CHAPTER THREE

RESEARCH DESIGN AND RESEARCH METHODS

3.1 INTRODUCTION

This chapter describes the research design, the setting of the study, target population, eligibility criteria, sample and sampling method and data collection procedures. Detailed description of the instrument as well as issues of reliability and validity are also presented. The chapter further elucidates the results of the pilot study and outlines the ethical considerations during the course of the study.

3.2 PURPOSE AND OBJECTIVES

For consistency, the purpose and objectives of this study are repeated here.

The purpose of this study was to describe and compare the two blood pressure techniques namely invasive and non invasive in order to assess the limits of agreement between the two readings obtained on patients in the adult critical care units in a tertiary health care institution, to determine the difference in terms of accuracy and sensitivity, to describe the factors that affect the accuracy of both techniques as well as to describe the reasons given by clinical practitioners for their choice of blood pressure monitoring techniques.

In order to meet this purpose, the following objectives were set:

- To establish whether there is a difference in terms of accuracy and sensitivity in the assessment of blood pressure using two different techniques of blood pressure monitoring.
- To determine what the difference is in terms of accuracy and sensitivity.
- To determine the factors that affect accuracy of both techniques in the critical care unit.
- To elicit the reasons given by practitioners for their choice of blood pressure monitoring technique in the critical care units.

3.3 RESEARCH DESIGN

A non experimental, descriptive, comparative, prospective two part study design was utilized to assess the limits of agreement between invasive arterial blood pressure and non invasive blood pressure monitoring in critically ill patients.

In a non-experimental research, the study is carried out in a natural setting and the phenomena are observed as they occur without manipulation of the variables (Brink, Van der walt, Rensburg, 2006) A non-experimental design was suitable for this study as there was no influence on the performance of the two blood pressure monitoring techniques (Burns & Groove, 2001).

Descriptive studies are a way of discovering new meaning, describing what exists, determining the frequency with which something occurs and categorizing information. (Burns & Grove, 2001). In this case, it applies to the frequency and indications of using two monitoring techniques simultaneously and the limits of agreement between the two

blood pressure measurements. Polit and Hungler (1997) states that at a descriptive level, research is aimed at describing a phenomenon of which little is known. In this study, descriptive research was used to determine the limits of agreement between invasive blood pressure and non invasive blood pressure measurements in relation to the procedure and techniques of monitoring the blood pressure.

A comparative design is a scientific comparison of different phenomenon in an effort to understand their origins of relationship (Burns & Groove, 2001). This was used in this study to compare invasive blood pressure and non invasive blood pressure monitoring techniques. The comparative design was suitable in this study because it examines and describes differences in variables in two or more groups that occur naturally in the setting; it provides an accurate portrayal of a particular event for the purpose of describing what exists and determining the means, ways and frequency with which an event occurs (Burns & Groove, 2001).

A prospective study allows the researcher to measure variables that are occurring during the study (Brink et al., 2006). It was selected because it allowed the researcher to examine and interpret patterns (extraneous variables) in the study group that may influence responses regarding the limits of agreements, the relationship between non invasive blood pressure and invasive blood pressure measurements in current clinical practice (Burns & Groove, 2001).

Further more, a prospective study was deemed appropriate because it would elicit information on the types of blood pressure machines, cuffs types, cuff sizes in relation to the upper arm circumference, visibility of good arterial waveform for invasive blood

pressure monitoring technique, the model of transducers, cannulas used, the servicing dates of the machines, dates and times that the arterial catheter was inserted and when the continuous flush system was set up.

A prospective design would also permit the researcher to counter check whether the non invasive blood pressure reading corresponded to the measurement that was recorded on patient's critical care chart. In addition, a prospective study would facilitate the observation of and incorporation of the characteristics of the research field into the study. These characteristics included the practices of using simultaneously and interchangeably the invasive blood pressure and non invasive blood pressure monitoring techniques in critical care settings as often observed by the researcher.

Thus a two part study was undertaken. Part one was to assess the limits of agreement between invasive blood pressure and non invasive blood pressure reading obtained on patients in five adult critical care units (n=5) while part two was to describe the reasons given by clinical practitioners (Doctors and critical care nurses) for their choice of blood pressure monitoring techniques in the critical care units.

3.4 **RESEARCH SETTING**

The research was conducted in five critical care units (n=5) in a tertiary teaching hospital. These were the coronary care unit, which admits different kinds of cardiac patients with acute chest pain, angina, cardiac angiograms; Cardiothoracic unit, which admits patients with open heart surgery like coronary artery bypass Grafts, heart valves repair or

replacement, repair of congenital heart valves and other defects; Neuro-surgical unit which admits patients with, neuro surgeries such as craniotomies, subdural hemorrhage drainage, spinal decompression; Trauma unit which admits patients with head injuries, multiple fractures from motor vehicle accidents, gunshots and patients with severe burns and Multidisciplinary critical care unit which admits patients with different kinds of critically ill medical patients with pneumonia, Acute Respiratory Distress Syndrome (ARDS), renal failure, sepsis and many more medical conditions .

The majority of surgical patients were intubated and mechanically ventilated post operatively because of anesthetic effects and metabolic changes. They also had arterial lines in situ which were used for continuous blood pressure monitoring and connected to cardiac monitors in order to monitor their vital signs continuously. Many of these patients also had blood pressure cuffs in situe connected to cardiac monitors to measure the non invasive blood pressure along with invasive blood pressure from the arterial line.

3.5 TARGET POPULATION

The target population in part one of the study comprised of all patients admitted to the five critical care units (n=5) over a three month period from 1/5/2004 to 31/8/2004.

A preliminary record review of the 2001-2002 statistics revealed that an average total number of 396 patients were admitted to the adult critical care units over a period of three months. This is an average of 130 patients per month.

The target population in part two of the study comprised of all clinical practitioners working in the five adult critical care units (n=5) at the tertiary teaching hospital. A preliminary record review conducted in February 2004 indicated that on average, 136 (n=136) clinical practitioners in total, were assigned to the five critical care units (n=5).

3.6 SAMPLE AND SAMPLING METHOD.

3.6.1 Sample

A sample is a subset of the population that is selected for a study (Burns & Grove, 2001) and sampling method is the process of selecting a group of people for a study. (Thus patients and clinical practitioners) (Burns & Grove, 2001). In this two part study, both patients and clinical practitioners will be discussed.

In part one of the study, following the discussion with a statistician from the medical research council (MRC) it was decided that a minimum of (n=80) subjects, instead of (n=100) as decided before would be appropriate to provide a good representation of the population from which the sample is drawn. A large sample is needed to obtain a confidence interval of 95% (Burns & Grove, 2003) in order to elicit the limits of agreement between non invasive blood pressure and invasive blood pressure monitoring. The reasons of the sample reduction were the following:

- There was difficulty in obtaining consent from relatives and patients who did not understand well the nature of the research and consequently did not give their consent.

- In the trauma and neuro–surgical critical care units, there were several unknown patients, some of them ended up in a comatose state and consent could not be obtained.
- In some of the CCUs there was a shortage of cuffs of all sizes and dynamap machines were faulty, this affected the sample size. Due to infection control policy, it was impossible to move one dynamap or cuffs from one cubicle to the next.
- Many patients did not meet all the inclusion criteria, the most difficult criteria to achieve was age, as most of the patients were above 50 years old. Therefore the researcher had to use stratified disproportionate sampling based on inclusion criteria and consent.

In part two on the other hand, a minimum of 50 subjects would be appropriate to elicit the choice and view of clinical practitioners as to the preferred technique of choice between invasive and non invasive blood pressure monitoring in critical care units.

3.6.2 Sampling Method

In part one of the study, following the pilot study the researcher opted to use non probability, purposive sampling method which involves conscious selection by the researcher of certain objects or elements to include in a study by following rigorously the study inclusion criteria (Burns & Grove, 2003).

Critical care nurses registry and documentations were used to access patients critical care charts in order to get the study‘s inclusion criteria and patients demographic data.

This method of sampling was aimed at ensuring that patients were obtained from each of the units and that the minimum numbers of patients required for establishing limits of agreements between invasive blood pressure and non-invasive blood pressure, was obtained.

After a record review of the critically ill patients admitted to the critical care units or the patient scheduled for theatre, the researcher selected patients based on inclusion criteria and informed consent. Sampling was done until the desired number of patients required for statistical analysis was obtained.

Inclusion criteria for the patient's sample were:

- Age between 18 and 50 years.
- Critical care admission acute illness/ injury with an APACHE II Score > 12.
- Presence of a radial arterial line for continuous invasive blood pressure monitoring less than 48 hours old.
- Presence of non invasive blood pressure device and cuffs of different sizes.

In part two of the study a random sampling method was used by means of questionnaire until the desired sample size was reached to all clinical practitioners who complied with all inclusion criteria. The random sampling methods usually provide a sample that is representative of the population, because each member of the population has a probability greater than zero of being selected for a study. Random sampling methods require greater researcher control and rigor than nonrandom or non-probability sampling methods (Burns & Grove, 2003).

Part two of the study aimed at exploring clinical practionners (Doctors and Nurses working in critical care units) choice and views on which blood pressure measurement method they generally believed to be more accurate, which method they found easier to use and what were their reasons to why they believed that such blood pressure method was easy or accurate than the other?

Inclusion criteria for the clinical practitioners were:

- Medical Doctors and Registered nurses.
- Working in either trauma, cardiothoracic, neuro-surgical critical care unit, coronary care unit or multidisciplinary critical care unit.
- More than two years of experience working in critical care unit.
- Having looked after a patient with both IBP and NIBP measurement methods.
- Provided that written consent to participate in the study was obtained.

3.7 DATA COLLECTION

3.7.1 Data collection Procedure

In part one of the study the relatives of the patients who met the eligibility criteria were approached during visiting hours and informed verbally about the nature of the study and the implication for their involvement in the study. Participants were assured of voluntary participation, confidentiality and anonymity during the study. The procedure in detail was provided including the researchers' contact number in case they required further information from the researcher. In the case where the patient was not in a position to

make an informed consent, a written information sheet and consent form were provided to the patients' relatives.

In the case of patients who were scheduled for elective surgery, the researcher viewed the theatre list of those patients who would automatically be admitted to the critical care unit, being a prospective study. Consent was then obtained from the patients pre-operatively. This applied particularly to patients in the cardiothoracic critical care unit.

Once consent was obtained and the patient was found to meet the eligibility criteria, the researcher introduced himself before starting data collection to the critical care nurse of the patients, patient's relatives and the patient and started by patient's data record review and the baseline assessment. The patient's baseline assessment consisted of recording the patient's heart rate, temperature, one IBP reading of systolic, diastolic and mean arterial pressure (MAP), one reading of NIBP reading of systolic, diastolic and mean arterial pressure (MAP), mode of ventilation, peak inspiratory pressure, pause inspiratory pressure, positive end-expiratory pressure (PEEP), analgesia, sedation, paralyzing agents and inotropic/ vasopressor support with dosages.

After all the reliability and validity checks were done, which consisted of leveling of the bridge, calibration, checking on the flushing system, air in the system and patency of the arterial line; the researcher started by taking one reading of invasive blood pressure (IBP) that included systolic, diastolic and mean arterial pressure. This was followed by checking the reliability and validity of non invasive blood pressure which consisted at checking of position and application of cuff on patient's arm, cuff width in relation to patient's arm circumference; the researcher proceeded by taking one reading of non invasive blood

pressure (NIBP) which also comprised of systolic, diastolic, mean pressure. During the IBP and NIBP recording, the researcher ensured that the patient was quiet, calm, not moving and the patient's environment was free of noise according to Thomas, et al., (2002).

After collecting data from both techniques the researcher established the difference between systolic, diastolic and mean arterial pressure.

The use of data collection via record review was selected because record review is considered as an economical source of information and it permits an analysis of trends over time (Brink, 2002).

In Part two of the study, from those clinical practitioners who met the inclusion criteria, consent was sought and questionnaires were handed out randomly according to Burns and Groove (2001:260) the purpose of randomization is to increase the extent to which the sample is representative of the target population, thus increase the validity of the study. Questionnaires were handed out until the desired sample size of 50 clinical practionners was reached.

Part two of the study which aimed at investigating clinical practitioner‘s (Doctors and Nurses working in critical care units) choice and views on which blood pressure measurement method they generally believe to be more accurate, which method they found easier to use and what were their reasons as why they believed that one blood pressure method was easy to use and more accurate than the other.

Invasive blood pressure

Validity and reliability of the equipment

The measurement of invasive blood pressure was obtained from the radial artery connected via a biomedical transducer (Deltran) transducer system connected to each patients cardiac monitor (Date & Engstrom, Drager solar 3000 M and Phillips) via internal modern and displayed by the presence of an automatically scaled arterial pressure wave form on the screen, if there was no waveform on cardiac blood pressure monitor any value would be meaningless, the reliability validity checks comprised of selecting the right size of canula and correct levels and zeroing the transducer at atmospheric pressure at least every four hours or as needed per patient's status to make sure that there was a normal arterial waveform with good systolic, diastolic, diacrotic notch, identify the various physiologic effects and troubleshoots deviation as necessary.

The invasive blood pressure waveform must correspond remarkably well to electro-cardiogram (ECG), and comparison between noninvasive oscillometric digital display blood pressure measurement and the invasive blood pressure measurement was used to correlate the accuracy of the blood pressure readings.

Reliability and the validity of the invasive blood pressure equipments and monitor were maintained by respective manufacturers and calibration procedure was described as a standardized procedure for all the instruments (Discussion with the respective products specialists and technicians). Record of the servicing dates were maintained by the respective company data base.

Non invasive blood pressure

Validity and reliability of the equipment

The measurement of non invasive blood pressure was obtained by each patient; the non invasive blood pressure monitor connected via cuff to an electronic monitor (Dynamap, Datex, Engstrom) is based on oscillometric method. Displays of non invasive blood pressure measurements were determined by a set time interval, correct cuff sizes were utilized at least two third of upper arm length and 40% of upper arm circumference, correct placement was checked (Finnie, Watts & Armstrong,1984)

Reliability and validity of the equipment were maintained by the respective company and calibrated as per service contract between the institution and the company, records of servicing was maintained in the respective company data base.

In part one of the study each of the patients' data was collected up to a maximum of 48 hour post admission to the critical care unit. The 48 hour period was selected in order to avoid bias and error from old arterial lines. Arterial lines as they get older, (depending on how they are being looked after) start to develop complications such as inflammation and infection at their insertion, swelling at the insertion, loss of arterial line patency, all of these cause the overdamping and underdamping of the arterial tracing which often alter the true invasive blood pressure reading.(McEllistrem, et al., 1990)

In part two of the study open-ended questionnaires were formulated using the random sampling method, which is the most widely used to determine opinions or attitudes of subjects (Burns and Grove, 2001). Questionnaires were handed out randomly to clinical

practitioners to answer different questions regarding their choice and views on IBP and NIBP techniques. (**See appendix C**)

3.7.2 Instrument

Two instruments were used in this study, included are a check-list in part one of the study and a questionnaire in part two of the study. Based on literature review, critical care unit charts and discussions with experienced nursing and medical consultants, the researcher developed a check-list for recording the data obtained from record review of the patients' critical care charts, hospital records and findings from observation of the reliability checks (**See Appendix B**).

The checklist in part one of the study comprised of four sections as follows:

In the first section, (**See Appendix A**) an evaluation of APACHE II score which measures the severity of illness of the patient was used in completing this sheet. The information was transferred to **Appendix B** of the patient baseline assessment of the data collection check list. Information of the level severity of illness was obtained once the patient was included in the study.

The second section of the checklist comprised of demographic variables such as gender, age, date of admission to the critical care unit, reasons for critical care admission, severity of illness APACHE II score, co-morbidity and time of data collection hours after admission to the critical care unit.

The third section of the checklist comprised of the patients baseline assessment variables such as heart rate, temperature, invasive blood pressure, non invasive blood pressure, mode of ventilation, peak inspiratory pressure, pause inspiratory pressure, PEEP, analgesia, sedation, paralyzing agents and inotropic/ vasopressor support with dosages. The base line assessment of the patient gives the researcher the whole picture of the patient, including the factors that are likely to influence invasive or non invasive blood pressure measurement. The base line assessment was done before the actual data collection. **(See Appendix B).**

The fourth section (**See Appendix B**) dealt with blood pressure measurements which also consisted of three parts. The first part in this section comprised of invasive blood pressure measurements. Baseline for systolic, diastolic blood pressure and mean arterial pressure was done followed by the measurement of systolic, diastolic blood pressure and mean for the IBP. The second part dealt with non-invasive blood pressure measurements. Baseline data (systolic, diastolic and mean) were recorded followed by NIBP reading (systolic, diastolic and mean). The third part in this section (**See Appendix B**) dealt with calculating the difference between IBP and NIBP (systolic, diastolic and mean blood pressure) of the two blood pressure measurement techniques in part one and two above).

Part two of the study, comprised of eight items to elicit clinical practitioners' response using an open-ended questionnaire. The clinical practitioner respondents completed the instrument once. The questionnaire was designed for clinical practitioners working in the CCU (**See Appendix C**). The questionnaire comprised of the clinical practitioner data, his/her professional experience in CCU, his academic qualifications and years worked in CCU. The questionnaire sought to find out which measurement of blood pressure the

clinical practitioners believed to be more accurate while monitoring patients in the CCU setting and to find out reasons why they believed this blood pressure measurement was accurate based on their answers. It also sought to find out the blood pressure measurement they generally find easiest to use and why.

3.8 PILOT STUDY

A pilot study, which is a smaller version of the proposed study, was conducted one month prior to the main study to develop and refine the methodology and the data collection instruments (Burns & Grove, 2003). It is defined much like the proposed study using similar subjects, same setting, same treatment and same data collection and analysis techniques. However, pilot study could be conducted to develop and refine a research treatment, a data collection tool or the data collection process (Burns & Grove, 2003) thus the pilot study could be used to develop a research plan rather than to test an already developed plan.

The pilot study for **part one** was conducted with six patients (n=6) from the same population to be studied.

In **part two,** the pilot study was conducted with four questionnaires given to clinical practitioners (n=4)

After the pilot study, with the assistance from a statistician from the Medical Research Council (MRC) an alteration was made to the data collection checklist in order to ease the

coding of data. Sample size of part one of the study was reduced from (n=100) to (n=80) patients due to the following reasons:

There was difficulty in obtaining the consent from relatives and patients who did not understand well the nature of the research and consequently did not give their consent.

In the trauma and neuro–surgical critical care units, there were several unknown patients, some of them were in comatose state and consent could not be obtained.

In some of the CCUs there was shortage of cuffs of all sizes and dynamap machines were faulty, this affected the sample size. Due to infection control policy, it was impossible to move one dynamap or cuffs from one cubicle to the next.

Many patients did not meet all the inclusion criteria, the most difficult criteria to achieve was age as most of the patients were above 50 years old.

3.9 ETHICAL CONSIDERATIONS

In order to protect the rights of human subjects and to meet the standards of scientific enquiry, the following ethical considerations were applied in this study:

Permission to conduct the study and access information from patients' records was sought and obtained from the five critical care units through the chief Executive Officer (see Appendix E)

The research proposal together with the instrument was presented to the committee for research on human subjects of the University of the Witwatersrand for ethical approval. The committee issued a certificate of clearance (see **Appendix G**).

The research proposal was submitted to the post graduate committee of the University of the Witwatersrand, Faculty of Health Sciences for their perusal and permission to conduct the study, permission was granted (See **Appendix I**).

Permission to conduct the study and access information from patients' records was sought and obtained from the five critical care units through the chief executive officer (see **Appendix H)**.

To ensure anonymity and confidentiality, patients' names were not used in the checklist. Instead, each patient was provided with an identity code number. Further more the data was to be stored in a secure place and patient identity was not to be reported on (Brink, 2002).

Permission was obtained in writing from the relatives on behalf of the patient in case of patients who were critically ill on admission (see **Appendix F**). There after, once the patient was in position to give consent he/she, was given an opportunity to do so before the data collected could be included in the study.

For patients who were scheduled for elective surgery, consent was obtained directly from them prior to the operation **(see Appendix F**). The voluntary nature of their participations, confidentiality, ability to withdraw from the study, after giving consent and access to the results of the study if they so wished were brought to their attention both verbally and in writing **(see Appendix F**).

Consent was obtained in writing from clinical practionners who wished to participate in the study **(See Appendix D**).

During data collection, the bridges that were not properly leveled to phlebostatic axis and not well calibrated, the researcher informed immediately the Sister in charge or the critical care nurse looking after the patient, in order to optimize the safety of the patient.

3.10 VALIDITY AND RELIABILITY OF THE STUDY

Validity

The validity of the study was maintained by sampling any patient and clinical practitioner that met the inclusion criteria and was willing to participate in the study to avoid bias.

Sizes of different BP cuffs were checked in relation to the patient's arms circumferences, and proper application before data collection.

All checks and balances including transducing, calibration, leveling and zeroing were done before data collection.

All the data collected was collerated first with other clinical hemodynamic variables and general condition of the patient.

Reliability

The reliability of a measure denotes the consistency of measures obtained in the use of a particular instrument and is an indication of the extent of random error in the measurement

method (Burns and Grove, 2001). The same measurement scale if administered to the same individuals at two different times, is reliable if the individuals' responses to the items remain the same (assuming nothing has occurred to change their responses) (Burns and Grove, 2001).

This was maintained in the study by ensuring that the same method of data collection and instrument was used throughout the study.

All the data was collected by the researcher alone and was collected independently without influence from any one.

An expert statistician verified data collected for accuracy and helped in the analysis of the data to ensure accuracy.

3.11 SUMMARY

This chapter addressed the research design and methodology with reference to the research setting, target population, sampling method and data collection procedures, the pilot study, validity and reliability of the instruments, equipment and ethical considerations in the study were also discussed.

The following chapter will deal with the data analysis and discussion of the results.