

The accuracy of non-invasive blood pressure monitoring when compared to intra-arterial blood pressure monitoring in patients with severe pre-eclampsia during an acute hypertensive crisis

by

Dr Sangita Dalla

Submitted in partial fulfilment for the

Master of Medicine



at

Stellenbosch University

Department of Obstetrics and Gynaecology
Tygerberg Hospital
Stellenbosch University
Faculty of Medicine

Promoter: Dr Eduard Langenegger
Co-promoter: Dr Gregory Petro
March 2010

Declaration

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the owner of the copyright thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

Date: March 2010

Copyright © 2010 Stellenbosch University

All rights reserved

Abstract

The accuracy of non-invasive blood pressure monitoring when compared to intra-arterial blood pressure monitoring in patients with severe pre-eclampsia during an acute hypertensive crisis

Principal investigator: Dr Sangita Dalla

Principal promoter: Dr Eduard Langenegger

Co-promoter and Statistician: Dr Gregory Petro

OBJECTIVE: The aim of this study was to compare the accuracy of non-invasive blood pressure measurements, using automated and manual devices, against invasive intra-arterial blood pressure measurements in patients with pre-eclampsia, during a hypertensive blood pressure peak.

STUDY DESIGN: In this prospective study, women admitted to the Obstetrics Critical Care Unit, with confirmed pre-eclampsia and acute severe hypertension, who had an intra-arterial line in situ, were asked to participate. During an intra-arterial blood pressure peak, both an automated oscillometric and a blinded manual aneroid sphygmomanometric blood pressure was recorded. These two methods of blood pressure measurements were compared to intra-arterial blood pressure measurements. The accuracy of a mean arterial pressure (MAP) ≥ 125 mmHg in detecting a systolic blood pressure (SBP) ≥ 160 mmHg, using all three methods, was also determined.

RESULTS: There was poor correlation between intra-arterial SBP and automated and manual SBP ($r = 0.34$, $p < 0.01$; $r = 0.41$, $p < 0.01$ respectively). The mean differences between automated and manual SBP compared to the intra-arterial SBP was 24 ± 17 mmHg ($p < 0.01$) and 20 ± 15 mmHg ($p < 0.01$) respectively. There was better correlation between intra-arterial diastolic blood pressure (DBP) and automated and manual DBP ($r = 0.61$, $p < 0.01$; $r = 0.59$, $p < 0.01$ respectively). The mean differences of the automated and manual DBP was not statistically significant when compared to the intra-arterial DBP. There was poor correlation between the intra-arterial MAP and the automated MAP ($r = 0.44$, $p < 0.01$) and good correlation with the manual MAP ($r = 0.56$, $p < 0.01$). The mean differences of the automated and manual MAP were statistically significant (5 ± 13 mmHg, $p < 0.01$; 8 ± 11 mmHg,

p < 0.01 respectively). The sensitivity of automated and manual methods in detecting a SBP \geq 160mmHg was 23.4% and 37.5% respectively. A MAP \geq 125mmHg in detecting a SBP \geq 160mmHg, when using intra-arterial, automated and manual methods of blood pressure measurements showed low sensitivity (35.9%, 21.9% and 17.2% respectively).

CONCLUSION: This study demonstrated that both the automated and manual methods of blood pressure measurements were not an accurate measure of the true systolic intra-arterial blood pressure, when managing pre-eclamptic patients with acute severe hypertension. In such situations, intra-arterial blood pressure monitoring should be used when possible. When this is not possible, manual aneroid sphygmomanometry is recommended. Underestimating blood pressure, particularly SBP, may lead to severe maternal morbidity and mortality.

Opsomming

Die akuraatheid van nie indringende bloeddruk monitering wanneer dit vergelyk word met intra-arteriele bloed druk monitering in pasiente met pre-eklampsie gedurende 'n episode van 'n akute hipertensiewe krisis

Primêre navorser: Dr Sangita Dalla

Promotor: Dr Eduard Langenegger

Statistikus en mede-promotor: Dr Gregory Petro

DOELWIT: Die doel van hierdie studie is om die akuraatheid van nie invasiewe bloeddruk metings, wanneer geneem met outomatiese en manuele aparate, te vergelyk met intra-arteriele bloed druk metings in pasiente met pre-eklampsie, gedurende 'n hipertensiewe bloeddruk piek.

STUDIE ONTWERP: In hierdie prospektiewe beskrywende dwarsnit studie, was pasiente wat toegelaat was tot die Obstetriesse Kritieke Sorg Eenheid met pre-eklampsie, akute erge hipertensie en 'n intra-arteriele lyn in situ gevra om deel te neem. Gedurende 'n intra-arteriele erge hipertensiewe piek is beide die outomatiese ossilometriese en die geblinde aneroïde sfigmometer lesing neergeskryf. Hierdie twee metodes van non invasiewe bloed druk lesings is vergelyk met intra-arteriele bloed druk lesings. Die akuraatheid van 'n gemiddelde arteriele bloeddruk $\geq 125\text{mmHg}$ om 'n sistoliese bloeddruk $\geq 160\text{mmHg}$ op te tel met gebruik van al die drie metodes is ook uitgewerk.

RESULTATE: Daar was swak korrelasie tussen intra-arteriele sistoliese bloed druk (SBD) metings en outomatiese en manuele SBD ($r = 0.34$, $p < 0.01$; $r = 0.41$, $p < 0.01$ onderskeidelik). Die gemiddelde verskille tussen outomatiese en manuele SBD wanneer vergelyk met intra-arteriele SBD was $24 \pm 17\text{mmHg}$ ($p < 0.01$) en $20 \pm 15\text{mmHg}$ ($p < 0.01$) onderskeidelik. Beter korrelasie was gevind tussen intra-arteriele diastoliese bloed druk (DBD) en outomatiese en manuele DBD ($r = 0.61$, $p < 0.01$; $r = 0.59$, $p < 0.01$ onderskeidelik). Die gemiddelde verskille tussen outomatiese en manuele DBD wanneer dit vergelyk was met intra-arteriele DBD was nie statisties betekenisvol nie. Daar was swak korrelasie tussen intra arteriele gemiddelde arteriele bloeddruk en outomatiese gemiddelde arteriele bloeddruk ($r = 0.44$, $p < 0.01$) en beter korrelasie met manuele gemiddelde arteriele bloeddruk ($r = 0.56$, $p <$

0.01). Die gemiddelde verskille van outomatiese en manuele gemiddelde arteriele bloeddruk was betekenisvol ($5 \pm 13\text{mmHg}$, $p < 0.01$; $8 \pm 11\text{mmHg}$, $p < 0.01$ onderskeidelik). Die sensitiwiteit van outomatiese en manuele metodes om 'n intra-arteriele SBD $\geq 160\text{mmHg}$ op te tel was 23.4% en 37.5% onderskeidelik. Die vermoë van 'n gemiddelde arteriele bloeddruk $\geq 125\text{mmHg}$ om 'n SBD $\geq 160\text{mmHg}$ op te tel, gemeet deur intra-arterieel, outomatiese en manuele metodes het lae sensitiwiteit getoon (35.9%, 21.9% en 17.2% onderskeidelik).

GEVOLGTREKKING: Hierdie studie het gedemonstreer dat outomatiese en manuele metodes van bloeddruk meting nie akurate metodes is om ware intra-arteriele sistoliese bloeddruk te meet in pasiente met erge pre-eklampsie tydens 'n erge hipertensiewe episode nie. In hierdie omstandighede moet intra-arteriele bloeddruk gemeet word indien beskikbaar. Indien dit nie beskikbaar is nie moet die manuele aneroïede sfigmomanometer gebruik word. Onderskatting van bloeddruk, veral sistoliese bloeddruk, kan lei tot erge moederlike morbiditeit en mortaliteit.

Acknowledgements

I would like to thank my principal promoter, Dr E Langenegger for all his support, guidance and encouragement during the period of my study.

I would like to thank my co-promoter and statistician, Dr G Petro, who has ensured time from his busy schedule to give me the motivation and understanding of statistics.

I would also like to thank all the staff working in the Obstetrics Critical Care Unit at Tygerberg Hospital, who assisted me with data collection, as without them this study would not have been possible.

Table of Contents

Declaration	2
Abstract	3
Opsomming	5
Acknowledgements	7
List of Figures	9
List of Tables	10
List of Addendums	11
Chapter 1 – Introduction and Literature Review	12
Chapter 2 - Methods	16
Chapter 3 – Results	19
Chapter 4 - Discussion	28
Conclusion	33
References	34
Appendix	37

List of Figures

Figure 1. Scatter plot comparing intra-arterial SBP measurements with automated SBP measurements	21
Figure 2. Scatter plot comparing intra-arterial SBP measurements with manual SBP measurements	22
Figure 3. Scatter plot comparing intra-arterial DBP measurements with automated DBP measurements	23
Figure 4. Scatter plot comparing intra-arterial DBP measurements with manual DBP measurements	23
Figure 5. Scatter plot comparing intra-arterial MAP measurements with automated MAP measurements	24
Figure 6. Scatter plot comparing intra-arterial mean MAP measurements with manual MAP measurements	25

List of Tables

Table 1. Patient characteristics with means and ranges	19
Table 2. Patient characteristics expressed as a percentage	20
Table 3. Pre-eclampsia complications	20
Table 4. Accuracy of other methods in detecting an intra-arterial SBP \geq 160mmHg	26
Table 5. Accuracy of other methods in detecting an intra-arterial MAP \geq 125mmHg	27
Table 6. Accuracy of MAP \geq 125mmHg, using all 3 methods, in detecting intra-arterial SBP \geq 160mmHg	27

List of Addendums

Addendum A	Participant information leaflet and consent form	39
Addendum B	Data capture sheet for patient characteristics	45
Addendum C	Data capture sheet for blood pressure readings	46

Chapter 1 – Introduction and Literature Review

One of the leading causes of maternal deaths in South Africa is directly related to hypertensive disease in pregnancy. In the Saving Mothers report 2002-2004, 628 of the 3406 maternal deaths were related to hypertensive disease in pregnancy. The commonest primary cause of hypertensive related deaths was eclampsia. The commonest final cause of death remains intracerebral haemorrhage.^{1,2}

Pre-eclampsia is pregnancy specific and of a multisystemic nature where the complication rates are high. It is associated with both maternal and foetal complications. Maternal complications include intracerebral haemorrhage, pulmonary oedema, renal failure, HELLP (haemolysis, elevated liver enzymes, low platelets) syndrome, abruptio placentae, disseminated intravascular coagulopathy and liver haemorrhage. Foetal complications include severe intrauterine growth restriction, asphyxia, preterm birth and death.^{1,3,4}

In the past, one of the main focuses of pre-eclampsia was an elevated diastolic blood pressure (DBP) $\geq 110\text{mmHg}$, and this was thought to be associated with an increased risk of intracerebral haemorrhage.⁵ Many earlier definitions of preeclampsia, including the classification by Davey and MacGillivray, did not even include systolic blood pressure (SBP) in their definition of hypertension.⁶ They felt that systolic blood pressure did not improve the diagnostic or prognostic significance of hypertension in pregnancy.⁷ As a result, the main focus of blood pressure management and treatment appeared to focus mainly on diastolic blood pressure.

In more recent years, the emphasis has changed to focus on more adequate management of systolic blood pressure. The Seventh Report of the Confidential Enquiries into Maternal Deaths in the United Kingdom stated that intracranial haemorrhage was the single most common cause of death and this was often due to inadequate treatment of systolic hypertension.⁸ A study done by Martin et al showed that just preceding a stroke, 96% of patients had a SBP $\geq 160\text{mmHg}$ and only 12.5% had a DBP $\geq 110\text{mmHg}$.⁹

It is thus crucial that hypertension in pregnancy is promptly and adequately managed.¹⁰ For blood pressure to be adequately managed, the accuracy of the methods used to measure blood pressure needs to be established. The standard method for measuring non-invasive blood pressure is sphygmomanometry and it is well recognised for its inaccuracy.¹¹ Automated blood pressure machines are widely used in South Africa, despite the fact that they tend to underestimate blood pressure.^{1,2,10} Intra-arterial blood pressure monitoring is considered to be the gold standard for accurate blood pressure measurement.^{10,12}

Penny et al made a comparison between intra-arterial blood pressure and three methods of non-invasive blood pressure measurement: conventional sphygmomanometry and two automated blood pressure devices. In women with pre-eclampsia, the automated devices significantly underestimated the systolic and the mean blood pressure. Conventional sphygmomanometry was found to underestimate the SBP and overestimate the DBP. Therefore the mean arterial pressure (MAP) was similar to that of the intra-arterial blood pressure.²

A similar study was done by Natarajan et al using different automated blood pressure devices. Both automated devices consistently underestimated the systolic and diastolic blood pressure when compared with mercury sphygmomanometry and intra-arterial measurements. Automated methods of blood pressure measurements were therefore not recommended for clinical use in patients with pre-eclampsia.¹⁰

Pomini et al showed that there was a poor correlation between manual auscultatory and automated oscillometric methods for the measurement of blood pressure in normotensive pregnant women. It was concluded that even though an underestimation of only 10mmHg was shown, this could result in a delay in the correct diagnosis of pre-eclampsia.¹³

A study done by Araghi¹² and colleagues noted that in overweight critically ill patients with hypertension, non-invasive methods of blood pressure monitoring underestimated the blood pressure when compared to the gold standard of intra-arterial blood pressure monitoring. They concluded that this might adversely affect therapeutic decisions and thereby have a negative effect on outcomes.

Blood pressure measurement is still the most common screening test used in the antenatal care of patients.¹⁴ Patients may present with pre-eclampsia and acute

severe hypertension at any level of healthcare. Often the first point of presentation is at a primary healthcare facility, whereby invasive blood pressure monitoring is not available. Many healthcare facilities use either automated blood pressure monitoring devices or manual sphygmomanometry. It is therefore important to determine the more accurate method, especially when considering acute severe hypertension, where there is an increased risk of complications.¹

Inadequate and inappropriate management may be instituted if errors are made in diagnosing hypertension. However, blood pressure is a haemodynamic phenomenon and it is affected by numerous factors. Some of these factors include an inherent variability, limitations of the device as well as the accuracy of the device used.¹⁵

Acute severe hypertension must be detected and treated. These patients deserve immediate and special attention in a high care or intensive care setting, where they can be administered antihypertensive treatment to reduce their risk of developing intracerebral haemorrhage.⁹ It is therefore of vital importance to correctly detect a SBP \geq 160mmHg or a DBP \geq 110mmHg to prevent a cerebral event.

In the Obstetrics Critical Care Unit (OCCU) at Tygerberg Hospital, adequate infrastructure and trained personnel are often available, allowing for the use of intra-arterial blood pressure monitoring when indicated. In the OCCU, the indications for intra-arterial blood pressure monitoring include acute severe hypertension not controlled with routine management requiring intravenous antihypertensive treatment, severe preeclampsia with organ dysfunction, recurrent eclampsia and hypertensive encephalopathy. However, in the labour ward at Tygerberg hospital, there are no routine facilities available for intra-arterial blood pressure monitoring. Therefore, the blood pressures of patients with severe pre-eclampsia in the labour ward are routinely measured, mostly using automated blood pressure devices and aneroid sphygmomanometers. If this method of obtaining blood pressure is remarkably inaccurate, it could result in undetected episodes of acute severe hypertension, resulting in an increased incidence of cerebral complications, intracerebral haemorrhage and death.

Severe pre-eclampsia is common in obstetric practice, and it is unclear as to whether invasive and non-invasive blood pressure monitoring may be used interchangeably. There are very few studies comparing intra-arterial blood pressure measurements with conventional sphygmomanometry and automated blood pressure devices. There

are even fewer studies comparing this in patients with pre-eclampsia. No studies were identified in this literature review, comparing invasive and non-invasive blood pressure monitoring in patients with severe pre-eclampsia, during a hypertensive blood pressure peak (i.e. SBP \geq 160mmHg or DBP \geq 110mmHg). However, gaining enough evidence with regards to this comparison is crucial to allow for adequate control of very high blood pressures, thus preventing both maternal and foetal morbidity and mortality.

The aim of this descriptive cross sectional study is to test the hypothesis that non-invasive blood pressure monitoring, especially when using automated devices, is not an accurate measure of blood pressure and often underestimates a true blood pressure reading when compared to intra-arterial blood pressure monitoring in pre-eclamptic patients with acute severe hypertension.

Chapter 2 - Methods

The study was conducted in the Obstetrics Critical Care Unit (OCCU) at Tygerberg Hospital. The University of Stellenbosch Research Ethics Committee approved the study protocol. The approval reference number was N08/10/308.

The sample size for blood pressure readings during hypertensive crises was calculated using the power of 80 with a confidence level of 95%. A normal distribution of the continuous variable was assumed for the calculation. A mean difference of 10mmHg was used and a standard deviation was calculated comparing intra-arterial systolic blood pressure with oscillometric automated systolic blood pressure.¹⁶ This calculation determined a sample size of 70 blood pressure readings in each group.

Patients admitted to the OCCU, who had acute severe hypertension and confirmed pre-eclampsia, where intra-arterial blood pressure monitoring was indicated, were asked to participate in the study. Written informed consent was obtained from all patients who agreed to participate, prior to being entered into the study. A copy of the consent form is attached (appendix A). Participating in the study did not compromise patient care or management in any way. Patients who fulfilled the above-mentioned inclusion criteria were consecutively recruited by the doctors working in the OCCU.

Pre-eclampsia was defined as the onset of hypertension with $\geq 2+$ persistent proteinuria after twenty weeks gestation.^{6,17} Acute severe hypertension was defined as either a systolic blood pressure (SBP) of ≥ 160 mmHg or a diastolic blood pressure (DBP) of ≥ 110 mmHg.^{9,18} A total of 23 patients were recruited over a period of six months, from August 2009 to January 2010.

Patients admitted to the OCCU who did not have severe pre-eclampsia, or those with pre-eclampsia who did not require an intra-arterial line for blood pressure monitoring, were excluded from the study. No patient received an intra-arterial line purely for the purposes of the study. Patients with severe pre-eclampsia, who were not admitted to the OCCU, were also excluded from the study.

The doctors in the OCCU performed the intra-arterial catheterisation. A 20 gauge radial artery set (BD critical care arterial cannula with flow switch) was used for continuous intra-arterial blood pressure monitoring. Before each data collection, a

rapid flush test was performed to test for the adequacy of the pressure monitoring system. The arterial waveform was observed and recorded from the monitor (Nihon Kohden BSM – 4113K). The automated oscillometric non-invasive blood pressure monitoring was also done using the Nihon Kohden BSM – 4113K monitor. The manual blood pressure was taken using the Welch Allyn Maxi Stabil 3 aneroid sphygmomanometer, which was A grade and validated to the British Hypertension Society protocol, as stated on the apparatus. All equipment is calibrated and serviced on a regular basis.

Each time the patient had a hypertensive blood pressure peak, i.e. either a SBP \geq 160mmHg or a DBP \geq 110mmHg on the invasive intra-arterial blood pressure monitor, an oscillometric automated blood pressure and a blinded manual blood pressure using the aneroid sphygmomanometer was immediately documented, followed by prompt treatment of the hypertensive peak. This was performed for a maximum of five hypertensive blood pressure peaks per patient. From this point, the automated oscillometric blood pressure will be referred to as the automated blood pressure, and the manual aneroid sphygmomanometer blood pressure will be referred to as the manual blood pressure.

The manual blood pressure was a blinded reading obtained by either nursing staff or medical doctors. The blood pressure monitor was covered with a screen, so that the nursing staff or medical doctor measuring and recording the manual blood pressure would remain unaware of the actual intra-arterial or automated blood pressure measurements.

Manual blood pressures were measured using the left arm with the patient semi-recumbent in the left lateral position. The left arm was at the level of the heart, as recommended by the Australasian Society for the Study of Hypertension in Pregnancy (ASSHP).¹⁷ The height, weight and the arm circumference at mid-arm level were documented for each patient to ensure selection of the correct cuff size.¹⁹ When measuring the manual blood pressure using aneroid sphygmomanometry, Korotkoff phase V was documented as the diastolic blood pressure.^{20, 21}

All demographic information and blood pressure measurements were documented on a data sheet (Appendix B and C).

Objectives:

The primary outcome of this study was to determine the accuracy of the automated and manual SBP when compared to the intra-arterial SBP.

The secondary outcomes were as follow:

1. To determine the accuracy of automated and manual DBP, when compared to the intra-arterial DBP
2. To determine the accuracy of the MAP of the automated and manual blood pressures, when compared to the intra-arterial MAP
3. To determine whether there is a correlation between the MAP \geq 125mmHg, using the three different methods of SBP measurement, and that of acute severe systolic hypertension i.e. SBP \geq 160mmHg.

Statistical methods:

All summary values are expressed as the mean \pm standard deviation, unless otherwise stated. Correlation was determined using the Pearson correlation coefficient. For continuous variables, a paired Student's t test was used to compare the mean differences between intra-arterial, automated and manual blood pressure measurements. A two-tailed P value of less than 0.05 was considered statistically significant. For categorical variables, clinically important cut-off points were used and data analysed using Chi-square tests. A P value of less than 0.05 was considered statistically significant. Statistical analysis was performed using STATA version 10.

Chapter 3 - Results

A total of 71 blood pressure readings for each method were collected over a period of six months. However, only 66 blood pressure readings were analysed. Five blood pressure readings could not be analysed due to incomplete or incorrectly documented data on the data collection sheet.

Twenty-three patients with the mean age of 27 years (range 16 – 40 years) with a mean gestational age of 32 weeks (range 22 – 40 weeks) were included in the study. All patients were currently being treated with antihypertensive medication. All patients had $\geq 2+$ persistent proteinuria on the urine dipstick. Patient characteristics are summarised below [Tables 1 and 2].

Table 1. Patient characteristics with means and ranges

	Mean/Median	Range
Age (yrs)	27	16 - 40
Gravidity (Median)	2	1 - 6
Parity (Median)	2	0 - 6
Gestation (wks)	32	22 - 40
Arm circumference (cm)	28	22 - 37
Weight (Kg)	72	45 - 110
Length (cm)	156	144 - 182
Body Mass Index (Kg/m²)	29.5	19.5 – 45.8
Systolic blood pressure (mmHg)*	166	139 - 220
Diastolic blood pressure (mmHg)*	111	90 - 150

*Reflects systolic and diastolic blood pressure at point of entry into the study

Table 2. Patient characteristics expressed as a percentage

	Patients (n)	Percentage (%)
Primigravida	7	30.4
Multigravida	16	69.6
New paternity	17	73.9
Antepartum	5	21.7
Postpartum	18	78.3
Previous pre-eclampsia	4	25
Chronic hypertension	1	4.3
HIV positive*	3	13
Smokers	4	17.4
Any alcohol consumption	3	13
Protein ($\geq 2+$)	23	100

* HIV, Human immunodeficiency virus.

The complications of pre-eclampsia encountered by the patients in the study are summarised below [Table 3].

Table 3. Preeclampsia complications

	Patients (n)	Percentage (%)
Pulmonary oedema*	8	34.8
HELLP syndrome†	7	30.4
Eclampsia	5	21.7
Renal dysfunction‡	5	21.7
Abruptio placentae	1	4.3
Intracerebral haemorrhage	1	4.3
Hypertensive encephalopathy	1	4.3
Subcapsular liver haematoma	1	4.3

* Diagnosed clinically and radiologically

† HELLP, haemolysis, elevated liver enzymes and low platelets⁹

‡ Oliguria < 100mls/4hrs; oliguria \leq 400mls/24hrs; increase in creatinine by 44mmol/l/day; acute deterioration in urea \geq 15mmol/l or of creatinine to \geq 400mmol/l/day²²

THE CORRELATION BETWEEN INTRA-ARTERIAL BLOOD PRESSURE MEASUREMENTS AND AUTOMATED AND MANUAL METHODS OF BLOOD PRESSURE MEASUREMENT

There was poor correlation between intra-arterial SBP measurements and automated SBP measurements. The correlation coefficient (r) = 0.34 ($p < 0.01$). The mean intra-arterial SBP was 172 ± 11 mmHg, whereas the mean automated SBP was 148 ± 18 mmHg, giving a mean difference of 24 ± 17 mmHg ($p < 0.01$). The scatter plot in Figure 1 shows that the automated instrument consistently underestimated intra-arterial systolic blood pressures.

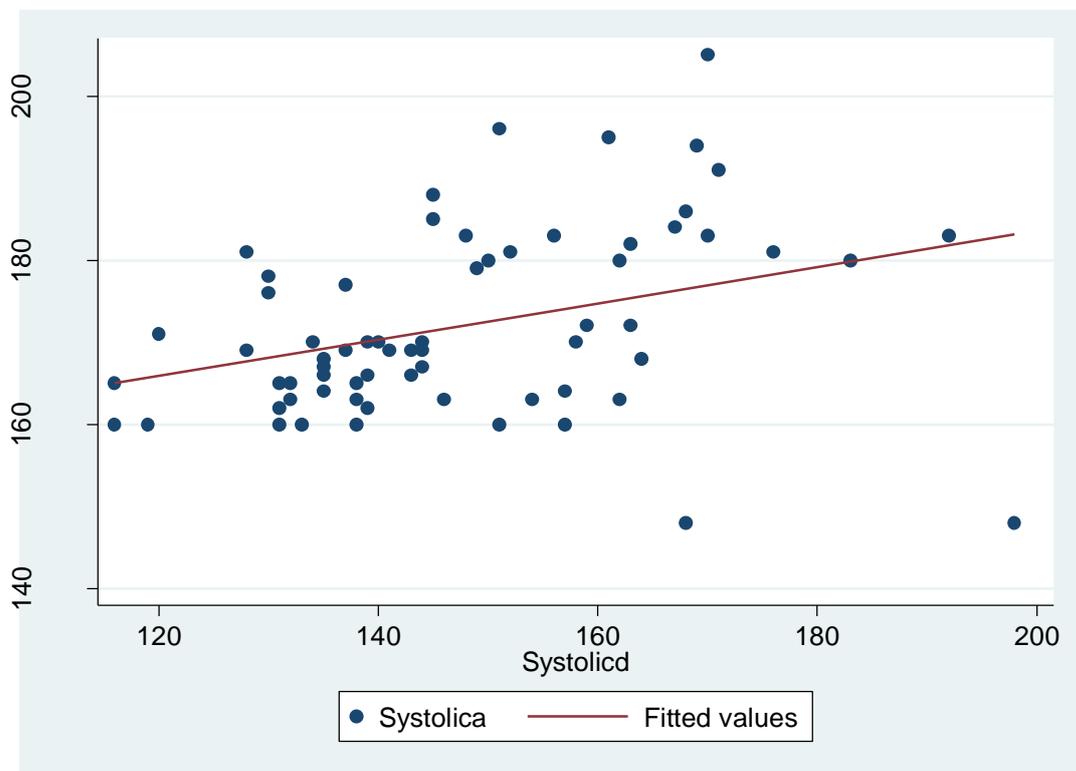


Figure 1. Scatter plot comparing intra-arterial SBP measurements with automated SBP measurements (x-axis = automated SBP; y-axis = intra-arterial SBP)

There was poor correlation when comparing intra-arterial SBP measurements with manual SBP measurements [$r = 0.41$ ($p < 0.01$)]. The mean manual SBP was 152 ± 15 mmHg with a mean difference of 20 ± 15 mmHg ($p < 0.01$). The scatter plot in

Figure 2 shows that the manual instrument also consistently underestimated intra-arterial systolic blood pressures.

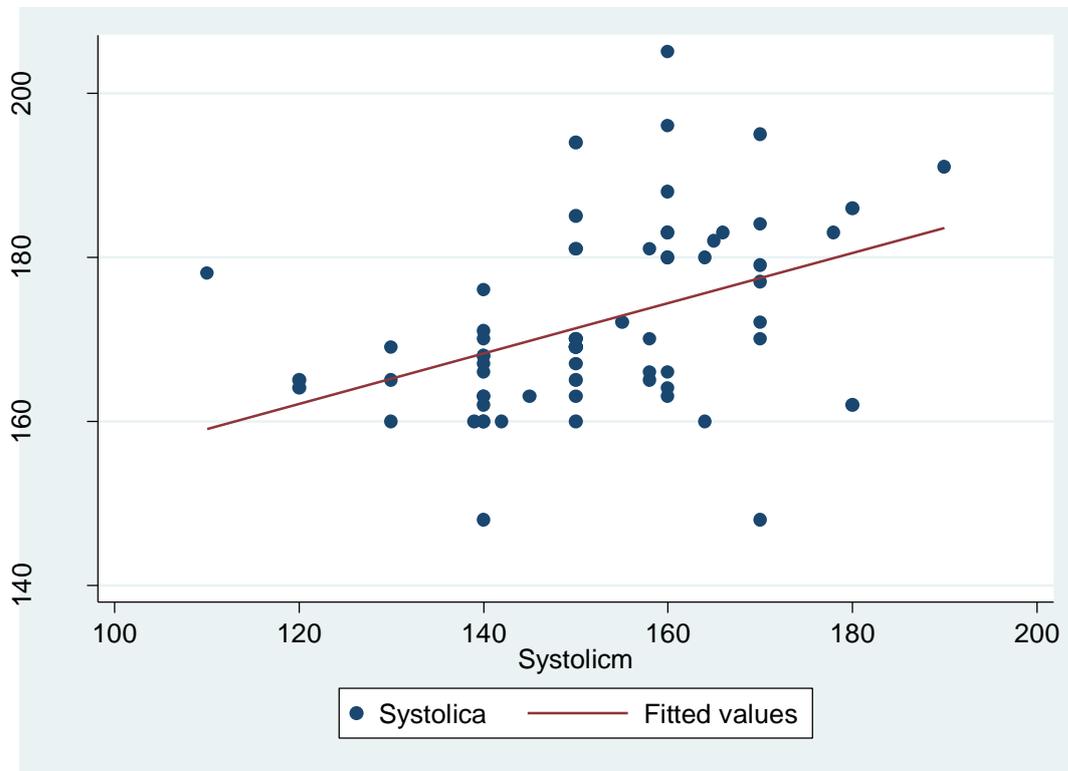


Figure 2. Scatter plot comparing intra-arterial SBP measurements with manual SBP measurements (x-axis = manual SBP; y-axis = intra-arterial SBP)

There was better correlation between intra-arterial DBP measurements and automated DBP measurements [$r = 0.61$ ($p < 0.01$)]. The mean intra-arterial DBP was 94 ± 11 mmHg. The mean automated DBP was 96 ± 12 mmHg with a mean difference of 2 ± 10 mmHg. This was not statistically significant ($p = 0.20$). The scatter plot in Figure 3 shows that the automated instrument often overestimated intra-arterial diastolic blood pressures.

There was also better correlation between intra-arterial DBP measurements and manual DBP measurements [$r = 0.59$ ($p < 0.01$)]. The mean manual DBP was 94 ± 14 mmHg with a mean difference of 1 ± 12 mmHg. This was not statistically significant ($p = 0.65$). The scatter plot in Figure 4 shows that the manual instrument both equally overestimated and underestimated the intra-arterial diastolic blood pressure.

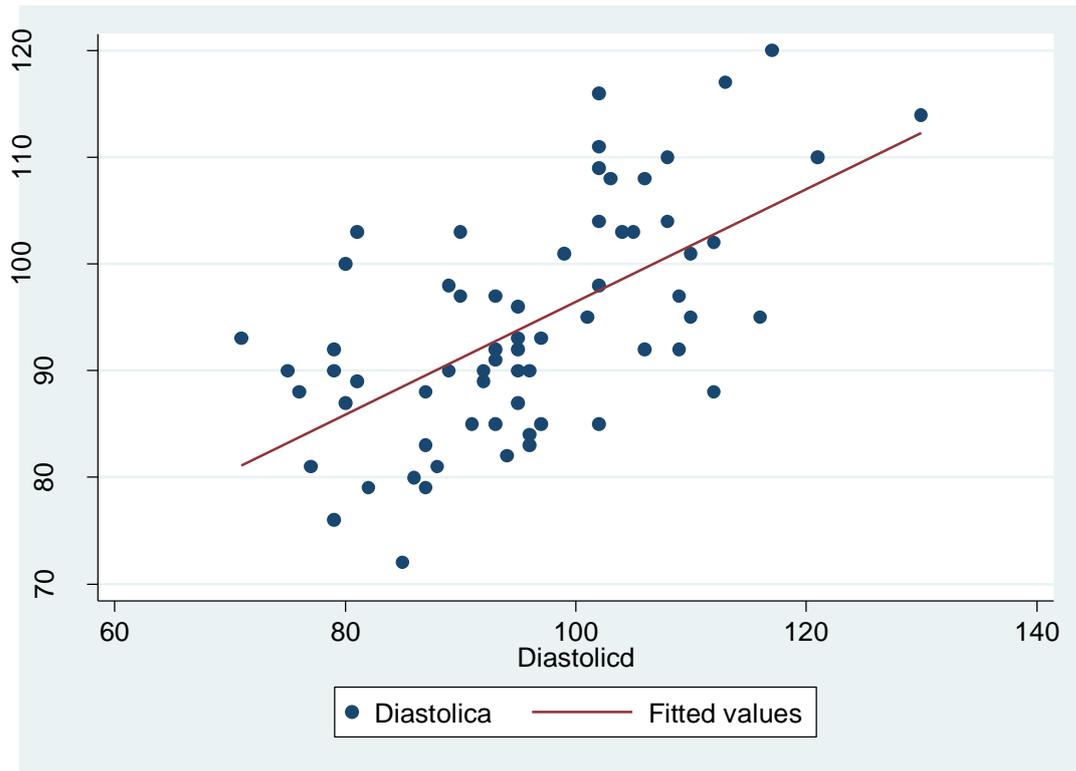


Figure 3. Scatter plot comparing intra-arterial DBP measurements with automated DBP measurements (x-axis = automated DBP; y-axis = intra-arterial DBP)

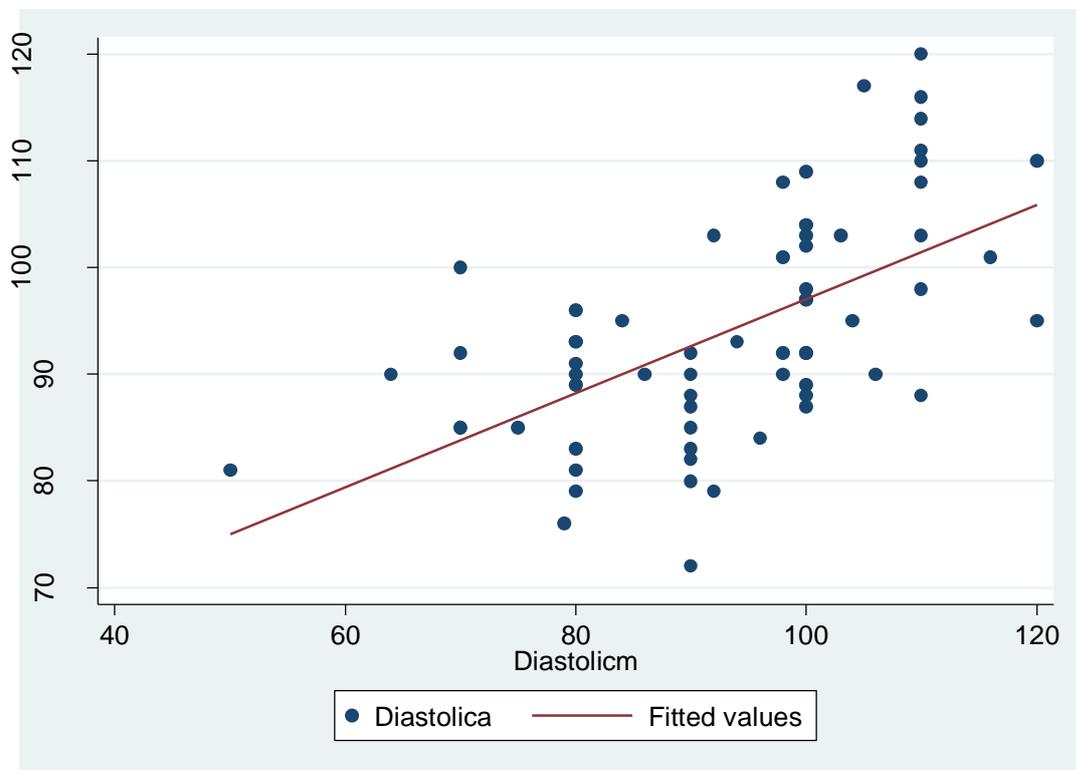


Figure 4. Scatter plot comparing intra-arterial DBP measurements with manual DBP measurements (x-axis = manual DBP; y-axis = intra-arterial DBP)

There was poor correlation when comparing the MAP of intra-arterial blood pressure with the MAP of the automated blood pressure [$r = 0.44$ ($p < 0.01$)]. The mean MAP for intra-arterial blood pressure was 121 ± 11 mmHg. The mean MAP for the automated blood pressure was 116 ± 13 mmHg with a mean MAP difference of 5 ± 13 mmHg ($p < 0.01$). The scatter plot in Figure 5 shows that the automated device consistently underestimated the intra-arterial MAP.

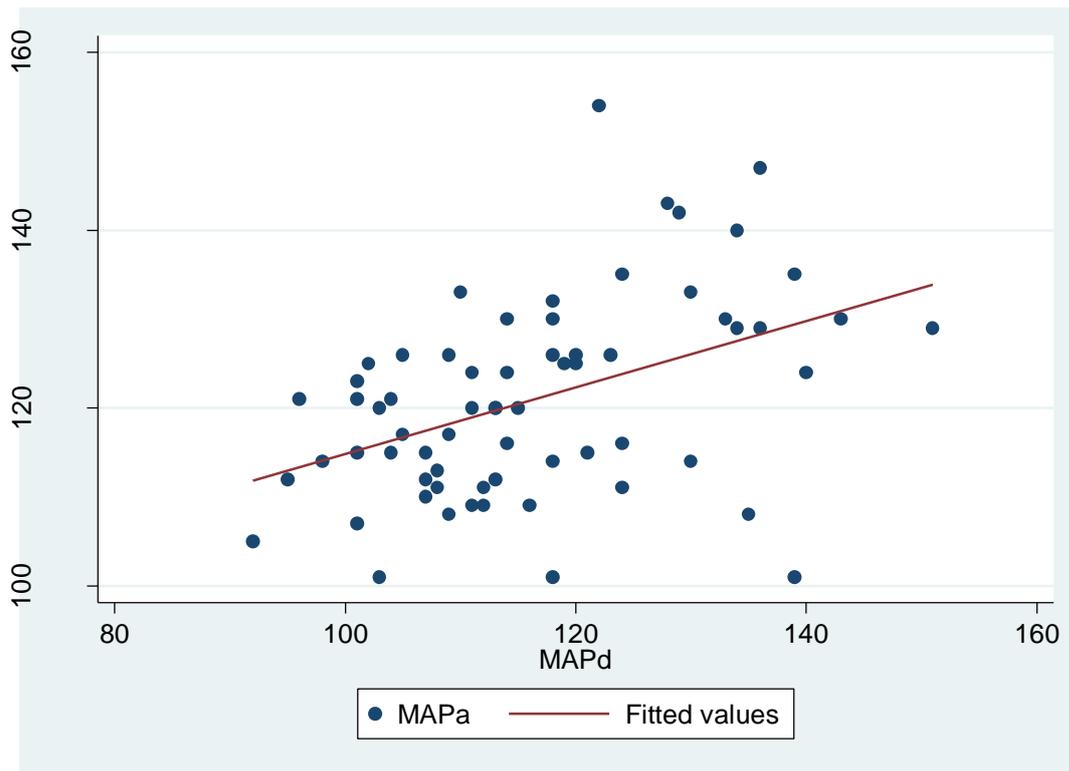


Figure 5. Scatter plot comparing intra-arterial MAP measurements with automated MAP measurements (x-axis = automated MAP; y-axis = intra-arterial MAP)

There was good correlation between the MAP of intra-arterial blood pressure and the MAP of the manual blood pressures [$r = 0.56$ ($p < 0.01$)]. The mean MAP for the manual blood pressure was 113 ± 13 mmHg and a mean MAP difference of 8 ± 11 mmHg ($p < 0.01$) was noted. The scatter plot in Figure 6 shows that the manual device also consistently underestimated the intra-arterial MAP.

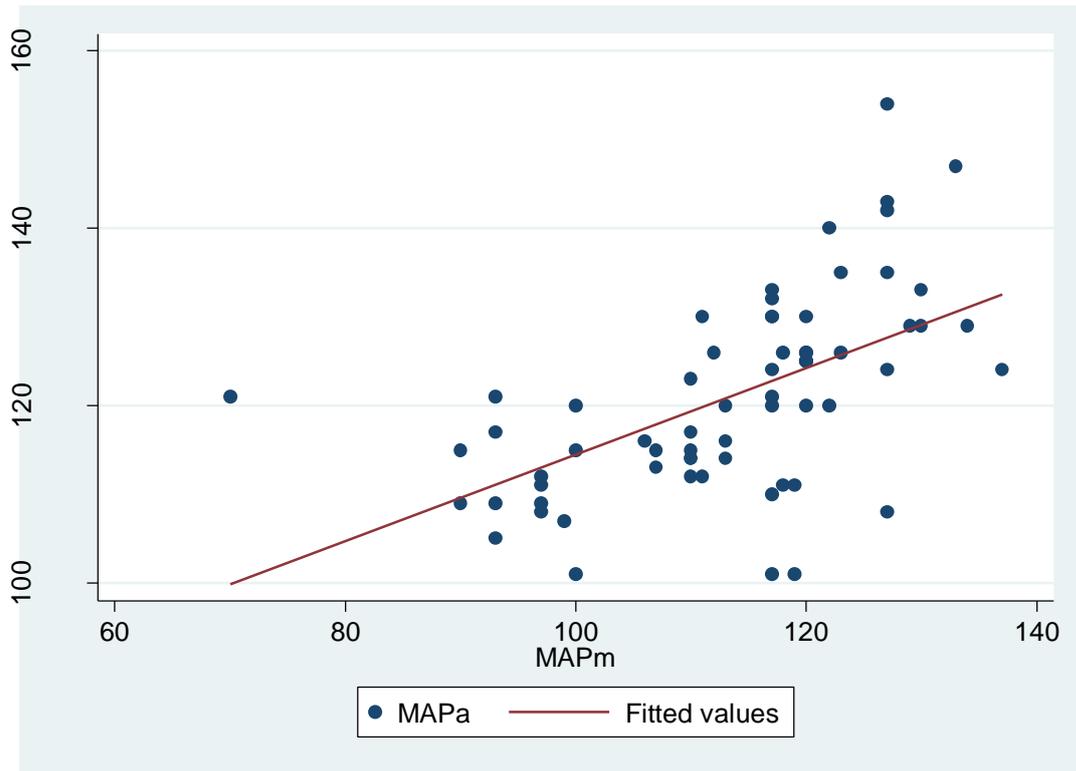


Figure 6. Scatter plot comparing intra-arterial MAP measurements with manual MAP measurements (x-axis = manual MAP; y-axis = intra-arterial MAP)

CATEGORICAL DATA DETERMINING THE ACCURACY OF VARIOUS BLOOD PRESSURE METHODS IN DETECTING ACUTE SEVERE HYPERTENSION

A SBP \geq 160mmHg was used as a marker for severe systolic hypertension as the National Enquiries into Maternal Death from the United Kingdom currently recommend treatment for SBP \geq 160mmHg in order to prevent intracranial haemorrhage.⁸

A MAP \geq 125mmHg was used as a marker of severe hypertension, as Sibai et al recommended the commencement of antihypertensive treatment in patients with severe pre-eclampsia when the MAP \geq 125mmHg.²³

The accuracy of other methods of SBP measurements i.e. automated oscillometric and manual aneroid sphygmomanometer in detecting an intra-arterial SBP \geq 160mmHg showed poor sensitivity [Table 4].

Table 4. Accuracy of other methods in detecting an intra-arterial SBP \geq 160mmHg

	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
Automated	23.4 % (14.75-35.13)	100 % (34.24–100)	100 % (79.61–100)	3.9 % (1.08–13.22)
Manual	37.5 % (26.67-49.75)	50 % (9.45-90.55)	96 % (80.46-99.29)	2.4 % (0.43-12.6)

Automated, oscillometric blood pressure; Manual, aneroid sphygmomanometer
CI, confidence level

The accuracy of other methods of MAP measurements in detecting an intra-arterial MAP \geq 125mmHg also demonstrated poor sensitivity but good specificity [Table 5].

Table 5. Accuracy of other methods in detecting an intra-arterial MAP \geq 125mmHg

	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
Automated	44 % (26.67-62.93)	90.2 % (77.45-96.14)	73.3 % (48.05-89.1)	72.6 % (59.05-82.89)
Manual	36 % (20.25-55.48)	92.7 % (80.57-97.48)	75 % (46.77-91.11)	70.4 % (57.17-80.86)

Automated, oscillometric blood pressure; Manual, aneroid sphygmomanometer
CI, confidence level

The accuracy of the MAP \geq 125mmHg in detecting episodes of acute severe systolic hypertension i.e. SBP \geq 160mmHg demonstrated poor sensitivity and specificity [Table 6].

Table 6. Accuracy of MAP \geq 125mmHg, using 3 methods, in detecting intra-arterial SBP \geq 160mmHg

	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
A-line	35.9 % (25.29-48.18)	0 % (0.0-65.76)	92 % (75.03-97.78)	0 % (0.0-8.57)
Automated	21.9 % (13.5-33.43)	50 % (9.46-90.55)	93.3 % (70.18-98.81)	2 % (0.35-10.3)
Manual	17.2 % (9.88-28.21)	50 % (9.45-90.55)	91.7 % (64.61-98.51)	1.9 % (0.33-9.77)

A-line, intra-arterial line; Automated, oscillometric blood pressure; Manual, aneroid sphygmomanometer
CI, confidence level

Chapter 4 - Discussion

In this study, both the automated and manual blood pressure devices significantly underestimated systolic blood pressure during an acute hypertensive blood pressure peak. The automated and manual methods of SBP measurements were not very accurate in detecting episodes of a SBP \geq 160mmHg. There was poor correlation between the automated and manual SBP measurements when compared to intra-arterial SBP measurements [$r = 0.34$ ($p < 0.01$); $r = 0.41$ ($p < 0.01$) respectively]. The automated SBP only agreed one third of the time when compared to the intra-arterial SBP. The manual SBP only agreed two fifths of the time when compared to the intra-arterial SBP. When comparing the mean automated and the mean manual SBP to that of the mean intra-arterial SBP, a statistically significant mean difference was found for each. The mean difference of the manual SBP was smaller than that of the automated SBP measurements (20 ± 15 mmHg vs. 24 ± 17 mmHg respectively). These findings were similar to that of a study done by Penny et al², where the mean difference of automated SBP was 15 – 18mmHg and conventional sphygmomanometry underestimated SBP by 7mmHg. In the study done by Natarajan et al, the automated oscillometric device significantly underestimated the mean SBP by 19mmHg when compared to the mean intra-arterial SBP.¹⁰ In our study, the automated SBP underestimated the intra-arterial SBP by up to 52mmHg. Even though the manual SBP underestimated the intra-arterial SBP by up to 68mmHg, the mean difference was 20 ± 15 mmHg, making this manual method of blood pressure measurement more accurate than automated methods when measuring systolic blood pressure. Both methods of SBP measurement will result in numerous undetected systolic events, resulting in inadequate intervention and possible intracerebral haemorrhage.

There was no significant difference found when comparing the mean automated and mean manual DBP to that of the mean intra-arterial DBP. The mean difference was small (-2 ± 10 mmHg, $p = 0.20$ and 1 ± 12 mmHg, $p = 0.65$ respectively). The automated DBP and the manual DBP overestimated the true intra-arterial DBP measurements 56% and 48.5% of the time, respectively. The automated DBP overestimated by up to 24mmHg while the manual DBP measurements were overestimated by up to 25mmHg. In the study by Natarajan et al, there was also no significant finding when comparing the mean automated oscillometric DBP to that of the mean intra-arterial DBP measurements, and they were found to be similar.¹⁰ In the study by Penny et al,

the mean automated DBP was underestimated by 11mmHg but the mean manual DBP also overestimated by 6mmHg.² However, systolic hypertension has become more important over recent years, owing to its close association with intracerebral complications.⁹

When recruiting patients for the study, either a SBP \geq 160mmHg or a DBP \geq 110mmHg was required, not both. Only 2 of 66 (3%) of the intra-arterial SBP readings were $<$ 160mmHg, indicating that systolic hypertension in our study group was far more common than diastolic hypertension when detecting acute severe hypertension. However, only 7 of 66 (10.6%) of the intra-arterial DBP readings were \geq 110mmHg. This could account for the small mean difference and lack of statistical significance when analysing methods of DBP measurements. Therefore, a greater sample size analysing DBP \geq 110mmHg is most likely needed, and this difference may change if more patients with DBP \geq 110mmHg only, are analysed.

The automated MAP only correlated with the intra-arterial MAP two fifths of the time, while the manual MAP correlated almost two thirds of the time. These findings were statistically significant [$r = 0.44$ ($p < 0.01$); $r = 0.56$ ($p < 0.01$)] respectively. The mean difference of the MAP of the automated blood pressure was smaller than the mean difference of the MAP of the manual blood pressure when compared to the mean difference of the intra-arterial MAP (5 ± 13 mmHg and 8 ± 11 mmHg respectively), both statistically significant. This is most likely explained by the fact that the automated DBP often overestimated the true intra-arterial DBP, resulting in the automated MAP value being closer to the intra-arterial MAP, than that of the manual MAP. In the studies by Penny et al and Natarajan et al, the automated devices underestimated MAP, which corresponded to the findings in this study.^{2,10}

The automated and manual methods of SBP measurements were not very accurate in detecting episodes of a SBP \geq 160mmHg. Neither were the automated and manual methods of MAP measurement very accurate in detecting a MAP \geq 125mmHg. The sensitivities of all methods were low, ranging from 23.4% to 44%. This implies that a SBP \geq 160mmHg will not be detected in up to 62% of cases when using automated or manual methods of SBP measurements. A MAP \geq 125mmHg will not be detected in more than 56% of the cases when using automated or manual methods of determining the MAP. The MAP may not always predict a high systolic blood pressure, especially with large pulse pressures.⁸

In this study, we used the cut-off point for MAP as $\geq 125\text{mmHg}$ in detecting a SBP $\geq 160\text{mmHg}$, as the findings in the study by Martin et al show that the majority of patients did not have a MAP $\geq 130\text{mmHg}$ (20.8% of patients) but almost half had a MAP $\geq 125\text{mmHg}$ (45.8% of patients) just prior to having a stroke.⁹ Sibai et al also considered a MAP $\geq 125\text{mmHg}$ an indication for the commencement of antihypertensive treatment in patients with severe pre-eclampsia.²³ In this study, a MAP $\geq 125\text{mmHg}$ was also not very accurate in detecting a systolic blood pressure $\geq 160\text{mmHg}$, when using all three methods of blood pressure measurements. There was a low sensitivity and specificity for all three methods thereby confirming the findings of Martin et al.⁹ This may have serious implications as many episodes of severe hypertension will not be detected and will therefore be left untreated, resulting in an increased incidence of serious maternal morbidity and even mortality, especially that of intracerebral haemorrhage. Even though the specificity was high most of the time, a high sensitivity would be far better appreciated, as it is more important to accurately detect severe hypertension as opposed to excluding it.

When comparing the complications rates of severe preeclampsia observed in our study with those observed in another study in Pretoria, South Africa, they varied somewhat.²² These differences may be due to differences in the population group studied, different management protocols and differences in hospital facilities and infrastructure. Pulmonary oedema was our most common complication (34.8%) encountered which was only found to be 26% in Pretoria. Our second most common complication was that of HELLP syndrome (30.4%), which was similar to that in Pretoria. Eclampsia and renal complications were the third and fourth most common complications in our study with an equal complication rate of 21.7% each. One patient in our study had the unfortunate complication of intracerebral haemorrhage. While the study was in progress, there was another patient who had been intubated and ventilated due to an intracerebral haemorrhage, and at least one other with hypertensive encephalopathy. They were not included in the study as the ability to obtain consent for inclusion into the study was not possible. This would have raised the rate of cerebral complications as high as 16%. This finding would be similar to the 14.4% of cerebral complications found in the study done in Pretoria.²²

In our methods, Korotkoff phase V was used when measuring the manual blood pressure as this has been shown to be more accurate than Korotkoff phase IV when documenting diastolic blood pressure during pregnancy. However, in some pregnant women, Korotkoff V is heard until the blood pressure is zero. Under these

circumstances, the use of Korotkoff IV to determine the diastolic blood pressure is acceptable.^{20, 21} Considering the fact that the majority of patients were reasonably ill, only five blood pressure readings were taken per patient for the sake of patient comfort.

As our search found no literature regarding a study of this nature, the assumption of a mean difference of 10mmHg was made after consultation with critical care consultants in the unit, along with observations of differences in blood pressure measurements when using different methods. The American Association for Medical Instrumentation states that when comparing indirect blood pressure measurements with direct blood pressure measurements, there needs to be a difference of less than 5mmHg, for an indirect reading to be considered accurate.²⁴ However, we assumed that a difference of 5mmHg may be too small for any clinical significance, and since our search found no study comparing the differences between the methods of blood pressure measurement at the time of a hypertensive blood pressure peak, a mean difference of 10mmHg was used.

One of the main strengths of this study was that it focussed on systolic hypertension during an acute hypertensive blood pressure peak. There were few or no studies that have looked at the accuracy of blood pressure measurements during a hypertensive peak. This is clinically relevant, as accurately determining the correct blood pressure will result in appropriate and timely intervention with antihypertensive treatment, thereby decreasing maternal morbidity and mortality. As the OCCU is a four bed unit, the study was conducted in a controlled environment, thus allowing for stringent quality control in methods of blood pressure measurement.

One of the weaknesses of this study was possible observer bias, which may have influenced the manual blood pressure measurements. Even though the nursing personnel or the doctor measuring the manual blood pressure was blinded to the intra-arterial and automated blood pressure readings, they may have known that the patient had acute severe hypertension. This could have resulted in the documentation of a manual blood pressure reading that is higher than the actual manual blood pressure measurement. Despite taking the above into consideration, the systolic manual blood pressure still underestimated the intra-arterial systolic blood pressure. Unfortunately, there were few patients with diastolic hypertension, and this may have influenced our findings when comparing the methods of diastolic blood pressure measurements.

The Nihon Kohden BSM – 4113K monitor used in this study measures automated oscillometric blood pressure and has not been validated for use in pre-eclamptic women. Neither has the Welch Allyn Maxi Stabil 3 aneroid sphygmomanometer been validated for this purpose. There are very few monitors that have been validated for use in women with pre-eclampsia. This may have influenced our findings with both manual and automated blood pressure measurements. However, automated oscillometric methods of blood pressure measurement are considered more reliable than automated auscultatory methods of blood pressure measurement.¹¹ This was also shown in the study by Natarajan et al whereby the automated auscultatory monitor consistently underestimated more blood pressure measurements than the automated oscillometric monitor when compared to mercury sphygmomanometry.¹⁰

Intra-arterial blood pressure monitoring still appears to be the gold standard when managing complicated pre-eclamptic patients with acute severe hypertension. Unfortunately, it is not possible to manage every patient with acute severe hypertension invasively, as an ongoing shortage of equipment and staff will be a limiting factor in our labour ward. Manual aneroid sphygmomanometry is still more accurate than automated oscillometric methods of blood pressure measurements. However, in a busy labour ward where a shortage of staff is still a reality, an automated method of blood pressure measurement would be more convenient but possibly detrimental. However, it is of utmost importance to be aware of the consequences of an undetected hypertensive blood pressure peak as the under treatment of blood pressure in patients with acute severe hypertension may lead to severe and possibly preventable maternal morbidity and mortality.

Conclusion

In conclusion, both the automated and manual methods of blood pressure measurements were not an accurate measure of the true intra-arterial blood pressure, when managing pre-eclamptic patients with acute severe hypertension. In such situations, intra-arterial blood pressure monitoring should be used when possible. When this is not possible, manual aneroid sphygmomanometry is recommended, as this is still more accurate than automated oscillometric methods of blood pressure measurement. Underestimating blood pressure, particularly SBP, may lead to severe maternal morbidity and mortality.

References

1. Moodley J. Maternal deaths due to hypertensive disorders in pregnancy: Saving Mothers report 2002-2004. *Cardiovasc J Afr* 2007; 18(6): 358-361
2. Penny JA, Shennan AH, Halligan AW, Taylor DJ, de Swiet M, Anthony J. Blood pressure measurement in severe pre-eclampsia (letter). *Lancet* 1997; 349:1518
3. Bergel E, Carroli G, Althabe F. Ambulatory versus conventional methods for monitoring blood pressure during pregnancy (Review). *Cochrane Database of Systematic Reviews* 2002, Issue 2. Art. No.: CD001231. DOI: 10.1002/14651858.CD001231.
4. Kazimierak W, Kowalska-Koprek U, Karowicz-Bilinska A, Berner-Trabska M, Lenczowska-Wezyk M, Brzozowska M, Kus E. 24-hour Holter measurement of blood pressure in pregnant women and effectiveness of the treatment. *Ginekol Pol.* 2008 Mar; 79(3): 174-176
5. Gogarten W. Preeclampsia and anaesthesia. *Curr Opin Anaesthesiol* 2009; 22:000-000
6. Davey DA, MacGillivray I. The classification and definition of the hypertensive disorders of pregnancy. *Am J Obstet Gynecol* 1988; 158: 892 – 898
7. Steyn W. Hypertension during pregnancy – what are we talking about? *Obstetrics and Gynaecology Forum* 2003 Feb; 13:1-2
8. CEMACH. Saving mothers' lives: Reviewing maternal deaths to make motherhood safer – 2003-2005. www.cemach.org.uk/publications/2007.
9. Martin JN, Thigpen BD, Moore RC, Rose CH, Cushman J, May W. Stroke and severe preeclampsia and eclampsia: a paradigm shift focusing on systolic blood pressure. *Obstet Gynecol* 2005; 105:246-254
10. Natarajan P, Shennan AH, Penny J, Halligan AW, de Swiet M, Anthony J. Comparison of auscultatory and oscillometric automated blood pressure monitors in the setting of preeclampsia. *Am J Obstet Gynecol* 1999 Nov; 181(5): 1203-1210
11. Marino PL. *The ICU book* 2nd edition. New York: Lippincott Williams & Wilkins, 1998.
12. Araghi A, Bander JJ, Guzman JA. Arterial blood pressure monitoring in overweight critically ill patients: invasive or non-invasive? *Critical Care* 2006; 10(2) R64

13. Pomini F, Scavo M, Ferrazzani S, De Carolis S, Caruso A, Mancuso S. There is poor agreement between manual auscultatory and automated oscillometric methods for the measurement of blood pressure in normotensive pregnant women. *J Matern Fetal Med.* 2001 Dec; 10(6): 398-403
14. Higgins JR, de Swiet M. Blood-pressure measurement and classification in pregnancy. *Lancet* 2001; 357: 131-35
15. Beevers G, Lip G, O' Brien E. ABC of hypertension. Blood pressure measurement. Part I – Sphygmomanometry: factors common to all techniques. *BMJ* 2001 April; 322:981-5
16. Dean AG, Sullivan KM, Soe MM. OpenEpi: Open Source Epidemiologic Statistics for Public Health, Version 2.3. www.OpenEpi.com, updated 2009/20/05
17. Brown MA, Hague WM, Higgins J, Lowe S, McCowan L, Oats J, Peek MJ, Rowan JA, Walters BNJ. The detection, investigations and management of hypertension in pregnancy: full consensus statement. Recommendations from the Council of the Australasian Society for the Study of Hypertension in Pregnancy.2000
18. Brown MA, Lindheimer MD, de Swiet M, Van Assche A, Moutquin JM. The classification and diagnosis of the hypertensive disorders of pregnancy: statement from the International Society for the Study of Hypertension in Pregnancy (ISSHP). *Hypertens Pregnancy* 2001; 20:IX-XIV
19. O' Brien E, Petrie J, Littler WA, de Swiet M, Padfield PD, Dillon MJ. Blood pressure measurement: recommendations of the British Hypertension Society. 3rd ed. London: BMJ Publishing Group, 1997.
20. Shennan A, Gupta M, Halligan A, Taylor DJ, de Swiet M. Lack of reproducibility in pregnancy of Korotkoff phase IV as measured by mercury sphygmomanometry. *Lancet* 1996; 347:139-42.
21. de Swiet M. K5 rather than K4 for diastolic blood pressure measurement in pregnancy. *Hypertension in Pregnancy* 1999; 18:iii-v.
22. Lombaard H, Pattinson RC, Backer F, Macdonald P. Evaluation of a strict protocol approach in managing women with severe disease due to hypertension in pregnancy: A before and after study. *Reproductive Health* 2005; 2:7
23. Sibai BM, Barton JR. Expectant management of severe preeclampsia remote from term: patient selection, treatment, and delivery indications. *Am J Obstet Gynecol* 2007; 196:514.e1-514.e9.

24. Davis RF. Clinical comparison of automated auscultatory and oscillometric and catheter-transducer measurements of arterial pressure. J Clin Monitor 1985; 1:114 – 119

Addendum A

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

The accuracy of non-invasive blood pressure monitoring when compared to intra-arterial blood pressure monitoring in patients with severe pre-eclampsia during an acute hypertensive crisis

REFERENCE NUMBER: N08/10/308

PRINCIPAL INVESTIGATOR: Dr S Dalla

**ADDRESS: Obstetrics High Care Unit
Tygerberg Hospital
Tygerberg
7505**

CONTACT NUMBER: 021 938 5968

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Committee for Human Research at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

The study will take place in the Obstetrics High Care Unit at Tygerberg Hospital. Initially, at least 20 patients will be recruited. If necessary, more patients will be invited to participate in the study.

The project aims to measure and compare three different ways in which we can measure the blood pressure in patients with severe pre-eclampsia. Pre-eclampsia is when the blood pressure is raised and there is protein in the urine. When pre-eclampsia is severe, the blood pressure is very high. This is very dangerous for both the pregnant mother and her baby. For the mother,

pre-eclampsia may result in the placenta separating from the uterus causing excessive bleeding, water on the lungs, kidney failure, bleeding and clotting problems, seizures, stroke and may even result in death. Complications for the baby include growth restriction, preterm birth and death. By doing this study, we will be able to determine which method is the most accurate for measuring the blood pressure. This will allow for us to better manage blood pressure, thereby preventing the above-mentioned complications.

If you have severe pre-eclampsia and are admitted to the Obstetric High Care Unit, we routinely measure the blood pressure with an intra-arterial line and an automated blood pressure device. An intra-arterial line is a plastic cannula, which is inserted into an artery in the arm. It is then connected via a thin plastic line to a monitor, so that we can directly measure the blood pressure. An automated blood pressure device has a blood pressure cuff attached to a small monitor. The blood pressure cuff is wrapped around the upper arm and the monitor will then automatically read your blood pressure. You may be familiar with this device, as it is often used at local clinics and pharmacies for measuring the blood pressure. This usually forms part of your routine management for blood pressure monitoring if you are admitted to the Obstetrics High Care Unit, whether or not you choose to participate in the study.

If you choose to participate in the study, a third method for monitoring the blood pressure will be done. This will be done each time the blood pressure is very high. Manual sphygmomanometry will be used. This means that a nurse or doctor will manually wrap a blood pressure cuff around your arm and personally listen to your blood pressure. This will be the only thing that is done in addition to your routine management whilst in the Obstetric High Care Unit.

All the blood pressure readings from all three methods from all the patients involved in the study will then be compared, and the most accurate method for measuring blood pressure will be determined.

No medication will be used for this study.

Why have you been invited to participate?

You have severe pre-eclampsia. As mentioned earlier, this is when the blood pressure is very high and is accompanied by protein in the urine.

You have been admitted to the Obstetric High Care Unit.

You already have, or require an intra-arterial line for blood pressure monitoring.

These are all the criteria that need to be fulfilled prior to being invited to participate in the study. You have been invited to participate in the study as you meet all the above-mentioned criteria that are required for inclusion into the study.

What will your responsibilities be?

There are no responsibilities that need to be fulfilled from your side.

Will you benefit from taking part in this research?

If the most accurate methods of measuring blood pressure can be established and used, it will largely improve management and reduce the complications of patients with severe pre-eclampsia. This will play an important role in decreasing the complications of stroke and death in young women. This will be of great benefit to future patients that are diagnosed with severe pre-eclampsia.

Are there any risks involved in your taking part in this research?

There are no risks involved in you participating in this study.

If you do not agree to take part, what alternatives do you have?

You are not obliged to participate in the study and your participation is completely voluntary. If you choose not to be a participant in the study, your treatment for severe pre-eclampsia will not be affected in any way. Your blood pressure will still be routinely monitored using an intra-arterial line as well as an automated blood pressure device. The only difference would be that we would no longer do a manual blood pressure reading each time you have a very high blood pressure peak.

Who will have access to your medical records?

All the information that we obtain from you, or your medical folder, will be kept strictly confidential. You will be allocated a number or a code, so your name will never be used. In this way, your identity will always be protected. In the event of your information being used in a publication or thesis, all information will be reported with anonymity. Only the principal investigator and the co-investigator will have access to your medical records.

What will happen in the unlikely event of some form injury occurring as a direct result of your taking part in this research study?

As the study only involves taking a manual blood pressure measurement in addition to your routine management in the Obstetrics High Care Unit, an injury occurring as a direct result of your participating in this research study is not likely.

Will you be paid to take part in this study and are there any costs involved?

You will not be paid to participate in the study, but your transport and meal costs will be covered if a study visit is necessary. There will be no financial costs involved for you if you do participate.

Is there any thing else that you should know or do?

You can contact Dr S Dalla at tel. 021-938 5968 if you have any further queries or encounter any problems.

You can contact the Committee for Human Research at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.

You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I agree to take part in a research study entitled , **The accuracy of non-invasive blood pressure monitoring when compared to intra-arterial blood pressure monitoring in patients with severe pre-eclampsia during an acute hypertensive crisis .**

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*)..... 2009.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator

I (name) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*)

Signed at (place)on (date) 2009.

.....
Signature of investigator

.....
Signature of witness

Declaration by interpreter

I (name) declare that:

- I assisted the investigator (name) to explain the information in this document to (name of participant) using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.

- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*)..... on (*date*)..... 2009.

.....
Signature of interpreter

.....
Signature of witness

Addendum B

THE HYPERTENSIVE CRISIS PROJECT

Name:
Folder no.:

Area:.....

Age:.....

Gravidity:..... Parity:.....

Race:.....

Gestation:..... Upper arm circum.....cm

Postpartum:..... yes no

Weight:.....kg Length: BMI:.....

BP:..... Protein:

New paternity:..... yes no

Previous PET:..... yes no

CHPT:..... yes no

RVD:..... yes no CD4:.....

PMhx:.....

Complications:..... hellp p oedema renal eclampsia

other

Smoker:..... yes no Quantity:

Alcohol:..... yes no Quantity:

MgSO4:..... yes no

AntiHPT's
used:.....

..... labetolol adalat nepresol tridil

adalat xl aldomet other.....

AntiHPT's before
pregnancy:.....

..... HCTZ atenolol adalat xl hydrallazine

enalapril amlodipine other.....43.....

Addendum C

The Hypertensive Crisis Project

Data Sheet

BP Readings

Name:
Folder no.:

1
2
3
4
5

A-line	MAP

Automated	MAP

Manual	MAP

