Accuracy of NIBP Measurements: Getting a Good Blood Pressure from that Conically Shaped Arm

Introduction

Traditional blood pressure cuffs have been evolving over the years, but the need to develop a blood pressure cuff for obese patients has rarely been addressed. The lack of cuffs for this patient population has led to inaccurate BP measurement, patient discomfort, and clinician anxiety in finding the correct size cuff for patients.

Statcorp Medical's UltraCheck® Curve™ Cuff was developed to provide clinicians with the proper instrument to overcome the issues associated with the use of the conventional blood pressure cuff on the obese or morbidly obese patient.

UltraCheck Curve Cuff utilizes the traditional interface which enables it to be connected to any auscultator or oscillatory monitoring apparatus.[1]

Objective

To demonstrate that the Statcorp Medical UltraCheck Curve Cuff performs functionally equivalent with conventional cylindrical cuffs within the size range of 38 to 54cm. while offering improved comfort to the patient and convenience to the clinician.

Scope

The primary physical difference between the UltraCheck Curve Cuff and conventional cuffs is the conical shape. The shape allows for better fit on large tapered arms. This study compares the readings obtained from the Curve cuffs to the predicate cylindrical cuffs to demonstrate that shape difference does not negatively impact the performance.

Subject Selection

Subjects were selected as informed volunteers from random locations throughout the United States using the criteria for establishing blood pressure measurement accuracy in AAMI SP10:2002, "Manual, Electronic or Automated Sphygmomanometers". At least 30% of subjects were male and at least 30% were female with upper arm circumferences ranging from 38 to 54cm. A minimum of 40% of the arm sizes were in the lower half (38-45cm) and 40% in the upper half (47-54cm) of the cuff size range.

Reference Cuff & Measurement Method

Since there is no single predicate cuff that covers the entire arm size range from 38-54cm, two Philips predicate cuffs were selected for use in the reference measurement to ensure entire ranges were covered. These are the Philips Large Adult, PN M4557B, with a range of 35-45cm and the Philips Thigh cuff, PN M4559B, with a range of 44-56cm. In the clinical environment today, thigh cuffs are used routinely on patients with arm sizes that exceed the largest arm cuffs as it is the only option currently available.

Acceptance Criteria

The results shall be deemed acceptable if the following conditions are met.

1. The Bland-Altman (scatter) diagrams for data collection method subsets should not indicate any significant offsets.

2. The mean and standard deviation meet the requirements of D3.4 of SP10 which are a mean of less than 5mmHg and a standard deviation of less than 8mmHg.
3. A second method of acceptance per SP10 consists of calculating the average deviation for each subject and performing the mean and standard deviation calculations on the average. In this case the requirement for standard deviation is dependent upon the calculation of the deviation of the means using the following table (Table F1 in SP10)

Sample mean error	0	±0.5	±1.0	±1.5	±2.0	±2.5	±3.0	±3.5	±4.0	±4.5	±5.0
St dev ≤	6.95	6.93	6.87	6.78	6.65	6.47	6.25	5.97	5.64	5.24	4.81

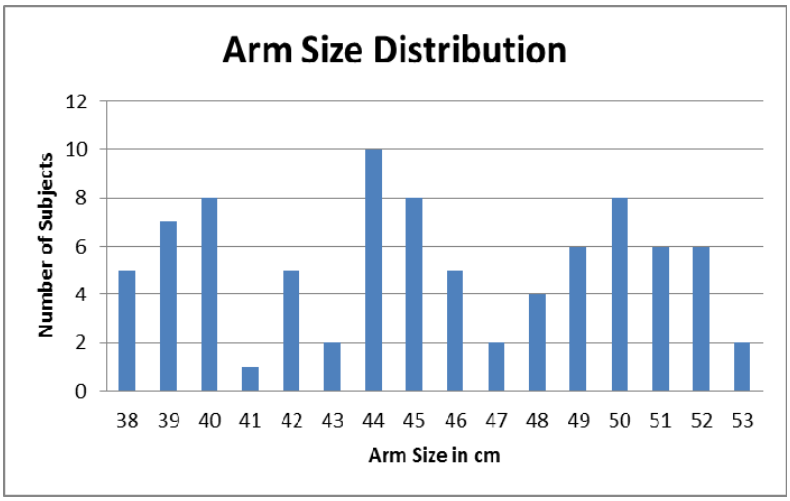
Data Collection Method[2]

The prospective study, spanning 9 months, was performed at various locations throughout the United States. Both auscultatory and oscillometric methods were used to collect the data.

Data Collection Results

1. This data represents a total of 85 subjects, 39 females and 46 males. This equals 46% females and 54% males which meets the minimum of 30% of each sex.
2. The number of subjects as a function of arm size is shown in Figure 1.

Figure 1



There are a total of 46 data points from 38-45 cm and 34 data points from 47-54 with 5 in the center at 46cm. This represents 54% of the data in the lower half and 40% in the upper half with 6% in the middle at 46 cm. This meets the criteria of 40% in each half.

3. The premise behind this study is that the Curve cuff functions substantially equivalent to the existing predicates. This would be independent of instrumentation used in reading the pressure as well as the particular predicate used as a reference. Some of the data was generated using the Philips XL Adult Cuff as a reference and a stethoscope along with an aneroid sphygmomanometer. The remainder of the data from this reference cuff as well as the data from the thigh cuff was collected using a Spacelabs Ultraview Monitor SL 91369. The scatter diagrams shown in Figures 2 – 5 indicate a slightly larger data spread for the Spacelabs Monitor compared to the stethoscope-sphygmomanometer method, it will become evident in the final analysis that it is insignificant.

Figure 2

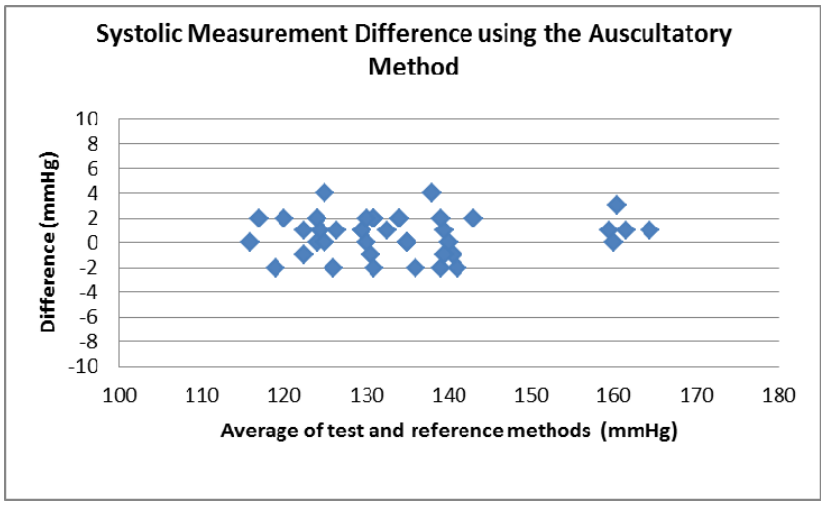


Figure 3

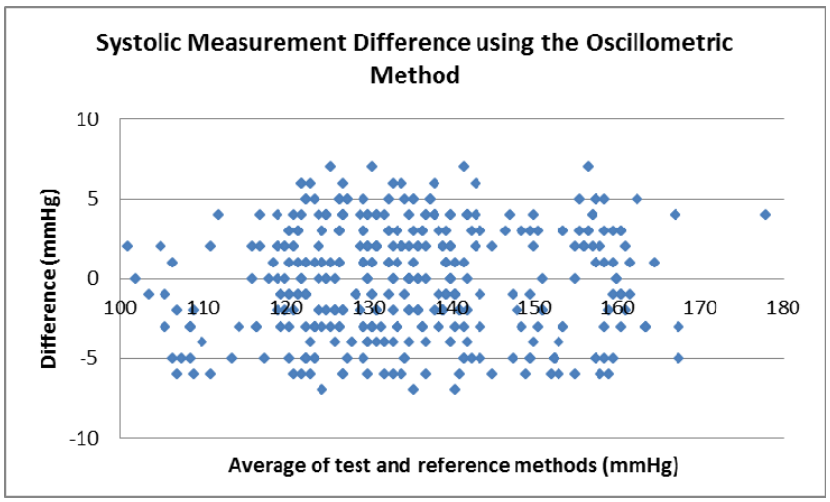


Figure 4

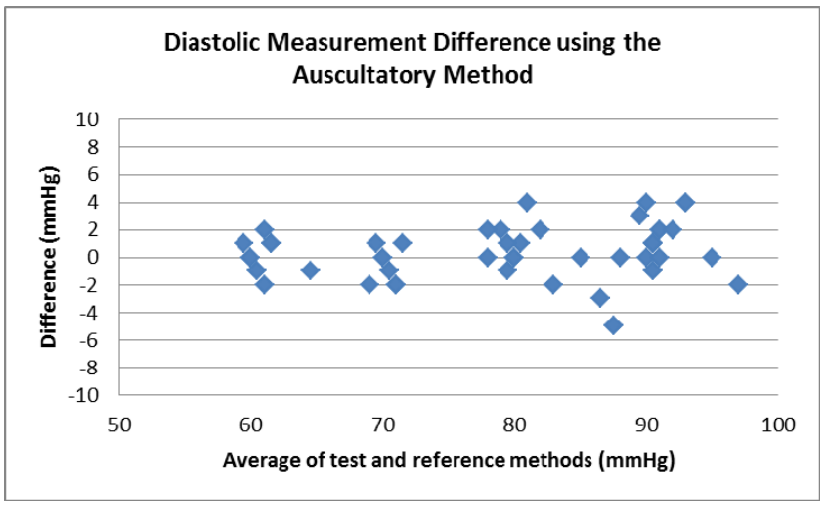
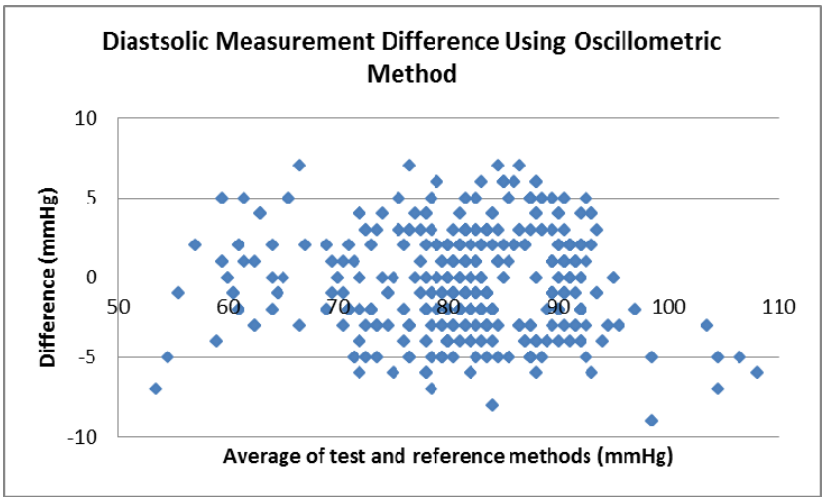


Figure 5



4. The statistical results are summarized below in the manner that is specified in section 4.4.5.1.B of SP10[3] using each of the recommended methods which consists of calculating the mean and standard deviation of the reference test cuff differences for each reference test data pair.

Method 1 (Raw subject data)

Test	# of subjects	Number of data points	Mean difference (mmHg)	Standard deviation (mmHg)	% of differences >5mmHG	% of differences >10mmHg
Systolic	85	425	-0.15	3.36	8.5%	0.0%
Diastolic	85	425	-0..29	3.16	6.6%	0.2%

The criteria applied to this method are such that the mean difference is to be less than 5mmHg and the standard deviation is to be less than 8mmHG, both of which are easily met.

5. In Method 2 each subject's reference measurements are averaged and subtracted from the average of the test measurements. The mean difference and standard deviation of these averaged differences is then calculated. This technique produces a lower standard deviation because of the data averaging but the mean differences are the same as Method 1.

Method 2 (Averaged subject data)

Test	# of subjects	Number of paired averages	Mean difference (mmHg)	Standard deviation (mmHg)	% of differences >5mmHG	% of differences >10mmHg
Systolic	85	85	-0.15	2.39	2.4%	0.0%
Diastolic	85	85	-0.29	2.00	3.5%	0%

The criteria applied to this method are taken from the below table (Table F1 in SP10):

Sample mean error	0	±0.5	±1.0	±1.5	±2.0	±2.5	±3.0	±3.5	±4.0	±4.5	±5.0
St dev ≤	6.95	6.93	6.87	6.78	6.65	6.47	6.25	5.97	5.64	5.24	4.81

Since the sample mean is less than .5 in, the standard deviation must be less than 6.93 which was easily met.

Data Conclusion

The measured mean difference between the reference and test cuff sets is essentially zero and can be considered negligible for systolic and diastolic measurements.

The standard deviation of the differences between the two cuffs is minimal and is explained by the temporal variation in human blood pressure and the inherent variability in the estimation techniques used (oscillometry and auscultatory).

Conclusion

The acceptance criterion was met. Therefore, it is concluded that the UltraCheck Curve Cuff functions equivalent to the predicate cuff. Patient feedback further substantiated that the cuff was perceived as comfortable on the arm as well as accurate when referenced against the predicate device.

1. *Pickering Thomas 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, December 2004, 2005;45:142-161, Hypertension.*
2. *Perloff D, et al., Human blood pressure determination by sphygmomanometry, 1993;88:2460-2470, Circulation.*
3. *Association for the Advancement of Medical Instrumentation, Manual, electric, or automated sphygmomanometers, ASNI/AAMI SP10:2002 & ANSI/AAMI SP10:2002/A1:2003.*
4. *Smith Liz, Practice Guidelines: New AHA Recommendations for Blood Pressure Measurement, October 2005, 72(7):1391-1398, American Family Physician.*