COMPARISON OF THREE NON-INVASIVE TECHNIQUES FOR THE MEASUREMENT OF HUMAN BLOOD PRESSURE

by

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ARLENE MAY PUTT
Professor of Nursing
This thesis is dedicated to my colleagues and special friends, Ms. Carol Brower, Ms. Cynthia Benzshawel, and Ms. Margaret De Santis. During the past year we have all learned that "risk equals growth."
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ABSTRACT

One hundred clients with varying health problems had their blood pressures monitored using three devices: a standard sphygmomanometer, an upper arm pressure sensor cuff, and a finger pressure sensor cuff. Each subject had six measurements taken at a single sitting, using each device once in a rotating fashion and then repeating the entire procedure once. A concise health history concerning the client's age, sex, weight, height, and past and present health status and usage of medications was obtained.

Bivariate correlational regression analysis was then conducted on the data collected. The results indicated that the reliability, validity, and device interchangeability for the finger cuff were markedly low. It was also discovered that the upper arm pressure sensor cuff's diastolic readings were also low for reliability, validity, and device interchangeability.

As a result of these findings, the programming within these units is being modified.
CHAPTER 1

INTRODUCTION

One of the most common parameters in evaluating the hemodynamic state of a patient is determined by measuring his blood pressure. According to Burch and DePasquale (1962), blood pressure measurement ranks first in the many objective procedures physicians employ to obtain quantitative data on their patients. On the basis of blood pressure determinations, diagnoses are made, patients treated, and treatment evaluated (King 1969; Ravin 1972). Obviously, then, the reliability of the accuracy of this measurement is very important.

The most accurate means for obtaining this information is directly, by intra-arterial lines (Berliner et al. 1960; Geddes 1970; Breit and O'Rourke 1974). Due to the special technique required, necessity of expensive equipment, unpleasantness, and potential danger to the patient, this method is seldom utilized except in the care of the critically ill. To date, the procedure most commonly used, due to its ease of performance and relative accuracy, has been the indirect auscultatory method. Yet, clinical experience and documentation in the literature suggests that this technique is fraught with potential error
(Wilcox 1961; Mitchell, Parlen and Blackburn 1964; Jarvis 1977).

Burch and DePasquale (1962) have stated that the indirect measurement of blood pressure is at best only an approximation; however, they believe that eradication of the avoidable errors in blood pressure measurement will enhance favorable comparison with the direct method of measurement. They classify the sources of error into four categories:

1. faulty technique, such as improper position of extremity, deflation of cuff too rapidly or too slowly, improper size or application of cuff;
2. defective apparatus, such as a leaky pneumatic system, a defective mercury or aneroid manometer;
3. observer error, reported extensively in the literature; and
4. failure to consider the patient adequately, i.e., taking into consideration time of measurement related to meals, smoking, bladder distention, climate, exertion, pain (sympathetic nervous system stimulation).

This classification is a compilation of those errors most commonly discussed in the literature (Rose 1965; King 1969; Lancour 1976). Therefore, the most prevalent technique for
securing a blood pressure measurement may, in many instances, be yielding inaccurate readings.

Until recently there have been no alternatives to this situation. However, an experimental blood pressure cuff has been invented by Jewett (1977) which may provide science with an alternate means of obtaining an indirect blood pressure measurement. This method operates on a pressure basis rather than sound, thereby eliminating the need for a stethoscope. The eradication of the stethoscope assists in the curtailment of potential errors as hearing may vary from one individual to another (Glor 1968; Geddes 1970; Mitchell and Van Meter 1971). Furthermore, following deflation the pressure sensor cuff displays a digital readout of the blood pressure reading. A digital readout aids in eliminating possible technique errors by enhancing visual acuity and removing problems associated with the placement of the mercury, or aneroid manometers (Correcting Common Errors in Blood Pressure Measurement 1965; Kirkendall, Burton, Epstein and Freis (1967). Initial testing with this cuff yields a more accurate recording than one obtained using the ascultatory method when both are compared to an intra-arterial line reading (Jewett 1977).

In addition to providing an optional means for acquiring blood pressure determinations, the pressure sensor cuff may supply medical science with an additional
answer to yet another difficulty concerning blood pressure measurement. The antecubital fossa of the upper arm has long been the customary location used for eliciting an auscultatory blood pressure measurement; however, clinical experience indicates that there are instances in which a substitute site would be desirable. For example, it is not feasible to obtain a blood pressure reading from the upper arm on patients with bilateral burns, contractures, or casts. Clinical evidence implies that acquiring an upper arm blood pressure recording on a patient with bilateral intravenous lines in the upper extremities is not advisable. Furthermore, it is sometimes difficult or impossible to elicit an upper arm reading on the obese patient. For the patient whose condition warrants frequent blood pressure readings, the auscultatory method utilizing the upper arm presents a constant disturbance of rest.

The only alternate locations used to date have been the thigh and ankle. Clinical evidence suggests that the thigh is not used with any great frequency because it necessitates either turning the patient, or requires the use of a larger cuff, which many facilities do not possess. In addition, nurses may be unfamiliar with the techniques employed to obtain blood pressure measurements at either the thigh or ankle.
With the advent of the pressure sensor cuff, medicine may have also been provided with the means to obtain a blood pressure reading at an area other than the upper arm, thigh, or ankle. A possible site which may be just as or more convenient to use in some clinical situations is the finger. Due to its location, the index finger is particularly accessible for cuff placement. This idea raises questions regarding the accuracy and reliability of the measurements which would be obtained. These questions have not as yet been answered.

Statement of the Problem

The problem is to evaluate the performance reliability and validity, as measuring devices of the upper arm pressure sensor cuff and finger sensor cuff separately, against the sphygmomanometer, and against each other.

Significance of the Problem

Most medical personnel have encountered situations in which it has been inadvisable or not feasible to obtain a blood pressure reading from the upper arm. Instances occur in which the patient may have severe bilateral contractures, burns, casts, traction, or, the patient may be too obese. In these cases, the clinician may find it impossible to obtain an indirect blood pressure measurement. Clinical experience suggests that one should not
take a blood pressure on an extremity that has an intravenous line in place. Yet, situations arise in which the patient may have intravenous lines in both of his upper extremities.

A further problem is the constant disturbance of a patient's rest in order to obtain these readings. To perform this procedure without awakening the patient is difficult.

Although the medical profession recognizes its limitations in regard to locations for obtaining an indirect blood pressure reading, there have been no solutions to this dilemma. The use of the index finger as an alternate site will provide medicine with an answer to the above-mentioned problems. As stated, the currently used auscultatory method for obtaining blood pressure readings is fraught with potential error. For this reason, a more accurate means for obtaining indirect upper arm measurements is also needed. The upper arm pressure sensor cuff may prove to be the instrument to fulfill this need.

**Statement of Purpose**

The purpose of this study is to determine to what degree there is a correlation between the blood pressure measurements obtained from an upper arm, using both the auscultatory method and the pressure sensor cuff, and a patient's index finger, using a pressure sensor cuff.
Conceptual Framework

The paradigm for this conceptual framework is illustrated in Figure 1.

Systemic arterial blood pressure represents a force which is the result of cardiac output and peripheral vascular resistance (Burch and DePasquale 1962; Guyton 1976). The measurement of this force affords the physician information in regard to the patient's health status (Burch and DePasquale 1962; Ravin 1972). Routinely, a blood pressure determination is obtained by listening for the onset and disappearance of the arterial or Korotkoff sounds (Kirkendall et al. 1967; Ravin 1972). These sounds, which occur in five phases, are a result of the inflation and deflation of a sphygmomanometer over an arterial vessel and are heard through a stethoscope. The standard site for this measurement is the antecubital fossa of the upper extremity.

With the advent of the microprocessor and microphone, there have been many advances in medical technology. The new invention by Jewett (1977) incorporates a microphone into the pneumatic line from a specially designed blood pressure cuff. Pressure waves caused by the Korotkoff phases are detected within the cuff and are transmitted to the microphone from which they are converted to a digital readout via a microprocessor (Jewett 1977).
Construct Blood Pressure

Hemodynamic Status

Methods of Measurement

Construct

Concept

Hypothesis

Korotkoff Sounds

Pressure Waves

Stethoscope and Sphygmomanometer to Upper Extremity

Pressure Sensor Cuff to Upper Arm or Index Finger

Fig. 1. Conceptual Framework
This method of measurement provides the medical profession with an alternate means for obtaining an indirect blood pressure reading. Also, because this method operates on a pressure principle rather than upon sound, the use of a stethoscope can be eliminated. As previously alluded to, the reliability of the reading may be increased due to the removal of several potential sources of error. By employing this technique for pressure measurement in the finger, the difficulties of using this site due to inaccessibility of an area for application of a stethoscope or microphone are overcome.

Of further importance to medical personnel is the availability of locations in which to obtain a blood pressure recording. The pressure sensor cuff may allow medicine to secure reliable accurate recordings from an index finger. Certainly, this would prove to be advantageous in many clinical situations.

The new pressure sensor cuff, if demonstrated to be a reliable and valid measuring device, may well prove to be a valuable contribution to the medical profession.

**Null Hypothesis**

Systolic and diastolic blood pressure measurements obtained in the index finger of an adult (age 21 and over) in a resting state at a single sitting will display no significant difference when compared to systolic and
diastolic readings acquired on the upper arm, using either a standard mercury sphygmomanometer or a pressure sensor cuff.

**Limitations**

The following were the limitations of this study:

1. The size of the study was limited to 100 adults (age 21 and over).

2. A pilot study conducted on six adults identified no variables which would affect the reliability and accuracy of blood pressure readings obtained on the index finger. However, a larger sample may illustrate these as yet unidentified variables which could impose limitations on the study.

**Assumptions**

1. Variables which may affect the blood pressure determinations obtained on a finger will be partially identified by this study.

2. These devices (upper arm pressure cuff and finger cuff) may be used interchangeably with a standard blood pressure cuff.

**Definition of Terms**

Following are the definition of terms used for this study:
1. **Blood pressure**: The force exerted by the blood on a unit area of wall of the blood vessel.

2. **Auscultatory blood pressure technique**: A method of obtaining systolic and diastolic readings through the interpretation of arterial sounds heard through a stethoscope.

3. **Microprocessor**: A mini-computer on a single solid state base which makes possible sophisticated ultra-small digital devices.

4. **Microphone**: As used in this text, the microphone is a small device having an electrical output proportional to the air column vibrations which it receives.

5. **Pressure sensor cuff**: An inelastic, inflatable envelope which completely circumscribes the extremity or digit on which it is placed.

6. **Digital readout**: A device which displays data in a single set of numbers.
CHAPTER 2

REVIEW OF LITERATURE

This chapter has been divided into three sections. In the first section the most commonly utilized methods for acquiring a blood pressure measurement are discussed. The second section information is presented on a new alternative method for obtaining an indirect blood pressure. In the third section customary sites for acquiring a blood pressure recording are discussed and an alternate site is suggested.

Most Commonly Utilized Methods for Acquiring a Blood Pressure Measurement

Arterial blood pressure may be defined as being the pressure or force exerted by the blood on a unit area of the wall of the blood vessel (Burch and DePasquale 1962; Guyton 1976). According to Burch and DePasquale (1962) this measurement is ranked first in the many objective procedures employed by physicians to obtain quantitative data on their patients. Its relative importance as a quantitative measure of alterations in human physiology cannot be disputed.

Historically, blood pressure was first measured in 1738 by Stephen Hale (Burch and DePasquale 1962). Hale
published the results of a series of experiments in which he measured directly the arterial blood pressure in a variety of animals (Burch and DePasquale 1962; Geddes 1970). Since that time, many advances have been made in the methods by which arterial blood pressure is measured directly and indirectly.

There are several methods by which this measurement can be obtained. The most precise reading is acquired directly by intra-arterial lines (Berliner et al. 1960; Geddes 1970; Breit and O'Rourke 1974). However, as previously mentioned, this method is usually employed only for those critically ill.

Indirectly, blood pressure can be measured through the interpretation of specific events in the course of cuff deflation (Ravin 1972). Currently, there are three commonly used techniques for determining indirect blood pressure levels:

1. The auscultatory method in which the systolic and diastolic levels are ascertained through the interpretation of arterial sounds utilizing a stethoscope.

2. The palpatory method in which the blood pressure levels are signified by the beginning of, and a change in the quality of, arterial pulses.

3. The oscillometric (visual) method in which the systolic and diastolic levels are revealed by the
beginning of, and a change in the nature of, "bounces" in the mercury column or deflections on the aneroid gauge.

(Burch and DePasquale 1962; Correcting Common Errors . . . 1965; Gruen 1968; Geddes 1970; Krausman 1975).

Because the accuracy of blood pressure measurements is critical to the clinician, studies have been conducted which compared these techniques against intra-arterial line readings or against each other in an attempt to determine which indirect method compared most favorably with intra-arterial line recordings.

Studies which have contrasted the oscillometric method against a simultaneous intra-arterial line reading have revealed that recordings obtained by this technique will only be a crude estimation of the actual blood pressure measurement. Investigation has revealed that factors influencing this method included the sensitivity of the manometer utilized, the visual acuity of the observer, and the lack of establishment of an exact criteria for this technique (Correcting Common Errors . . . 1965; Geddes 1970; Krausman 1975). Or, as summarized by Krausman (1975, p. 287),

The oscillometric method has achieved only limited acceptance as an experimental or clinical tool. Continued controversy and conflicting experimental evidence among investigators as to the establishment of the exact criteria for the
recording of accurate systolic and diastolic pressures have seriously diminished confidence in the oscillometric method.

Similar studies have been conducted on the palpatory method. These experiments have revealed, for the most part, that the palpatory method is not as accurate as the auscultatory method when both are contrasted to an intra-arterial line reading. However, there is some controversy reported within the literature as to the exact technique used in this method and the degree of inaccuracy. For example, Krausman (1975) reported a variation of as much as 30 millimeters below a direct intra-arterial reading. In this study, the radial artery had been the site palpated. In contrast, Putt's (1966) comparison on auscultatory and palpatory recordings revealed a mean difference between the two methods of 5.74 to 7.00 millimeters of mercury. As stated by Putt in her 1966 study (p. 314), "these figures are well within the mean error of 8.00 millimeters of mercury that the American Heart Association states may be expected for individual readings of systolic and diastolic pressures in normal persons." In this study, Putt utilized the brachial artery. As Putt indicated, this disparity between results obtained from the two arteries demonstrates the need for further research into this area. Most authorities state that the palpatory method is the technique used to measure blood pressure when
all other indirect methods fail, are not available, or are not feasible due to hearing impairment or ear infection (Burch and DePasquale 1962; Putt 1966; Geddes 1970; Krausman 1975).

The literature clearly indicates that due to its relative accuracy and ease of performance, the current preferred technique for obtaining an indirect blood pressure reading is by auscultation (Berliner et al. 1960; Burch and DePasquale 1962; Kirkendall et al. 1967; Geddes 1970; Ravin 1972; Krausman 1975).

The auscultatory method for obtaining a blood pressure is based on the interpretation of arterial or Korotkoff sounds through a stethoscope during the deflation of a sphygmomanometer (Burch and DePasquale 1962; Geddes 1970; Ravin 1972). The mechanism of the Korotkoff sounds has never been completely understood. It is believed that these sounds originate from the turbulence of flow as the blood enters the narrow segment of the artery under the compression cuff (Burch and DePasquale 1962; Geddes 1970). Generally, systolic pressure is considered the point at which the initial tapping sound is heard for at least two consecutive beats, and diastolic pressure is the point at which the sounds become muffled (Kirkendall et al. 1967).
Although this method is considered to be the most meticulous of the indirect methods, limitations as to its accuracy and reliability have been frequently reported in the literature. Glor (1968), in a study on reproducibility of auscultatory blood pressure readings, reports a lack of consistency by personnel in readings on an individual patient. Mitchell and Van Meter (1971) have pointed out in a later study that reproducibility of blood pressure recorded on patients' records by nursing personnel is difficult to achieve. Foley (1971) has revealed that there may be a variation in blood pressure due to position changes. Rose (1965) and Wilcox (1961) both discussed the variability in observers in their estimations of blood pressure equipment in relation to the accuracy of recordings. Thielen (1975) and King (1969) discussed the need for standardization of the technique utilized to obtain an auscultatory reading that would be reliable from one recording to the next. Kirkendall et al. (1967), Burch and DePasquale (1962), and Guyton (1976) explained the significance of sympathetic nervous system stimulation on blood pressure, and related the importance of cuff width and placement, the effect of arm position, and deflation rate on accuracy and reliability of auscultatory determinations. Jarvis (1977) and an article in the *American Journal of Nursing* (Correcting Common Errors . . .)
1965) explained the significance of the positioning of the manometers.

Kirkendall et al. (1967) reported in *Circulation* recommendations for the procedure for obtaining blood pressure determinations by auscultation in an attempt to reduce or eradicate sources of potential error. These recommendations have been adopted by the American Heart Association.

The literature reviewed has revealed these recommendations as being widely accepted. However, continued inaccuracy in measurements indicates that clinicians should adhere more closely to the stated recommendations or that a superior alternate method for acquiring an indirect blood pressure reading should be developed.

**An Alternative Method for Obtaining an Indirect Blood Pressure Measurement**

Much research has been conducted in an attempt to devise a superior method for obtaining an indirect blood pressure measurement. Since the accuracy of the auscultatory method has been shown to be dependent, in part, on the clinician who has obtained the reading, science has attempted to invent an automated technique.

Gruen (1968), King (1969), and Labarthe (1976) have all reported on the present automated devices. Their investigations have illustrated that the automated methods
produced thus far have not proven to be superior to the auscultatory techniques. These authorities stated the primary reason for the lack of improvement in accuracy to be an inability of the machines to clearly detect the Korotkoff sounds. Therefore, the device did not always receive a definite enough signal from which it could determine systolic or diastolic readings.

The new cuff invented by Jewett (1977) may resolve that problem. According to Jewett, this cuff differs from others because it operates on a pressure basis rather than sound. The pressure waves detected by the cuff are transmitted to a microphone, which, in turn, relays the information to a microprocessor, which then displays a digital readout of the blood pressure, thereby eliminating entirely the need for a stethoscope.

Initial testing conducted on animals has revealed this method to be more accurate than the auscultatory technique when both are compared to a reading obtained by an intra-arterial line (Jewett 1977).

With the advent of this new cuff, science may have been provided with a superior method, in terms of accuracy and ease of performance, for acquiring an indirect blood pressure determination.
Customary Sites for Obtaining an Indirect Blood Pressure and a Proposed Alternate Site

Documentation has revealed the antecubital fossa of the upper arm to be the recommended site for obtaining an indirect blood pressure reading (Burch and DePasquale 1962; Kirkendall et al. 1967; Geddes 1970).

Clinical experience has indicated that there are instances when it is neither feasible nor advisable to use this site; for example, when the patient has bilateral burns, contractures, casts, or intravenous lines in place. Obesity has also proven to be a problem in obtaining an accurate blood pressure. In these circumstances, it has been recommended that the popliteal fossa of the thigh be utilized (Burch and DePasquale 1962; Kirkendall et al. 1967; Geddes 1970). Clinical evidence has suggested that this substitute site is not always practical or desirable to use as the patient must be turned to obtain the most accurate reading.

In extreme circumstances, clinical experience has indicated that the ankle may be utilized to obtain a blood pressure reading. The absence of any literature on this technique has implied that this method must be infrequently used.

Over the years, numerous investigations have been carried out as to the feasibility of using the digit as an alternate site for obtaining a blood pressure. Various
devices have been invented and discarded due to their inaccuracy or inappropriateness in technology for the medical setting, or their inability to obtain a diastolic reading (Weaver and Bohr 1950; Gaskell and Krisman 1958; Ball, Pallett and Shillingford 1961).

More recently, Gundersen and Dahlen (1975, p. 743) reported on the accuracy and ease of performance of the digital device in a study performed on newborn infants.

The study demonstrated that measurements of the systolic blood pressure in the index finger may be performed without technical problems and without disturbing the sleep or influencing the intra-arterial blood pressure.

They further reported the difference between mean values of direct and indirect systolic pressure in this study to be from 7 to -2 millimeters of mercury. However, the technology involved in this device does not allow for diastolic readings.

Therefore, science has continued to be limited in the sites which can be utilized to readily obtain systolic and diastolic blood pressure measurements.

The incorporation of Jewett's (1977) technology into a minicuff may provide medicine with an alternate site for obtaining a blood pressure.
CHAPTER 3  

METHODOLOGY  

This chapter includes a discussion of the research design, a description of the sample, the steps taken to ensure the rights of human subjects, the data collection method, and the statistical analysis intended to test the relationships between the variables.  

Research Design  

The study was a descriptive correlational design. In order to test the proposed hypothesis, a series of six systolic and diastolic blood pressure readings was obtained from each subject at a single sitting. These measurements consisted of two recordings from the upper arm using a mercury sphygmomanometer and stethoscope, two measurements from the upper arm using a pressure sensor cuff, and two readings from the index finger using a pressure sensor cuff. Since blood pressure is most frequently measures by auscultation, this method of measurement was added to the study as an "industry standard" to assess the validity of the new devices.  

The purpose of acquiring paired measurements by each method was to permit computation of inherent error
variabilities and reliabilities by bivariate correlation-regression of the coupled measurements. From these analyses, run in parallel for systolic and diastolic pressures, judgments whether one blood pressure apparatus was more reliable or variable than another could be made.

The next step was to examine the relationships between the blood pressure readings obtained by different methods. For example, measurements acquired on a digit as opposed to readings obtained on the upper arm using auscultation, using the averages of the paired measures as the most reliable data for each. Bivariate correlation-regression was again used for this analysis. This provided information regarding the consistency of the devices to one another, thereby testing for apparatus interchangeability; thus criterion validity was established for the experimental devices.

Variables which might have affected blood pressure readings obtained on a digit had not yet been fully identified. Therefore, it was determined that with little effort one could elicit enough information regarding the client's health history on a computerized data collection form to acquire some gross knowledge regarding the identification of these variables for future study. This information was acquired by examination of the bivariate
correlation-regressions mentioned above for influences by "background" variables (i.e., disease, medication, obesity).

**Description of Sample**

The population from which the sample was chosen consisted of clients who frequented a health care clinic in the southwest. The sample consisted of 100 adults (age 21 and over). The subjects were selected by the researcher as they entered the health clinic. No attempt was made to include or exclude any client. Selection was based solely on convenience for the researcher.

**Protection of Human Rights**

Authorization was received from The University of Arizona Human Subjects Committee to carry out the study. Each of the subjects was asked to read the consent form. If the clients agreed to participate in the study, they signed a consent form (see Appendix A).

To further assure protection of human rights in this study, all data were coded and computer analysis was done via the code number. Anonymity was ensured in that names were not recorded by the researcher.

**Data Collection Method**

The researcher approached any adult entering the health care clinic to explain the study and ask for their
participation. As previously mentioned, no attempt was made to include or exclude any clients.

Once participation was agreed upon and the consent form signed, the client was seated in an examining room and a data collection form was completed (see Appendix B). Following the completion of the data form, the equipment was displayed to the client. Equipment for this study included a standard mercury sphygmomanometer, a Tycos stethoscope, a pressure sensor cuff for the upper arm, and a pressure sensor cuff for the finger. All equipment was provided to the researcher by the inventor of the pressure sensor cuffs, Jewett. The same equipment was used for all testing. Validity of these tools was ascertained by comparing a reading obtained by this equipment against a reading secured by an intra-arterial line. Validity testing was conducted by Jewett.

A total of six systolic and diastolic blood pressure measurements was then obtained and recorded on each client. These readings were taken in two series of three recordings per series. Each series consisted of a reading from the upper arm using the auscultatory method and pressure sensor cuff and a reading from the index finger using a pressure sensor cuff.

Following a discussion with consultants Putt, nurse clinician; Jewett, electrical engineer; and Gaines,
statistician, it was determined that the measurements would be obtained in the following rotating pattern: upper arm -- auscultatory; upper arm -- pressure sensor cuff; digital -- pressure sensor cuff, and, then, digital -- pressure sensor cuff; upper arm -- pressure sensor cuff; upper arm -- auscultatory. This order of administration was deemed adequate based on a Latin Square design pilot test of three adult subjects which demonstrated that the order of obtaining the blood pressure measurements did not make any difference. A minimum of one minute's time was allotted between measurements.

No discrimination was made as to whether the right or left arm or digit was used for the readings. However, if the right extremity was chosen, then all readings on that client were performed on that extremity. The index finger was selected for the digital pressures because it represented the digit which would be the easiest for cuff placement. The upper extremity was supported at heart level during all recordings.

The researcher followed the procedure recommended by the American Heart Association for obtaining and recording the auscultatory pressure. Briefly summarized, these recommendations include: a cuff width 20 percent wider than the diameter of the limb on which it is to be used; the extremity supported at heart level; a deflation
rate of two to three millimeters of mercury per second; the mercury manometer placed in a vertical position; the observer viewing the sphygmomanometer at eye level; and the bladder of the blood pressure cuff centered around the antecubital fossa.

As previously discussed, stimulation of the sympathetic nervous system may alter blood pressure. Therefore, the researcher attempted to place each client at ease by proper introductions, explanation of the study, and display of the equipment to be used. If the researcher discovered any factor or factors about the client which could have altered the blood pressure due to sympathetic nervous stimulation, a notation and check mark on "other" of the data collection form was made.

The same researcher obtained and recorded all the information compiled. The data collection portion of this study was conducted within a two-month time span.

**Data Analysis**

The relationships between the variables (blood pressure readings obtained on the upper arm by auscultation and pressure sensor cuff, and blood pressure measurements acquired on a digit utilizing a pressure sensor cuff) were examined with bivariate correlation-regression analysis. This analysis was achieved in the following manner:
1. The relationships between each paired blood pressure reading were examined by bivariate correlation-regression analysis to test reliability.

2. Discrepancy scores between paired measurements were correlated with background and history factors to identify subject-based sources of unreliability.

3. A composite or average of each pair of measurements was then obtained for use in the criterion validity and device interchangeability analysis.

4. Bivariate correlation-regression analysis was again used to determine the relationships between the blood pressure readings obtained by the experimental methods and the standard sphygmomanometer readings to establish criterion validity.

5. A second set of discrepancy scores, between the systolic and diastolic readings by the two experimental methods and the corresponding sphygmomanometer readings were also obtained. This was done to establish any correlation between the background characteristics and the lack of criterion validity.

6. A device interchangeability analysis for the experimental methods was also performed.
7. Where relevant, statistical significance for this study was evaluated at the 0.05 level.
CHAPTER 4

PRESENTATION AND ANALYSIS OF DATA

The characteristics of the sample and the statistical analyses of the data collected are presented in this chapter.

Characteristics of the Sample

The sample was composed of 100 adult subjects -- 40 males and 60 females -- who entered a health care clinic for various reasons. The clinic was located in a southwestern university town.

The minimum age of the subjects was 21 and the maximum 78. The range for weight was 80 to 221 pounds, and height 55 to 77 inches. A summary of age, weight, and height distributions of the 100 clients is presented in Table 1.

Table 1. Age, Weight and Height Traits of the Sample According to Mean, Standard Deviation, Skewness, and Kurtosis

<table>
<thead>
<tr>
<th>Traits</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Skewness</th>
<th>Kurtosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>37.5</td>
<td>13.4</td>
<td>0.78</td>
<td>-0.27</td>
</tr>
<tr>
<td>Weight</td>
<td>152.2</td>
<td>31.9</td>
<td>0.22</td>
<td>-0.74</td>
</tr>
<tr>
<td>Height</td>
<td>66.8</td>
<td>4.2</td>
<td>0.14</td>
<td>-0.19</td>
</tr>
</tbody>
</table>
The skewness and kurtoses figures in Table 1 indicate that there was no notable deviation from normality in the distribution of the ages, weight, or height of the subjects.

The data collected from the subjects regarding their health history and current medications is summarized in Table 2.

Table 2. Characteristics of Sample: Health and Medication History of Subjects

<table>
<thead>
<tr>
<th>Reported Items</th>
<th>Subjects Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health History</strong></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>15</td>
</tr>
<tr>
<td>Cardiac Dysfunction</td>
<td>12</td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td>2</td>
</tr>
<tr>
<td>Endocrine Dysfunction</td>
<td>6</td>
</tr>
<tr>
<td>Peripheral Vascular Disease</td>
<td>1</td>
</tr>
<tr>
<td>Blood Disease</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td><strong>Current Medications</strong></td>
<td></td>
</tr>
<tr>
<td>Cardiac Drugs</td>
<td>3</td>
</tr>
<tr>
<td>Diuretics</td>
<td>3</td>
</tr>
<tr>
<td>Antihypertensives</td>
<td>4</td>
</tr>
<tr>
<td>Hormones</td>
<td>6</td>
</tr>
<tr>
<td>Others</td>
<td>15</td>
</tr>
</tbody>
</table>
Statistical Analysis

The means of all the readings obtained, the standard deviations, and the number of subjects from which the blood pressure measurements for each were obtained are displayed in Table 3.

The figures shown in Table 3 reveal that the finger cuff was notably more prone to failure in obtaining measurements than either of the other two methods. Out of 200 attempts for a systolic reading, the finger cuff failed 18 times, which is a 9 percent failure rate. Of 200 attempts to obtain a diastolic reading, the finger cuff failed 20 times, for a 10 percent failure rate.

As seen in Table 3, the standard deviations for the standard sphygmomanometer and pressure sensor cuff systolic measurements are similar on both trials. However, the standard deviation for the diastolic measurement is higher for the pressure sensor cuff than the standard sphygmomanometer. This indicates a greater error variability; therefore, standard methods are most reliable.

The standard deviations for the finger cuff measurements, both systolic and diastolic, are greater than either of the other two devices used, suggesting the greatest error variability.
Table 3. Descriptive Summary of Systolic and Diastolic Pressure Measurements According to Mean of all Readings, Standard Deviation, and Numbers for the Standard Sphygmomanometer, Upper Arm Pressure Sensor Cuff, and Finger Cuff

<table>
<thead>
<tr>
<th>Method</th>
<th>Trial I</th>
<th></th>
<th>Trial II</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean of All Readings</td>
<td>Standard Deviation</td>
<td>N=</td>
<td>Mean of All Readings</td>
</tr>
<tr>
<td>Standard Sphygmomanometer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>119.1</td>
<td>16.0</td>
<td>100</td>
<td>117.5</td>
</tr>
<tr>
<td>Diastolic</td>
<td>80.5</td>
<td>11.9</td>
<td>99</td>
<td>79.7</td>
</tr>
<tr>
<td>Upper Arm Pressure Sensor Cuff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>115.3</td>
<td>16.2</td>
<td>99</td>
<td>114.4</td>
</tr>
<tr>
<td>Diastolic</td>
<td>80.4</td>
<td>17.2</td>
<td>99</td>
<td>17.3</td>
</tr>
<tr>
<td>Finger Cuff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>131.3</td>
<td>24.5</td>
<td>93</td>
<td>131.4</td>
</tr>
<tr>
<td>Diastolic</td>
<td>84.4</td>
<td>30.1</td>
<td>91</td>
<td>79.4</td>
</tr>
</tbody>
</table>
The results of test-retest reliability correlations of the paired measurements for the three methods are displayed in Table 4.

### Table 4. Test-Retest Reliability Correlations of Systolic and Diastolic Measurements for the Standard Sphygmomanometer, Upper Arm Pressure Sensor Cuff, and Finger Cuff

<table>
<thead>
<tr>
<th>Method</th>
<th>Correlation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Sphygmomanometer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>.86</td>
<td>100</td>
</tr>
<tr>
<td>Diastolic</td>
<td>.82</td>
<td>99</td>
</tr>
<tr>
<td><strong>Upper Arm Pressure Sensor Cuff</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>.83</td>
<td>97</td>
</tr>
<tr>
<td>Diastolic</td>
<td>.63</td>
<td>97</td>
</tr>
<tr>
<td><strong>Finger Cuff</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>.53</td>
<td>88</td>
</tr>
<tr>
<td>Diastolic</td>
<td>.27</td>
<td>87</td>
</tr>
</tbody>
</table>

In measurement evaluation research, it is desirable for reliability coefficients to be as high as possible, preferably .95 and above. However, a range of .80 to .85 may be considered more or less normal for blood pressure
measurements, considering the inherent variability of blood pressure itself and the potential for error attributable to the indirect nature of the measurement procedures.

The analysis results displayed in Table 4 illustrate that the coefficients for the readings obtained by the standard sphygmomanometer, both systolic and diastolic, and the upper arm pressure sensor cuff systolic readings are above .80. However, the coefficient for the diastolic readings obtained by the upper arm pressure sensor cuff is well below that level. Furthermore, the coefficients for both systolic and diastolic readings obtained by the finger cuff are even lower, with the reliability for the diastolic readings being extremely low; therefore, the results of this analysis do not permit rejection of the null hypothesis examined in this study.

To explore the unreliability, a discrepancy score was constructed for each pair of readings used in the reliability analysis by dividing the absolute value of the difference between the readings by their average. These scores were then correlated with the subject's background characteristics to ascertain whether any of these factors could be identified as a potential cause of the observed unreliability. Only two of these correlations -- those for the finger cuff diastolic discrepancy scores with sex
and with renal disease — attained statistical significance at the 0.05 level, but they did so with $r^2$ values less than 0.07, far below the level necessary to judge them clinically relevant.

With these results, further analysis is really not warranted since the validity of unreliable measuring devices is of limited interest. However, since the appropriate data is available and since the results of the validity analysis complement those of the reliability analysis, examination of those results is instructive.

The averaging of the paired measurements provided a means for further analysis. Criterion validity correlations for the two experimental methods against the auscultatory readings are presented in Table 5.

<table>
<thead>
<tr>
<th></th>
<th>Systolic</th>
<th>Diastolic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finger cuff</td>
<td>.44 (n=88)</td>
<td>.40 (n=86)</td>
</tr>
<tr>
<td>Upper arm pressure sensor cuff</td>
<td>.82 (n=97)</td>
<td>.38 (n=96)</td>
</tr>
</tbody>
</table>
The above figures reveal that the correlation between the upper arm pressure sensor cuff and the sphygmomanometer systolic measurements is in excess of .80, indicating that the upper arm pressure sensor cuff is a fairly effective substitute for the standard sphygmomanometer for systolic readings. Its validity coefficient is in the same range as the reliability coefficients for systolic readings by both methods. The other three validity coefficients are too low for them to be considered effective alternatives to the auscultatory method.

A second set of discrepancy scores between the systolic and diastolic readings by the two experimental methods and the corresponding sphygmomanometer readings were defined. Specifically, the absolute value of the differences between, for example, the upper arm pressure sensor cuff systolic readings and the sphygmomanometer reading was divided by the sphygmomanometer reading. These were then correlated with the background characteristics to identify potential causes of the lack of criterion validity.

The results revealed no correlations which attained statistical significance at the 0.05 level.

A device interchangeability analysis for the experimental methods revealed a .34 squared correlation on 86 subjects for systolic readings and a .24 for
diastolic measurements on 85 subjects, indicative of very low agreement between them.
CHAPTER 5

DISCUSSION OF FINDINGS AND RECOMMENDATIONS

Discussion of Findings

It has been demonstrated that the finger cuff is not reliable in measuring either systolic or diastolic blood pressures. The upper arm pressure sensor cuff was found to be reasonably reliable in measuring systolic pressures but not diastolic.

Validity analysis of the experimental devices against the auscultatory method illustrated again that systolic readings obtained on the upper arm using the pressure sensor cuff were valid but diastolic readings were not. Neither systolic nor diastolic readings were found to be valid using the finger cuff.

In relation to device interchangeability, the finger cuff cannot at this time be used interchangeably with an upper arm pressure sensor cuff.

Recommendations

The results of this study indicate that the finger cuff does not produce consistently accurate measurements. Furthermore, the upper arm pressure sensor cuff also revealed inconsistencies in its diastolic readings.
Therefore, this investigator recommends (1) additional design work be conducted on both devices, and (2) further testing as soon as modifications have been made.

The only alternative to further engineering work would be to use a multiple measurement technique in which a series of pressures would be obtained and averaged to derive the reading used clinically. This would improve the performance of the devices. However, this alternative would probably be unrealistic in an actual clinical setting due to the increased time involved.

As a result of these findings and recommendations, modification of the programming within these units is being made in order to improve the reliability of this technique as a measurement of blood pressure.
CHAPTER 6

SUMMARY

The major purpose of this study was to determine the correlations between blood pressure measurements obtained on a finger using a pressure sensor cuff on the upper arm using a pressure sensor cuff and a standard sphygmomanometer and stethoscope.

Blood pressure measurements were obtained on 100 adult clients in a health care clinic. Each client had six readings taken at a single sitting. These readings were taken in two series of three recordings per series. Each series consisted of a reading from the upper arm using a standard sphygmomanometer and stethoscope, and pressure sensor cuff, and a reading from the index finger using a pressure sensor cuff.

A short health history consisting of information regarding the current usage of medications and any significant past or present illness was obtained on each client along with their sex, age, weight, and height. This was done in order to determine what "background influences," if any, would affect the functioning of the finger cuff.

Bivariate correlation regression analysis was the primary analytic tool used for assessment of device
reliability, and criterion validity against the sphygmmomanometer readings, device interchangeability, and the influence of the background factors. The results revealed:

1. The finger cuff was more prone to failure than either the upper arm pressure sensor cuff or the standard sphygmmomanometer.

2. The finger cuff displayed a greater error variability than either of the other devices in both systolic and diastolic readings.

3. The upper arm pressure sensor cuff demonstrated a greater error variability in diastolic readings than the sphygmmomanometer but less than the finger cuff.

4. The reliability coefficients for the finger cuff were markedly low.

5. The upper arm pressure sensor reliability coefficients for diastolic readings were also somewhat low.

6. The influences of background variables were not found to be significant as a cause of device unreliability.

7. Validity correlation coefficients on the measurements obtained by the finger cuff were below the accepted standard.
8. The upper arm pressure sensor validity correlation coefficient for the diastolic readings obtained was below the accepted standard.

9. A device interchangeability analysis revealed that the finger cuff cannot be used interchangeably with either the upper arm pressure sensor cuff or the standard sphygmomanometer.

Therefore, modification or redesign of the finger cuff is indicated before it can be used in clinical practice. Furthermore, the inconsistency of the upper arm pressure sensor cuff diastolic readings indicate that this device also needs redesign or readjustment.

When this has been accomplished, retesting of both devices is recommended.

Due to these findings and recommendations, the programming within these units is being modified.
APPENDIX A

SUBJECT’S CONSENT FORM

Project Title: Blood Pressure Comparisons

This is a study about the relationship between blood pressure measurements on the upper arm and finger. The information obtained in this study may help in future patient care.

Your participation in this study consists of answering a few questions about your health history and allowing me to take your blood pressure six times.

You can be assured of the confidential handling of the information obtained in this study. Your name will not be used. The information will be coded and analyzed by a computer.

I have read the above "Subject's Consent." The nature, demands, risks, and benefits of the project have been explained to me. I understand that I may ask questions and that I am free to withdraw from the project at any time without incurring ill will (or affected my medical care).

I also understand that this consent form will be filed in an area designated by the Human Subjects Committee with access restricted to the principal investigator or authorized representatives of the particular department.

Subject's Signature ____________________________ Date ________
Witness' Signature ____________________________ Date ________
### BLOOD PRESSURE COLLECTION DATA

<table>
<thead>
<tr>
<th>Study No.</th>
<th>Page No.</th>
<th>NOTE: 1=Yes, unless an actual value is required</th>
</tr>
</thead>
</table>

#### MEDICATIONS
- Cardiac
- Diuretics
- Antihypertensives
- Hormones
- Other

#### HEALTH HISTORY
- Hypertension
- Cardiac Dysfunction
- Renal Dysfunction
- Endocrine Dysfunction
- Peripheral Vascular Disease
- Other

#### Being Treated for Blood Disease

#### BP READINGS

<table>
<thead>
<tr>
<th>Person</th>
<th>1st Person</th>
<th>2nd Person</th>
<th>3rd Person</th>
<th>4th Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm (auscultatory) 1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Arm (auscultatory) 2</td>
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<td></td>
</tr>
<tr>
<td>Arm 1</td>
<td></td>
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</tr>
<tr>
<td>Arm 2</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Finger 1</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Finger 2</td>
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<td></td>
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LIST OF REFERENCES


