm and upper arm noninvasive blood pressure. *Blood Press Monit* **12(1)**, 17-22 (2007).
20. Palatini, P. *et al*. Wrist blood pressure overestimates blood pressure measured at the upper arm *Blood Press Monit*. **9(2)**, 77-81 (2004).
21. Nehls-Wasoff, D. *et al*. Developmental Study to Evaluate the Effect of Adipose Tissue Thickness on Noninvasive Blood Pressure Clinical Services Short Report – CS#**337**. 1-8 (2005).
22. O'Rourke, M.F. and Nichols, W.W. McDonald's Blood Flow in Arteries: theoretical, experimental and clinical principles. London: Hodder Arnold; (2005).
23. Agabiti-Rosei, E. *et al*. Central Blood Pressure Measurements and Antihypertensive Therapy: A Consensus Document. *Hypertension* **50**, 154-160 (2007).
24. Ogden, C.L. *et al*. Prevalence of obesity in the United States, 2009–2010. NCHS data brief, no 82. Hyattsville, MD: National Center for Health Statistics. 2012.
25. ANSI/AAMI/ISO 81060-2:2009 Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type

imagination at work

GE Healthcare
8200 West Tower Avenue
Milwaukee, WI 53223
U.S.A.

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