

PREGNANCY OUTCOMES IN WOMEN RECEIVING INTRAPARTUM
EPIDURAL ANALGESIA AT THE CHRIS HANI BARAGWANATH
ACADEMIC HOSPITAL A 6-MONTH REVIEW.

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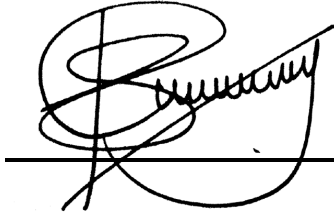


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JOHANNESBURG

Dissertation submitted to the Faculty of Health Science, University of the Witwatersrand, Johannesburg, in partial fulfillment of the requirements for the degree of Master of Medicine in Obstetrics and Gynaecology.

DECLARATION

I, Veneshree Padayachee declare that this dissertation is my own work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

A handwritten signature in black ink, appearing to read 'Veneshree Padayachee', is written over a horizontal line that spans the width of the page.

01 December 2016

To my husband, for being my inspiration and my guiding light. To my sister and dad, for selflessly walking this journey with me. To my mum, I am because you were.

ABSTRACT

Objectives This study had two objectives. The first was to describe the maternal outcomes and complications associated with epidural analgesia and the neonatal outcomes of babies born to women receiving intrapartum epidural analgesia. The second was to assess the progress of labour in women receiving epidural analgesia and the incidence of caesarean section and assisted vaginal deliveries.

Study design This was a cross sectional retrospective descriptive study of all women who received intrapartum epidural analgesia and the neonates born thereof between 01/05/2015 and 31/10/2015.

Methods Women who received intrapartum epidural analgesia were identified from the epidural registers at the Chris Hani Baragwanath Academic Hospital (CHBAH). The medical records of these women and their neonates were retrieved and the relevant data reviewed, captured and analysed.

Results There were a total of 9305 women that delivered between 01/05/2015 and 31/10/2015, of which 302 received intrapartum epidural analgesia. The incidence of epidural use during this period was 3.24%. The median gestational age at delivery was 38.9 (37 - 42) weeks' gestation. The incidence of epidural related complications was 17%, comprising of hypotension (13.4%) and other minor complications (3.6%) with no associated morbidity or mortality. Eighty-four (29.7%) of the women had poor progress of labour pre and post epidural and 13 (4.6%) women post epidural only. Oxytocin for augmentation of labour was used in 96 (32.8%) women. The incidence of prolonged second stage of labour was 26.9% with an average duration of 63 ±33 minutes, with a longer duration observed in primigravid women.

There were 142 (50.2%) normal vaginal deliveries, 23 (8.1%) assisted vaginal deliveries and 118 (41.7%) caesarean sections, of which fetal distress (23%) was the main indication.

There were a total of 62 cardiotopographs (CTG), that changed from reactive to suspicious post epidural, of those 52 neonates were born with an Apgar score of >7.

Of the 283 neonates delivered, 278 (98.2%) neonates were born alive with 258 (91.2%) neonates with Apgar scores of >7 and 23 (8.1%) with Apgar scores <7. The incidence of adverse neonatal outcomes was 4.2%. The fetal outcomes stratified by maternal, epidural and labour outcomes reflected neither associative nor causal relationship to adverse fetal outcomes.

Conclusion At the CHBAH, intrapartum epidural analgesia uses resulted in a maternal complication rate of 17%, with no reported maternal morbidity or mortality. There was no statistical increase in the incidence of poor progress of labour, use of oxytocin and caesarean section or assisted vaginal deliveries. Two hundred and fifty eight (91.2%) neonates were born with Apgar scores of >7, and an adverse neonatal outcome rate of 4.2%. Therefore the benefits of epidurals analgesia outweigh the risks.

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1.0 INTRODUCTION AND LITERATURE REVIEW

Epidural analgesia offers better pain relief than any other method employed to date and is the gold standard of analgesia in labour. It provides effective pain management as labour progresses, and enables better co-operation from the labouring woman, as it does not cause drowsiness. A Cochrane review on the effects of epidural analgesia intrapartum showed that it offered better pain relief together with a reduction in the need of additional analgesia and a decreased risk of maternal acidosis, but is associated with increased risk of assisted vaginal deliveries, maternal hypotension, prolonged second stage of labour and oxytocin usage.¹

Neonatal outcomes showed that better pain relief provided by epidurals resulted in a decreased incidence of maternal metabolic acidosis, fetal acidosis and Apgar scores <7 when compared to intravenous opioid analgesia.¹

Since its initiation in 1946, the beneficial effects of epidural analgesia have resulted in an increased use throughout the world including developing countries.

Evaluation of the epidural service at the Chris Hani Baragwanath Academic Hospital (CHBAH), in terms of maternal and neonatal outcomes as well as the progress of labour will provide valuable insight into factors which may influence pregnancy outcomes and hence the need for this study.

1.1 The history of analgesia use in labour

Pain management began with simple techniques of distraction, application of warm olive oil and herbs to the body and measures such as venesecting women so as to decrease blood supply to the brain inducing a coma like state and therefore decreasing the central nervous system reaction to pain.²

During the 1800s, pharmacological interventions resulted in better pain relief with drugs such as nitric oxide, chloroform and opioids in particular morphine. The idea of pain free

labour bore two perspectives: one was that if “God” intended labour to be pain free it would have been and that the complications including poor fetal outcomes were due to painless labour. The second perspective was that pain relief was necessary and welcomed.²

Over the years it became imperative that adequate analgesia be available to women in labour, and has been endorsed by the American College of Obstetricians and Gynecologist (ACOG), who stated "Labour results in severe pain for many women. There is no other circumstance where it is considered acceptable for a person to experience severe pain, amenable to safe intervention, while under a physician's care".³

In the 19th century the first neuraxial analgesic, was introduced into obstetric practice, in which a Swiss obstetrician injected 0,01g of cocaine into the subarachnoid space. The major complication reported was post-dural headaches.⁴

In 1931, the caudal epidural was used in which a needle was introduced at the caudal level and a catheter left within the space to allow for repeated injections as labour progressed. In early 1960, lumbar epidurals replaced caudal epidurals, as lumbar epidurals provided more comfort for the women and was easier to perform. Lumbar epidurals required less analgesia, maintained lower limb and abdominal muscle motor function and decreased the effect on the sympathetic nervous system with less hypotension.⁴

1.2 Physiology of pain in labour

During the first stage of labour, the pain experienced is related to regular uterine contractions as well as dilatation of the cervix, and is best described as cramping and visceral in nature. Pain perception arises in mechanoreceptors that are stimulated due to intense pressure generated by contractions and activation of chemoreceptors, due to myocellular injury, release of bradykinins, histamine, serotonin and acetylcholine in the uterus and cervix. Sensations from A delta and C afferent pain fibers collectively join

along the right and left cervical plexus, from here they are transmitted to the hypo gastric plexuses where pain transmission is then carried towards the spinal cord in the lumbar paravertebral sympathetic chain. Nociceptors enter the spinal cord via the dorsal nerve roots of T10-L1 and travel to the thalamus, brainstem and cerebellum via the spinothalamic tract. A final synapsis occurs within the thalamus before projections to the sensory cortex, where painful stimuli are perceived.⁵

The pain experienced during the second stage originates from the distention and stretching of the perineum and pelvic floor, and is somatic in nature and better localized.⁶ Transmission of pain is then sent via the pudendal nerve, which originates from the second to the fourth sacral nerve.⁵ The hallmark of this stage is Ferguson's reflex, which results in intense uterine contraction and further activation of pain pathways.⁵

1.2.1 Consequences of painful labour on the mother

Painful labour is associated with activation of the sympathetic nervous system and increase in the plasma concentrations of epinephrine, which activates the beta-adrenergic systems that can offer tocolytic properties. The elevated levels of catecholamines in particular that of epinephrine especially during painful labour, leads to an increase in cardiac output and total peripheral resistance, which in turns leads to decreased placental blood flow, which may compromise fetal well being.^{6,7}

While this may be well tolerated by healthy women and their babies, the sympathetic overdrive seen with strong uterine contractions may exacerbate pre existing cardiac and/or haemodynamic compromise. These autonomic changes also result in deteriorating metabolic acidosis, which can be transmitted to the fetus resulting in poor Apgar scores at birth.⁶

A painful labour experience can have a negative impact on a female, leading to fear of pain in the next pregnancy, increased requests for caesarean sections and even emotional withdrawal from sexual partners. Painful labour leads to uterine dystocia and

uncooperative women particularly during the second stage of labour, resulting in prolonged labour, traumatic deliveries and increased incidence of caesarean delivery.^{6,7}

1.2.2 Effect of painful labour on the fetus

It has been shown that severe maternal pain and anxiety during latent phase of labour correlates with fetal CTG changes during the active phase of labour and resultant lower Apgar scores. Painful uncoordinated labour leads to increased levels of norepinephrine and epinephrine. This results in vasoconstriction of the uterine arteries and uteroplacental insufficiency may occur.⁸

The effects of painful, uncoordinated contractions may lead to a further decline in placental perfusion and a state of hypoxemia within the fetus, metabolic acidosis and CTG changes such as decreased variability, recurrent late and variable decelerations and bradycardia.⁹ These CTG changes result in an increased need for expedited delivery, via caesarean section or if favorable assisted vaginal delivery. Therefore painful labour is associated with increased rates of caesarean section and assisted vaginal deliveries, together with their associated fetal complications.¹⁰

1.3 Analgesia used in labour

Currently there are multiple options available for analgesia in labour and these include pharmacological and non-pharmacological methods, which may be regional or non regional. Non-pharmacological methods, are non invasive with a good safety profile for women and babies but there is limited data on their efficacy. Pharmacological methods despite their risk of adverse effects are used as the primary method of pain relief. Non-pharmacological methods can be combined with pharmacological interventions to increase their effectiveness. Ultimately analgesia should be tailored to the needs and circumstances of the women in labour.¹¹

1.3.1 Non-pharmacological analgesia used intrapartum

Non-pharmacological analgesia while not commonly used, has the advantage of minimal side effects. Many of the non-pharmacological techniques are inadequately studied due to a small population size therefore making it difficult to comment on its efficacy as a labour analgesic. These methods include transcutaneous electrical nerve stimulation (TENS), relaxation/breathing techniques, temperature modulation with hot or cold packs, water immersion, hypnosis, massage, acupuncture and aromatherapy.⁹

1.3.2 Pharmacological analgesia used intrapartum

1.3.2.1 Non Regional analgesia used intrapartum

Nitrous Oxide

Nitrous oxide, which consists of 50% nitric oxide in oxygen, is an inhalational agent, that increases release of endorphin, dopamine and other natural pain relievers in the brain. It does not completely relieve the pain of labour but instead creates “diminished pain”, through its anti-anxiety effect. Its onset of action is within 20-30 seconds and maximal effect at 45 seconds. The advantage lies in the ease of use, safety profile for both women and their new born, with no need for physician supervision and can be used in resource poor areas where other analgesia is not readily available. Its also provides women with control over their own pain management.¹²

The side effects include drowsiness, disorientation and nausea with a minimal incidence of loss of consciousness. While nitrous oxide may provide pain relief in labour, it is not comparable to that of systemic opioids, in that systemic opioids showed a reduction of pain by 1,5 points on a visual analogue scale versus a 0,5 reduction with nitrous oxide.⁶

Nitrous oxide is not available for use at CHBAH.

Systemic Analgesia

Pethidine is the most commonly used systemic analgesic during the labour process. Studies conducted on the efficacy of pethidine as an adequate analgesic intrapartum reports that it offered slightly better relief than the placebo but the adverse effects to mother and fetus outweighs the minimal reduction in pain.¹³

Rather than effective analgesia, its primary mechanism of action is heavy sedation and labour pain is not sensitive to systemic administration of pethidine or morphine. Pethidine's side effect profile includes delayed gastric emptying, sedation, dose dependent respiratory depression and its active metabolite may result in convulsions.^{12, 13} Pethidine readily crosses the placenta and is detectable in the fetus within a minute achieving equilibrium with maternal plasma levels within 6 minutes.¹⁴

The effects of pethidine on the baby which include respiratory depression, poor suckling, slower establishment of breastfeeding, thermoregulation impairment and Apgar scores of <7 at birth, may be attributed to the presence of its long acting metabolite norpethidine (half life 60 hours).¹⁴

Other systemic analgesia available but not used in our setting is that of morphine, diamorphine and fentanyl.

1.3.2.2 Regional Analgesia

Regional analgesia, which includes epidural analgesia, together with its modified delivery systems such as patient-controlled epidural analgesia and combined spinal epidural technique, is the preferred method of analgesia intrapartum. In particular epidurals provides improved labour analgesia with better maternal and fetal outcomes in comparison to older methods such as inhaled nitrous oxide, parental opioids and non-pharmacological methods.¹⁵ While evidence exists on the benefits of epidural analgesia use intrapartum, the incidences of its use in developing countries are relatively low in comparison to developed countries 7.5% vs. 50%.^{1,15} The decreased use of epidural as a

labour analgesia is based on reservations from medical staff and women in labour, based on the ideas that epidural analgesia prolongs labour and increases the risk of caesarean and assisted vaginal delivery.^{16,17,18} Epidural analgesia has been shown to be associated with an increased duration of second stage of labour by 15,55 minutes (95%CI 7.46 to 23.63 minutes) and an increased incidence of operative vaginal delivery, RR 1.3 (CI 95%).¹

1.4 Epidural Analgesia

1.4.1 What is an Epidural?

Epidural anaesthesia is a form of regional anaesthesia commonly referred to as neuraxial blocks, produced by injection of a local anaesthetic agent into the lumbar area of the spine in the epidural space (between the spinal cord and the dura). The injection may provide both motor and sensory loss by blockage of pain signals in and around the site of insertion.

1.4.2 Anatomy of the Epidural Space

The epidural space begins cephalad at the foramen magnum and extends caudally to the sacrococcygeal membrane. It is bound anteriorly by the posterior longitudinal ligament, posteriorly by the anterolateral surface of the vertebral lamina and the ligamentum flavum and laterally by the pedicles of the vertebrae and the intervertebral foramen.

1.4.3 Contraindications to Epidural use

Absolute contraindications to the use of epidural anesthesia include uncorrected hypovolemia as this could lead to severe maternal compromise due to the sudden decline in blood pressure within the first 120 minutes of epidural insertion, raised intracranial pressure, infection at site of insertion, patient refusal and allergies to any of the drugs used.¹⁹

Relative contraindications to the use of epidural anesthesia include coagulopathy, fixed output states, active maternal hemorrhage, uncooperative patient, spinal abnormalities, sepsis and positioning problems.¹⁹

1.5 Epidural analgesia in obstetrics practice

Epidural analgesia offers the most effective, reliable method of analgesia during the labour process. Besides the marked pain relief, other advantages include the ability to provide surgical anesthesia, for instrumental or operative delivery and laceration repair.¹⁹

The rate of regional analgesia, particularly that of epidural use has increased substantially over the past 5 years with more than 50% of women receiving intrapartum analgesia in most developed countries. The wide spread use was contributed to factors like improved maternal and fetal safety profiles associated with epidural use.²⁰

Epidural analgesia blocks the maternal stress response, thereby allowing the women to be in control of her labour and reverses the unwanted physiological consequences of painful labour.^{1,19,20} Advantages to intrapartum epidural use is classed with the relative risk of prolonged labour, caesarean and assisted delivery and use of oxytocin for augmentation of labour.

1.5.1 Benefits of intrapartum epidural analgesia

Epidural intrapartum analgesia was compared to non-epidural intrapartum analgesia and no analgesia. Epidural analgesia was shown to provide better pain relief with a weighted mean difference of 2.60 (95% CI -3.82 to -1.35) using the visual analogue scale.¹

The adequate pain relief associated with epidural analgesia decreases the metabolic acidosis often associated with painful labour. This in turn results in improved neonatal outcomes, improved Apgar scores and a reduction in neonatal admissions. This then allows for early bonding between mother and child and initiation of breast-feeding. Unlike other methods of analgesia such as nitrous oxide and pethidine, epidural analgesia does not cause drowsiness and therefore facilitates cooperation by the woman during the

labour process. A Cochrane review, that evaluated the neonatal outcomes of women that received epidural analgesia compared to non-epidural use, reported a lower risk of umbilical pH below 7.2 within the epidural group.^{1,21} Moreover, epidural analgesia provides pain relief for assisted vaginal delivery and episiotomies.^{1,14}

Epidural analgesia provides sufficient pain relief to eliminate the need for systematic opioid use and the side effects associated with its use, and even after 15 hours of epidural exposure the Apgar score and time to sustained respiration remained unaffected in healthy neonates.¹⁴

Epidural analgesia is beneficial in women that have co morbidities particularly that of preeclampsia and cardiac disease, as it results in peripheral vasodilation, decreased venous return and decreases maternal blood pressure.^{22,23} A study that looked at the effect of epidural analgesia on the Doppler velocimeter of the umbilical and uterine arteries in normal and preeclamptic women recorded an improvement in umbilical flow post epidural analgesia. Epidural analgesia therefore provides both maternal and fetal benefit, through improved uteroplacental blood flow and decreased in maternal mean arterial pressure.^{24,25} This would be beneficial in obstetrics, considering that preeclampsia complicates 2-3% of all pregnancies globally and Frank, et al. reported a 5.8% incidence of proteinuric hypertension in pregnancies in a Sowetan population.²⁶ Women with cardiac pathology other than fixed cardiac output states e.g. mitral stenosis would benefit, in that epidurals due to its effective analgesic properties decrease the release of catecholamine and in turn decrease the cardiac output. The increase in cardiac output, which is seen with intense pain, can be fatal to a heart that is already compromised.²³

Additionally, if at any point during the labour process a woman requires a caesarean section the epidural can always be supplemented to provide surgical anaesthesia and prevent the likelihood of general anaesthesia.

1.5.2 Maternal complications associated with epidural use

The use of regional analgesia, particularly epidural analgesia has increased over the past 10 years within developed countries, due to its safety profile and low risk of long-term severe complications. In an audit conducted in France the incidence of severe complications was 5 in 10000, comparable to Scott, et al. who reported a 1 in 1000 risk.^{27,28}

1.5.2.1 Accidental dural puncture

Postdural puncture headache (PDPH) is the most common complication of epidural analgesia with an incidence of 0-30%.²⁹ It commonly occurs within 7 days of the epidurals insertion and resolves within 14 days and is typically postural in nature, resulting from leakage of cerebrospinal fluid and a decrease in intracranial pressure with a compensatory cerebral vasodilation.^{18,30}

Postdural puncture headaches, while usually self-limiting should be treated conservatively for 24 hrs. If no resolution occurs within 24 hours, active management should be instituted, as it may be associated with severe mortality.²⁰ The definitive treatment for persistent postdural puncture headache is an autologous epidural blood patch (i.e., sterile injection of 15 to 20 mL of the patient's fresh blood into the epidural space, preferably at the site of the dural puncture).^{18,29,30}

1.5.2.2 Hypotension

The incidence of maternal hypotension is 10%, and is similar for both epidural analgesia and combined spinal- epidural analgesia.^{19,31} Maternal hypotension occurs as a result of a decrease in the sympathetic chain afferent outputs leading to vasodilation and a sudden reduction in both systolic and diastolic blood pressure, usually occurring during the onset of epidural analgesia. This complication is tolerated in women and their fetus without any pre existing compromise, particularly placental insufficiency. The placenta lacks the ability

to autoregulate and any decline in maternal blood pressure particularly MAP below 65 mmHg can result in a decline in placental blood flow and CTG changes.¹⁷

Controversy exists on whether or not to preload women with a crystalloid solution prior to epidural placement. A study conducted on 95 normotensive women, assigned to receive 1000 ml of crystalloid fluid pre epidural versus no fluid, reported no benefit. The frequency of hypotension was 6% versus 10% in the control group.³² Dyer R, et al. and Hofmyer G, et al. reported similar findings.^{32,33,34} Dyer R, et al. further concluded that preloading women with crystalloid solution may induce atrial natriuretic peptide secretion, leading to vasodilation and hypotension.³³ Women should rather be monitored closely and measures instituted early with the use of epinephrine as hypotension can result in decreased utero placental blood flow and an 8% incidence of transient fetal heart rate deceleration.³⁵ This is of clinical significance as most clinicians view the change in fetal heart rate negatively and tend to book women for caesarean section deliveries.

1.5.2.3 Pyrexia

Women in labour who receive epidural analgesia are more likely to experience pyrexia with an overall 3 times greater risk compared to non epidural use (RR 3.34, 95% CI 2.63-4.23).¹ There is an incidence of 24% in nulliparous women versus 8% in multiparous women. Initially it was thought that all women who receive epidural analgesia intrapartum have an increase in core body temperature, but the current consensus is a 20% incidence of pyrexia. An overall increased incidence of pyrexia appears by four hours of exposure and increases with increasing duration.³⁵ The major consequence of this is an increase in metabolic rate, cardiac output and oxygen demand, which could be benign to the healthy woman but complicate management of women with cardiac or pulmonary diseases.^{35,36}

1.5.2.4 Failed epidural analgesia

Failed epidural analgesia or inadequate pain relief is a complication, seen more often in the obstetric woman when compared with surgical women. Failure rates, range from

13,5% - 24% in intrapartum obstetric women compared to 4% in surgical women.^{20,37}

Epidural failure is multi-factorial and some common causes include; increased Body mass index (BMI), which is related to difficulty in placement and technique, fetal positioning and analgesic effect of the initial dose. In terms of the fetal position, a posterior lie is associated with an increased labour duration, uncoordinated uterine contractions and increased hormonal release all of which increases the intensity of uterine contraction beyond the analgesic effects of epidural analgesia.³⁷

1.5.2.6 Other Complications

Other less common complication includes infection at site of placement, including meningitis, spinal analgesia, high spinal, death and paralysis. The incidence of transient or permanent neurological complications is reported to be between 1/1000 to 1/1000000. Epidural hematoma occurs in 1/15000 healthy women and is more commonly seen in women with haemostatic abnormalities. Cardiac arrest has been reported in 1/10000.²⁷

1.5.3 Labour associated complications

Epidural analgesia is often associated with increased rates of caesarean section deliveries for uterine dystocia. The cause of the increased rate is still unclear and may be due to the effects of epidural anaesthesia on motor blockage with decreased perception of uterine contraction or failure of descent of the fetal head. The motor blockade, associated with epidural use may result in relaxation of the pelvic floor muscles, which may alter the descent and rotation of the fetal head, leading to labour dystocia. Several retrospective studies based on epidural analgesia and their effect on labour showed a consistent increase in the duration of the first and second stage of labour, use of oxytocin, assisted vaginal and caesarean deliveries.^{38,39} Other studies refute such conclusions on the basis that women who request epidural analgesia, may already have features of poor progress and/or dystocia secondary to pain, and therefore the event of caesarean delivery may be due to the pain rather than the initiation of epidural analgesia.^{40,41,42}

Anim-Somuah M, et al. who performed a systemic review of all trials that assessed the

effect of epidural analgesia on the relative risk of caesarean section, which included a total of 6534 women, reported no evidence of a significant difference in the risk of caesarean delivery (RR 1.07, 95% CI 0.93 to 1.23, 20 trials) with epidural use versus non epidural use.¹ Gribble R, et al. studied the effect of an “on demand epidural service” and the effect on the caesarean section rate. He found no difference in the caesarean section rate before the epidural service compared to after its introduction.⁴³

Thorp J, et al. reported an increased frequency of caesarean delivery among nulliparous women who received epidural analgesia compared to those that received narcotic analgesia 2.2% versus 25%, $p < 0.05$.³⁸

Ramin S, et al. completed a randomized control trial that looked at the effect of epidural analgesia with intravenous pethidine on the effects of labour and found a two fold increased risk of caesarean section deliveries with the use of epidural analgesia.³⁹

Dickson J, et al. conducted a trial on factors influencing the selection of analgesia in spontaneous labouring nulliparous women at term. In this study they randomized nulliparous women to either the epidural or non-epidural analgesia group during their antenatal visits. They reported a cross over rate of 61.3% from the non-epidural group to the epidural group, with the painful labour being the main reason for cross over. He further concluded that epidural analgesia and choice thereof is not a random event and more an indicator of abnormal labouring patterns.⁴⁰ The findings are similar to a study conducted by Halpern S, et al. that suggested that nulliparous women are more likely to request epidural analgesia due to the increased risk of labour dystocia.⁴¹

A recent UK based trial, COMET assessed the effects of different epidural regimes on the mode of delivery. The study randomly assigned 1054 nulliparous women to the traditional epidural regimen (intermittent 10 mL boluses of 0.25% bupivacaine), low-dose combined spinal–epidural regimen (CSE) (bupivacaine 2.5 mg and fentanyl 25 mcg, followed by a 15 mL bolus of 0.1% bupivacaine and 2 mcg/mL fentanyl when the spinal component wears off with intermittent 10 mL boluses of this combination of drugs), or low-dose infusion epidural regimen (bolus of 15 mL 0.1% bupivacaine and 2 mcg/mL fentanyl

followed by an infusion of 10 mL/hour of same). They reported a higher rate of spontaneous vaginal deliveries within the low dose infusion epidural group compared to the traditional group (43% vs. 34%). They also reported a decrease in caesarean section and operative deliveries. This suggests that traditional higher dose epidural regimes could have been responsible for the relative increased risk of caesarean sections and operative deliveries, reported in the past.⁴²

Zhang J, et al. evaluated the rate of caesarean section, instrumental deliveries and prolonged labour with the introduction of epidural analgesia. He reported that despite the rapid increase in epidural usage (1%-85%, over 1 year) the rates of caesarean section deliveries remained the same. He also reported no increased incidence of instrumental deliveries (adjusted relative risk, 1.0; 95% confidence interval, 0.8-1.4), no increase in duration of the first stage of labour, but noted an increase in the duration of the second stage of labour by 25 minutes.⁴⁴

Ramin, et al. concluded that the relative risk of a prolonged second stage of labour with epidural use was 9.6 CI 95%.³⁹ Similar findings were reported by Zhang J, et al.⁴⁴, Anim-Somuah M, et al¹ and the COMET trial.⁴² Each concluded an average increase in duration of 15 minute, with Zhang J concluding the average duration being higher in nulliparous women compared to multiparous women, 70 minutes vs. 35 minutes respectively.^{1,38,40,41,42}

American Congress of Obstetrics and Gynecology Committee Opinion who previously published that “epidural does increase the incidence of caesarean deliveries” has after recent meta analyses concluded that epidural analgesia does not increase the rates of caesarean deliveries (odds ratio 1.00–1.04; 95% confidence interval, 0.71–1.48).⁴⁵

Another associated risk of epidural analgesia is the increased incidence of oxytocin use, Timothy J, et al. a medical endocrinologist looked at the effect of epidural analgesia on serum concentration of cortisol, beta-endorphins, plasma glucose and lactate and mean plasma oxytocin concentration 10 minutes post epidural and throughout labour.⁷ Although the study population only consisted of 9 women it demonstrated a decrease in stress

biomarkers, with no change in glucose, lactate or serum oxytocin levels throughout labour, suggesting that if epidural does interfere with progress of labour the mechanism is not through a decrease in oxytocin secretion.⁷ A study conducted on the effects of epidural analgesia on the second stage of labour found that, women who receive intrapartum epidural are 3,5 times more likely to receive oxytocin for augmentation of labour in comparison to women who receive other forms of analgesia. Within this study however, of the 101 women who requested epidural analgesia for pain management, 69 (68.3%) women received oxytocin for augmentation of labour prior to epidural placement with only 20(19.8%) women receiving oxytocin after epidural analgesia, therefore suggesting the presence of painful dysfunctional labour prior to epidural request, suggesting once again an associative rather than a causal relationship.⁴⁶ A similar study conducted by Lewis L, et al. studied which came first, the oxytocin or epidural analgesia and found that 62% of women who received epidural analgesia, had an oxytocin infusion started prior to the placement of the epidural catheter. The study also showed that 21% of women received oxytocin after the placement of the epidural catheter.⁴⁷

Much debate still exists on the use of epidural analgesia as a form of intrapartum analgesia and its effects on the labour process.

1.5.4 Fetal complications

Epidural analgesia can have a direct and indirect effect on the fetus. The direct effect is due to systematic absorption of opioids. Epidural analgesia however does not depend on maternal systematic absorption for its mechanism of action. Therefore the likelihood of direct fetal effects is rare. The indirects effects are a result of the alteration in maternal physiological and biological changes.⁴⁸ Due to the rapid onset of pain relief seen with epidural analgesia intrapartum there is a decline in maternal stress response and a resultant imbalance in norepinephrine and epinephrine levels. This imbalance leads to a loss in the relaxant effects on the uterus produced by epinephrine leading to uterine hypertonicity and fetal heart rate abnormalities.^{48,49}

Raynold F, stated that “instead of examining the effect of any procedure on the newborn, various surrogate outcomes such as maternal blood pressure, fetal heart rate, duration of labour, need for oxytocin, delivery type and even maternal fever are assumed to equate with fetal/neonatal welfare”.⁴⁸ This is particularly true for epidural analgesia, as most health professional and women are more concerned of its effect on labour and transient risk of CTG changes as opposed to its beneficial effect for the neonate.

Epidural analgesia is associated with an 8% transient risk of CTG changes post-epidural placement.³² A meta-analysis of nine trials reported a transient risk of fetal bradycardia within one hour of epidural administration in 7.3 % of women in comparison to 4.8% of women in whom epidural analgesia was not used, [RR] 1.81, 95% C.⁴⁹

The proposed theory on fetal heart rate changes is that epidural analgesia, through its rapid onset of action results in uterine hyperstimulation. This theory is supported by a study done that looked at the incidence of elevation in uterine basal tone in women that received combined spinal epidural (CSE) compared to traditional epidural analgesia and its effect on the fetal heart rate patterns. Sixty four percent of women had changes in fetal heart rate patterns in the CSE group compared to 16% in the traditional group.⁵⁰

A meta analysis of controlled trials on systemic opioids versus epidural analgesia showed no difference in incidence of fetal heart rate changes between the two groups. It did however report better neonatal outcomes in the women who received epidural analgesia as opposed to systemic opioids.⁵¹

Maternal hypotension secondary to epidural analgesia has been shown to result in fetal heart rate abnormalities. The placenta lacks the ability to auto regulate and is dependent on maternal blood pressure for perfusion. Any decline in maternal blood pressure can lead to decreased fetal oxygenation and CTG changes.⁵¹ Some studies have postulated that preloading women with intravenous fluid has been shown to decrease the incidence of fetal heart rate abnormalities following epidural analgesia (p=0.025, OR 0.03 95% CI).^{32,33,34}

Epidural analgesia is associated with improved neonatal outcomes, better Apgar scores and lower risk of having an umbilical pH <7.2 (RR0.80 95%CI 0.66-0.96) when compared to systemic opioids.^{1,21,51} There is also a reduction in need for naloxone and admission into neonatal ICU. Schockets M, et al. looked at the neonatal outcomes and umbilical artery pH post delivery of 110 babies whose mothers had epidural analgesia compared to women who had no analgesia. He reported similar pH values between the two groups, but significantly higher paCO₂ within the epidural group, suggesting a reduction in maternal hyperventilation and fetal metabolic acidosis.⁵² Therefore epidural analgesia is associated with improved neonatal outcomes when compared to non epidural analgesia and no analgesia. Early studies reported that neonates born to women who received epidural analgesia had lower neonatal neurobehavioral scores.²¹ Longitudinal studies showed no difference in scores between neonates born to women who had received epidural compared to those that received no analgesia or non epidural analgesia.^{1,21}

2.0 PROBLEM STATEMENT

Epidural analgesia is the most effective means of labour relief; limiting access to such service based on the assumption that it increases suboptimal outcomes in obstetric would force many women to endure severe labour pain.⁴⁵

The provision of an epidural service is limited by anaesthetic staff availability and therefore accessible to a select few. The quality and outcomes of the epidural services at CHBAH has never been evaluated and hence the need for this study. This institution has the largest number of deliveries in South Africa, on average performing 17000 deliveries per annum with an epidural services operating Monday to Friday, 8 am to 16pm. This would be the ideal place to evaluate outcomes of such a service. The results will facilitate positive reinforcements in offering such services with information on likely outcomes for women, midwives and doctors, and facilitate the development of guidelines for the management of women receiving epidural analgesia intrapartum.

2.1 Objectives of the study

To describe the:

1. Maternal outcomes and complications in women receiving intrapartum epidural analgesia.
2. Neonatal outcomes of babies born to women who receive labour epidural analgesia.

To assess the:

1. Progress of labour in women receiving intrapartum epidural analgesia.
2. Incidence of caesarean section and instrumental deliveries in women receiving intrapartum epidural analgesia.

3.0 MATERIALS AND METHODS

3.1 Setting

This study was conducted in the Maternity Unit at CHBAH, a tertiary care institution situated in Soweto, and provider of medical care to a population of 1,3 million people and is the referral center for primary and secondary health care facilities, as far as Klerksdorp within the North West Province.

The Department of Obstetrics and Gynaecology, has 21 beds for women in active phase of labour, 16 latent phase beds, 7 high care beds and an admission ward. On average there are about 420 deliveries, performed each week. These include both normal vaginal deliveries and caesarean sections, with an average caesarean section rate of 40% weekly. The department has two operating theatres that function over a 24-hour period, 7 days a week.

The average turnover time in labour ward is 15 – 20 hours. Clinical assessment of women occurs hourly by sisters and 2 hourly by doctors. Due to the large number of women at CHBAH and the limited resources available many women do wait on average 2 hours before adequate management can be established, especially in respect to caesarean section deliveries. The standard waiting time for caesarean section differs depending on the triage system, in that emergencies of maternal or fetal nature e.g. antepartum haemorrhage and fetal distress usually taking precedence and set at 1 hour, where semi urgent caesarean sections e.g. poor progress with no fetal compromise averaging 3,5 hours. Women who present in labour with features suggestive of poor progress or prolonged latent phase of labour and who have not had a previous caesarean section are managed initially with oxytocin. The oxytocin regimen used at CHBAH is, 2 units of oxytocin in 200 ml normal saline at a rate of 12 ml/hr, increasing to 24 ml/hr, 36 ml/hr and 48 ml/hr every 30 minutes up until the establishment of adequate contractions. The maximum dose is 72 ml/hr.

An epidural service at CHBAH offers analgesia to women intrapartum particularly during the active phase of labour. The service is available Monday to Friday 8h00 to 16h00, with a dedicated anaesthesiologist at any given time. On average the expected number of epidurals per week is 15 or 3 per day. The anaesthesiologist offers the service to women that are in active phase of labour, and obtains informed consent prior to the procedure. The informed consent details the procedure, the benefits of epidural analgesia in term of labour, alternative analgesia available and the risk associated with such a procedure. Once the woman is agreeable to the epidural service, she signs the consent and is prepared for epidural placement. The epidural protocol is as follows:

- The epidural trolley is checked daily.
- Women that would benefit from epidural analgesia are Identified. Ideal candidates would be women in the active phase of labour, with no contraindications to epidural analgesia.

- Before an epidural is performed consent is obtained from the women. Baseline vitals such as BP, heart rate and temperature is obtained. The women's intravenous line is checked and a urinary catheter is inserted.
- The epidural pack is opened in an aseptic manner, together with the following items:
 - epidural set
 - needles/syringes for local anaesthetic infiltration to skin and for a test dose
 - drug ampoules:
 - 2 x 2% lignocaine
 - 1 x 200ml 0.9% sodium chloride
 - 1 x fentanyl 100ug
 - 1 x 10ml 0.5% bupivacaine
- An epidural mix consisting of 10ml 0.5 ml bupivacaine, 2 ml fentanyl(100ug) and 38 ml 0.9% sodium chloride is drawn up.
- The women is placed in a seated position and landmarks are identified. Local anaesthetic is given subcutaneously.
- The epidural catheter is inserted. After placement of the epidural, a test dose is given and if no motor block occurs the first bolus of 5 ml of epidural mix is given.
- After the initial bolus of drug and after each top-up bolus, the BP, pulse, oxygen saturation, level of consciousness, presence of a motor block and fetal heart rate is recorded every 5 minutes for the next 30min, thereafter, half-hourly.
- If abnormality is noted such as a systolic BP < 100mmHg, HR< 60 or > 110bpm, SPO₂ < 92%, decreased level of consciousness or presence of a motor block, the following is done:
 - Commencement of a Vasopressors and wait for response
 - Exclude aortocaval syndrome
 - Commence resus if needed
 - Give supplemental oxygen

- Check patient observations

The labour ward is fully equipped with resuscitation equipment and theatre facilities within the vicinity for potential complications.

3.2 Study Design

This was a retrospective cross sectional descriptive study of all women who received intrapartum epidural analgesia and the neonates born thereof between 01/05/2015 and 31/10/2015.

3.3 Study population

The study population comprised all women who received epidural analgesia intrapartum and the neonates born to these women at CHBAH.

3.4 Inclusion Criteria

All women who received epidural analgesia for labour during the study period, including the neonates born to these women.

3.5 Exclusion Criteria

Any women that had incomplete records or no records.

3.6 Definitions

For the purpose of this study the following definitions were used:

Antenatally booked: at least one antenatal clinic visit with risk factor assessment and the testing of maternal blood for Rhesus status, rapid plasma reagin test, HIV and haemoglobin levels.

Latent Phase of labour: presence of labour and the cervix is <4 cm dilated and ≥1 cm long.⁵³

Active Phase of labour: begins at 4 cm of cervical dilation and is characterized by rapid cervical dilation and descent of the presenting fetal part.⁵³

Neonatal birth Trauma: Injuries to the infant that result from mechanical forces during the birth process.

Poor Progress: a cervical dilatation rate of less than 1 cm/hr in the active phase of labour in the nulliparous women, and a dilation rate of less than 1,5 cm/hr in the multiparous women, and/or the partogram crosses the alert line.⁵³

Prolonged Second stage of labour: no descend of the fetal head onto the pelvic floor after 2 hours of full dilatation, and/or delivery has not occurred after 45 minutes of pushing in a nulliparous women, or 30 minutes of pushing in a multiparous women.⁵³

Instrumental deliveries: a delivery in which an operator uses either forceps or a vacuum device to extract the fetus from the vagina. Also referred to as operative or assisted vaginal deliveries.

Spinal analgesia: Anaesthesia produced by injection of a local anaesthetic solution into the spinal subarachnoid space, resulting in both motor and sensory blockage

Low Apgar score: Apgar score of less than seven at birth.

Fetal distress: compromise of the fetus during the antepartum or intrapartum period assessed by means of an NST in keeping with NICE guidelines, in terms of a pathological trace.

Table 1 CTG tracing as per modified ACOG and FIGO:

Parameter	Baseline rate (bpm)	Variability (bpm)	Decelerations	Accelerations
Reactive	110-160	>5	none	present
Suspicious	<110 or >160	<5 or >25 for >40 minutes	early/variable decelerations prolonged decelerations > 3 minutes	present
Pathological	<100 or >180 Sinusoidal pattern	<5 for >90 minutes	Atypical variable late decelerations or prolonged decelerations >3 minutes	absent > 40 minutes

Fetal outcomes will be subdivided:

No adverse fetal outcome: relates to a live well baby at discharge with no need for admission immediately post delivery.

Adverse fetal outcome: constitutes one of the following: Apgar score < 7, demise within 28 days, fresh stillbirth, intrauterine fetal death, cephalohaematoma or hypoxia ischemic encephalopathy.

Combined adverse fetal outcomes: cephalohaematoma and demise within 28 days, low Apgar scores and hypoxic ischemic encephalopathy, Apgar score < 7 and demise within 28 days.

Preeclampsia: diastolic blood pressure of 90 mmHg or more, on 2 occasions at least 4 hours apart or a single diastolic blood pressure reading of 110 mmHg, with $\geq 1+$ proteinuria on a urine dipstick.⁵⁸

Mean Arterial Pressure: the average arterial pressure during a single cardiac cycle, calculated as $MAP = [(2 \times \text{diastolic}) + \text{systolic}] \text{ divided by } 3$.

Baseline Mean Arterial Pressure: mean arterial pressure taken just prior to placement of epidural catheter.

Change in Mean Arterial Pressure: any change in mean arterial pressure from the baseline not equal or greater than 10% decrease from baseline, or meeting the definition of hypotension.

Hypotension: blood pressure lower than 90/60 mmHg, or a $MAP < 60$ mmHg with or without the presence of symptoms.

Pyrexia: body temperature greater than 38.3°C as per the World Health Organization.

Failed Epidural: Epidural or CSE procedures resulting in inadequate analgesia or no sensory block after adequate dosing at any time after initial placement, inadvertent dural puncture with the epidural needle or catheter, or any technique requiring replacement or alternative management⁵⁹

3.7 Data collection

Women that received epidural analgesia intrapartum were identified from the epidural registers at the CHBAH. The medical records of these women were retrieved and the relevant data reviewed, captured and analyzed. If the medical records were not obtained, detailed of the delivery and outcomes were found within the maternity registers held at the hospital. Details of the neonatal outcomes of these women were sought from the maternal records and the neonatal registry. In order to maintain anonymity each women received a

study number. The data sheet only reflects the study number and data pertaining to the study.

3.8 Variables recorded

The following variables were recorded:

Maternal

Age, parity, gravidity, booked/unbooked, gestational age, maternal weight, maternal illnesses, booking bloods, race

Epidural Analgesia

Observations: blood pressure, heart rate, temperature, respiratory rate; before and after epidural placement, intra epidural significant event, difficulty with placement of epidural, level of epidural analgesia, density of block, complications associated with epidural analgesia.

Labour

Total duration of labour, rate of cervical dilation, use of oxytocin, duration of oxytocin before and after epidural placement, duration of second stage of labour.

Delivery

Mode of delivery, indications for caesarean section, instrumental deliveries, presence of postpartum hemorrhage, blood transfusion, hysterectomy, high care or ICU admission, other complications.

Neonatal outcomes

Birth weights, corticosteroid requirements, fetal heart rate monitoring before and after epidural placement, 1 minute Apgar scores, neonatal admission to NICU, birth trauma, significant morbidity and perinatal mortality.

A detailed list of variables recorded is reflected on an attached copy of the data sheet (Appendix A).

3.9 Data Analysis

Data was analysed using Epi Info v3.5.1 software, with the aid of a statistician. Descriptive statistics were employed, means with standard deviations and medians with ranges. Frequencies were expressed in percentages. For variables less than 5, Fischer exact test was used to calculate p-values and for the remaining data greater than 5 an Annova test was used. A p-value of <0.05 was used to determine statistical significance.

3.10 Ethical Considerations

The study was only commenced after the Postgraduate Committee and Human Research Ethics Committee (Medical) of the University of the Witwatersrand gave approval. (Appendix B). Clearance certificate no: M151120.

Permission to conduct the study was obtained from the Chief executive office at CHBAH, heads of department – Obstetrics & Gynaecology and Anaesthesiology. (Appendix C). All women in the study remain anonymous with each being allocated a specific study number. The data sheet only reflects the study number and data pertaining to the study. Details of the women were only available to the researcher and the supervisors. Data will be kept secure for 5 years.

The study adheres to South African Good Clinical Practice Guidelines and the Declaration of Helsinki.

3.11 Funding

The only costs incurred were that of stationery and data capturing, which were borne by the researcher.

4.0 RESULTS

There were 9305 women who delivered between 01/05/2015 and 31/10/2015, of which 302 women received intrapartum epidural analgesia. The incidence of intrapartum epidural analgesia was 3.24% or 32/1000.

The medical records of 19 women were excluded from analysis as the records for 2 women were not found, 5 were booked for elective caesarean sections and 3 were transferred out to another hospital and outcomes not known. There was also 1 epidural placement failure and the procedure abandoned, and eight women with incomplete records. This resulted in the analysis being conducted on a sample size of 283 women.

4.1 Maternal Characteristics

Table 2 Maternal Characteristic

Variable		Mean $\pm$ SD Median(range) Number (%) n=283
Age in years		26.1 $\pm$ 6.1
Parity		0 (0-4)
Gravidity		2 (0-6)
Race	Black	279 (98.6)
	Coloured	1 (0.4)
	Indian	2 (0.7)
	White	1 (0.4)
Gestational Age in Weeks at delivery		38.9 $\pm$ 1.6
HIV Seropositive		46(16.3)
Cardiac disease in pregnancy		2 (0.7)
Hypertensive disorders in pregnancy		17 (5.0)
Epilepsy		1 (0.4)
Asthma		5 (1.8)

The maternal characteristics of the 283 women analysed are reflected in Table 2 above. The mean maternal age was 26.1 with a standard deviation of 6.5 years. The median parity and gravidity was 0 (range 0-4) and 2 (range 0-6) respectively. The mean gestational age at delivery was 38.9 $\pm$ 1.6 weeks. There were 46 (16.3%) women who

were HIV positive, all of whom were on antiretroviral therapy at delivery. There were 17 (5%) women with pregnancy related hypertensive disorders, which included gestational hypertension and preeclampsia. There were also 2 (0.07%) women with cardiac diseases, 1 (0.4%) with epilepsy and 5 (1.8%) asthmatics. Racial variation included, Black 279 (98.6%), Coloured 1 (0.4%), Indian 2 (0.7%) and White 1 (0.3%).

4.2 Maternal outcomes and complications

Table 3 Maternal Outcomes and complications associated with epidural analgesia

Variable		Mean $\pm$ SD Number(%) Median (range) n=283
Blood pressure	Baseline MAP	93 (76-120)
	MAP 15 minutes post epidural	77 (50 – 100)
	Women with change in MAP*	90 (31.8)
	Women with increase in MAP	3 (1.1)
	Women with decrease in MAP	87 (30.7)
Heart rate	Baseline heart rate	97 (80 -120)
	Heart rate 15 minutes post epidural	90 (60 – 140)
	Women with change in Heart Rate	39 (13.8)
	Women with increase in Heart Rate	30 (10.6)
	Women with decrease in Heart Rate	9 (3.2)
Temperature	Baseline temperature	37 (36.2 – 37.9)
	Temperature 15 minutes post epidural	37 (36 – 39)
	Women with change in Temperature**	3 (1.1)
Complications	No complications	235 (83.0)
	Hypotension	38 (13.4)
	Spinal Analgesia	1 (0.4)
	Pyrexia	2 (0.7)
	Failed Epidural	4 (1.4)
	Maternal respiratory Distress	1 (0.4)
	High Spinal	1 (0.4)
	Other	1 (0.4)

* Any change in MAP not meeting the definition for hypotension. **Any change in temperature not meeting the definition of pyrexia. MAP= Mean arterial pressure

Table 3 and 4 reflects the maternal outcomes. Ninety women (31.8%) had a change in mean arterial pressure, where 87 (29.5%) had a decrease and 3 (1.1%) an increase in mean arterial pressure. The mean change in MAP pre and post epidural was a 30% $\pm$ 12 decrease from baseline. A change in heart rate was seen in 39 (13.8%) of the women, of which 30 (10.6%) experienced an increase and 9 (3.2%) a decrease in heart rate. An increase in temperature was seen in 3 (1.1%) women, with no decrease noted. Of the 283 women who received intrapartum epidural analgesia, 48 (17%) women experienced complications. These complications included: hypotension 38 (13.4%), spinal analgesia 1 (0.4%), pyrexia 2 (0.7%), failed epidural 4 (1.4%), maternal respiratory distress 1 (0.4%) and high spinal 1 (0.4%). One women (0.4%) developed meningitis after being discharged with the epidural in situ. There was no associated mortality.

Table 4 Epidural related complications based on Maternal Factors

Variable	Epidural Related Complications		
	No complications	Complications	p value
	Mean $\pm$ SD Median(range) Number(%)	Mean $\pm$ SD Median(range) Number(%)	
	n=235	n=48	
Age in years	26.2 $\pm$ 6.3	24.5 $\pm$ 3.1	0.90
Race			
Black (279)	233 (99.1)	46 (95.3)	0.13*
Indian (2)	1 (0.4)	1 (2.1)	0.31*
White (1)	0	1 (2.1)	0.17*
Coloured (1)	1 (0.4)	0	1.00*
Baseline MAP	93.5 $\pm$ 10	95.3 $\pm$ 4.3	0.76
MAP 15 minutes post epidural	80.5 $\pm$ 12.8	74.1 $\pm$ 8.2	<0.01
Mean decrease in MAP	17.9% $\pm$ 10.5	34.6 % $\pm$ 20.5	<0.01
Baseline HR	96.5 $\pm$ 14.1	87.5 $\pm$ 10.3	0.59
HR 15 minutes post epidural	92.0 $\pm$ 16.3	102.7 $\pm$ 16.3	<0.01
Mean change in HR	17% $\pm$ 5.5	28% $\pm$ 9.5	<0.01
Comorbidities			
Gestational hypertension	9 (3.8)	1 (2.1)	1.00*
Preeclampsia	5 (2.1)	0	0.60*
Chronic hypertension	2 (0.9)	0	1.00*
Cardiac	2 (0.9)	0	1.00*
HIV	38 (16.2)	8 (16.6)	1.00*

*p value calculated using Fischer exact test MAP= Mean arterial pressure, HR = heart rate HIV= Human Immunodeficiency Virus

Table 4 reflects maternal characteristics sub-divided according to epidural complications. The mean maternal age of women with epidural complications were 24.5 ± 3.1 years, which was similar to that of women without complications; 26.2 ± 6.3 years.

Baseline mean arterial pressure and heart rate showed no significance in term of epidural complications nor did the presence of maternal co morbidities. The average decline in MAP of women with epidural complications was significantly higher than the decline in MAP in women with no complications (34.6% versus 17.9% respectively, $p < 0.05$). A larger number of women with epidural complications had a significant increase in heart rate post epidural (28% versus 17%, $p < 0.05$). None of the women who had adverse outcomes, had pre-eclampsia or cardiac disease.

4.3 Labour associated factors

4.3.1 Peripartum factors

Table 5 Labour Outcomes

Variables		Mean $\pm$ SD Number(%) n=283
Prolonged latent phase of labour		69 (24.4)
Poor progress of labour	Pre epidural	96 (33.9)
	Pre and Post Epidural	84 (29.7)
	Post Epidural only	13 (4.6)
Oxytocin usage for Augmentation of labour		97 (34.2)
Second stage of labour	Mean Duration	63 $\pm$ 33.3
	Duration > 60minutes	76 (26.9)
	Duration >120 minutes	14 (4.9)
	Average duration in primigravidas	79 $\pm$ 39.1
	Average duration in multigravidas in minutes	40 $\pm$ 35

The peripartum findings are described in Table 5. Sixty-nine (24.4%) women had a prolonged latent phase of labour, of which none received intrapartum epidural analgesia during the latent phase of labour. There were 193 (65.4%) women with poor progress of labour, 96 (33.9%) of whom had poor progress prior to epidural analgesia, 84 (29.7%) had poor progress pre and post epidural and 13 (4.6%) women with poor progress post epidural only.

Oxytocin for augmentation of labour was used in 97 (34.3%) of the women.

The average duration of the second stage of labour was 63 minutes $\pm$ 33.3, with a mean duration of 79 minutes $\pm$ 39 in primigravidas and 40 minutes $\pm$ 35 in multigravidas. Seventy-six (26.9%) women had a prolonged second stage beyond 60 minutes, with 14 (4.9%) women having a second stage duration greater than 120 minute.

Table 6 Maternal and labour factors associated with prolonged second stage of labour

Variable	Duration of second stage of labour <60 minutes Mean $\pm$ SD Median(range) Number(%)	Duration of second stage of labour >60 minutes Mean $\pm$ SD Median(range) Number(%)	p value
	N= 207	N= 76	
Age in years	27.8 $\pm$ 5.9	24.0 $\pm$ 5.6	<0.01*
Parity	2	0	<0.01*
Comorbidities			
gestational hypertension	3 (1.4)	1 (1.3)	1.00**
preeclampsia	2 (0.9)	0	1.00**
cardiac	2 (0.9)	0	1.00**
HIV	21 (10.1)	10 (13.2)	0.52*
Decrease in MAP mmhg	25.9 $\pm$ 14.7	19.8 $\pm$ 13.8	0.71*
Complications			
hypotension	12 (5.8)	14 (18.4)	<0.01*
Use of oxytocin for Augmentation of Labour	70 (33.8)	46 (60.5)	0.05*
Duration of oxytocin in minutes	113 $\pm$ 160	213 $\pm$ 150	0.05*
Poor Progress of Labour	33 (15.9)	22(28.9)	0.12*

*p value calculated using Anova. **p value calculated using Fischer exact test. HIV= Human Immunodeficiency virus, MAP= Mean arterial pressure.

Maternal and labour factors sub-divided by evidence of prolonged second stage of labour are reflected in Table 6. The average age of women with prolonged second stage of labour was 24 $\pm$ 5.6 years vs. 27.8 $\pm$ 5.9 years in those women who did not have a prolonged second stage of labour $p < 0.05$.

A statistically significant difference was noted in duration of the second stage with respect to parity of the women. Significantly more women of zero parity had longer durations of the second stage of labour, $p < 0.05$. The average duration of oxytocin was higher in women with prolonged second stage than those without, 224 minutes vs. 113 minutes, but not of significant value. There was no significant difference noted amongst the groups with respect to comorbidities and change in MAP. However the presence of hypotension as a complication of the epidural analgesia showed significance in relation to prolonged second stage of labour.

4.3.2 Mode of delivery

Table 7 Mode of delivery

Variable			Mean $\pm$ SD Number(%) n=283
	NVD		142 (50.2)
	Instrumental delivery		23 (8.1)
	Caesarean Section		118 (41.7)
	Indication for Caesarean Section	Other	7 (2.5)
		Prolonged LPL	2 (0.7)
		Poor progress of labour	21 (7.4)
		Fetal distress	65 (23.0)
		APH	5 (1.8)
		Failed assisted delivery	0
		Delayed second stage of labour	7 (2.5)
		Cephalopelvic Disproportion	10 (3.5)

NVD = Normal vaginal delivery, LPL= Latent phase of labour, APH= Antepartum hemorrhage.

Table 7 reflects the mode of delivery as well as the indications for caesarean deliveries.

Of the 283 women, 142 (50.2%) had normal vaginal deliveries, 23 (8.1%) women had assisted vaginal deliveries and 118 (41.7%) delivered via caesarean section.

Indications for caesarean sections included: prolonged latent phase of labour 2 (1.7%), poor progress of labour 21 (7.4%), fetal distress 65 (23%), antepartum haemorrhage 5 (1.8%), delayed second stage of labour 7 (2.5%) and cephalopelvic disproportion 10 (3.5%).

Table 8 Mode of delivery stratified by maternal and fetal characteristics pre and post epidural.

Variable	Mode of Delivery			
	NVD Mean $\pm$ SD Median(range) Number(%) n=142	C/S Mean $\pm$ SD Median(range) Number(%) n=118	Assisted Vaginal Delivery Mean $\pm$ SD Median(range) Number(%) n=23	p-value
Age	26.4 $\pm$ 6.3	25.8 $\pm$ 6	24.9 $\pm$ 5	0.49*
Parity	1 (0-4)	1 (0-4)	0 (0-4)	0.09*
Gravidity	2 (0-4)	2 (0-4)	1 (0-4)	0.07*
Baseline MAP	92.9 $\pm$ 11.9	94.2 $\pm$ 11.6	91.7 $\pm$ 11.4	0.50*
Baseline HR	95.3 $\pm$ 14.6	96.4 $\pm$ 13.4	100.6 $\pm$ 17.5	0.24*
Decrease in MAP (mmHG)	18.6% $\pm$ 20.09	23.9% $\pm$ 20.13	29.6% $\pm$ 27.42	0.01*
Change in HR (bpm)	11% $\pm$ 4.4	20% $\pm$ 5.6	5.6% $\pm$ 7.8	0.00*
Interepidural complications				
hypotension	16 (11.3)	14 (11.9)	8 (34.8)	0.00**
Spinal Analgesia	0	1 (0.8)	0	0.50**
Failed Epidural	0	3 (2.5)	1 (4.3)	0.06**
fever	0	2 (1.7)	0	0.50**
Maternal distress	0	1 (0.8)	0	0.50**
Use of Oxytocin	94 (66.2)	77 (65.3)	14 (60.9)	0.90*
Total duration of Oxytocin	147 $\pm$ 247	169 $\pm$ 283	237 $\pm$ 291	0.30*

*p value calculated using Anova. **p value calculated using Fischer exact test.

Mode of delivery stratified by maternal characteristics, epidural and labour factors are reflected in Table 8. Maternal factors, such as age, parity and gravidity show no statically significance in terms of mode of delivery.

A significantly higher decline in MAP was noted in women who delivered via caesarean section and assisted vaginal delivery in comparison to the NVD group, p value<0.05, together with an increase in heart rate greatest within the caesarean section deliveries.

It is also noted that majority of women with epidural complications (majority been hypotension) deliver via caesarean section (65% vs 45%, p<0.05). Use of oxytocin and the duration thereof shows no statically value with regard to mode of delivery.

4.4 Fetal and neonatal associated factors

4.4.1 CTG changes

Table 9 CTG changes post epidural

Variables	CTG PRE EPIDURAL Number(%) n= 283	CTG POST EPIDURAL Number(%) n=283
Reactive	266 (94.3)	204 (72.1)
Suspicious	14 (5)	76 (26.8)
Pathological	2 (0.7)	2 (0.7)

Every woman in labour had intermittent CTG tracings done. There were a total of 266 (94.3%) women who had reactive tracings prior to the placement of the epidural. Of the remaining women: 14 (5%) had a suspicious tracing, which was represented by a single deflection from the norm in baseline, variability, or presence of decelerations and 2 (0.7%) women with pathological tracings. CTG tracings done immediately after placement showed a decrease in the number of reactive tracings from 266 (94.3%) to 204 (72.1%). There was also an increase in the number of suspicious tracings from 14 (5%) to 76 (26.8%) with no changes in the number of pathological tracings. The variables included, changed in heart rate 19(30.6%), change in variability 10 (16.1%), and new onset decelerations 2 (3.2%).

Table 10.1 CTG pre and post epidural stratified by Apgars<7

Variables	Neonatal Apgar score<7 at birth		
	CTG post epidural placement		
CTG pre epidural placement	Reactive	Suspicious	p valve
Reactive n= 266	9	10	0.13*
Suspicious n= 14	0	4	

* p value calculated using Fischer exact test

Table 10.2 CTG pre and post epidural stratified by Apgars>7

Variables	Neonatal Apgar score>7 at birth		
	CTG post epidural placement		
CTG pre epidural placement	Reactive	Suspicious	p valve
Reactive n= 266	194	52	<0.01*
Suspicious n=14	0	9	

* p value calculated using Fischer exact test

Table 10.1 and 10.2 reflects changes in CTG pre and post epidural stratified by Apgar score at birth. Of the neonates that were born with Apgar scores <7, there were 9 (3.2%) traces which were reactive pre and post epidural, 10 (3.5%) that had changed from reactive to suspicious and 4 (1.4%) that remained suspicious post epidural (p value<0.12). Of all the neonates with Apgar scores >7, 194 (68.6%) were reactive pre and post epidural, 52 (18.4%) changed from reactive to suspicious and 9 (3.2%) that were suspicious pre and post epidural (p value<0.05).

4.4.2 Neonatal outcomes

Table 11 Neonatal outcomes

Variable			Number (%) n = 283	
Apgar score at Birth	Apgar score < 7		23 (8.1)	
	Apgar score > 7		258 (91.2)	
Neonatal outcome	Born Alive		278 (98.2)	
	No Adverse Outcome		269 (95)	
	Adverse outcome	Birth Trauma		0 (0)
		FSB		2 (0.7)
		ENND		2 (0.7)
		Cephalohaematoma		3 (1.1)
		HIE		5 (1.8)
Required Admission to TICU	Apgars<7 at 10 minutes		4 (1.4)	
	Respiratory Distress		2 (0.7)	
	Neonatal Sepsis		1 (0.4)	

FSB= fresh stillbirth, ENND= early neonatal death, HIE = hypoxic ischemic encephalopathy, TICU= transitional intensive care

The neonatal outcomes can be seen in Table 11. Of the 283 neonates delivered, 278 (98.2%) neonates were born alive, with 258 (91.2%) having Apgar scores of >7 and 23 (8.1%) Apgar scores <7. Two hundred and sixty nine (95%) neonates were born with no adverse outcomes and 12 (4.2%) were born with adverse outcomes. There were 2 (0.7%) were intrauterine deaths not related to labour. The adverse outcomes were as follows: 2(0.7%) early neonatal deaths, 3 (1.1%) cephalohaematomas, 5 (1.8%) neonates with hypoxic ischemic encephalopathy and 2 (0.7%) fresh stillbirths. The cause of the early neonatal deaths was attributed to severe respiratory distress and neonatal sepsis. Seven neonates required admission to transitional intensive care unit (TICU), 4 (1.4%) for Apgar

scores <7 at 10 minutes, 2 (0.67%) for respiratory distress and 1 (0.3%) for neonatal sepsis. There were no admissions to the neonatal intensive care unit.

Table 12 Neonatal outcomes reflected by mode of delivery

Variable	Mode of Delivery			
	NVD Mean $\pm$ SD Number(%) n=142	C/S Mean $\pm$ SD Number(%) n=118	Assisted Vaginal delivery Mean $\pm$ SD Number(%) n=23	p-value
Apgar scores				
<7	7 (4.9)	15 (12.7)	1 (4.3)	0.30*
>7	133 (93.7)	103 (87.3)	22 (95.7)	0.30*
Fetal Outcomes				
Alive	140 (98.6)	112 (94.9)	20 (86.9)	0.25*
Cephalohaematoma	0	0	2 (8.7)	0.30*
FSB	2 (1.4)	0	0	0.24*
ENND	0	2 (1.7)	0	0.25*
HIE	0	4 (3.4)	1 (4.3)	0.25*

* p value calculated using Fischer exact test. NVD= Normal vaginal delivery, C/S= Caesarean section, FBS= fresh stillbirth, ENND= early neonatal death, HIE = hypoxic ischemic encephalopathy.

Table 12 reflects fetal outcome based on mode of delivery. As already noted 142 (50.2%) women delivered via NVD and of those 133 (93.7%) neonates were born with Apgar scores >7 and 7 (4.9%) with Apgar scores <7, with 2 (1.4%) neonatal adverse outcomes. Of the 118 (41.7%) neonates born via caesarean section 15 (12.7%) had Apgar scores <7, 103 (87.3%) with Apgar scores >7 and 6 (11.1%) neonates with adverse outcomes. There were 23 (8.1%) assisted Vaginal deliveries, 1 (4.3%) neonate had an Apgar score <7, 22 (95.7%) had Apgar scores >7 and there were 3 (13%) adverse outcomes. In terms of Apgar scores and fetal outcome, mode of delivery reflected not statistic benefit or risk.

Table 13 Fetal outcome stratified by maternal, epidural and labour outcomes

Variable	FETAL OUTCOME		
	No adverse outcome Mean $\pm$ SD Median(range) Number(%) n=269	Adverse outcome Mean $\pm$ SD Median(range) Number(%) n=12	P-value
Maternal Age	26.1 $\pm$ 6.0	23.1 $\pm$ 2.0	0.19
Parity	1 (0-2)	0 (0-1)	0.16*
Gestational Age	38.9 $\pm$ 1.5	38.7 $\pm$ 2	0.12
Decrease in MAP	21.9 $\pm$ 21.2	14.7 $\pm$ 10.9	0.56
Interepidural complications			
No complications	224 (83.2)	8 (66.7)	0.95
Hypotension	36 (13.4)	4 (33.3)	0.07
Spinal Analgesia	1 (0.4)	0	1.00*
Failed Epidural	4 (1.5)	0	1.00*
Fever	2 (0.7)	0	1.00*
High spinal	1 (0.4)	0	1.00*
Maternal respiratory distress	1 (0.4)	0	1.00*
Mode of Delivery			
NVD	140 (52)	4 (33.3)	0.33*
Caesarean Section	107 (39.8)	7 (58.3)	
Assisted Vaginal deliveries	22 (8.2)	1 (8.3)	
Duration of Oxytocin use	170 $\pm$ 271	90 $\pm$ 200	0.63
Duration of second stage of Labour	40 $\pm$ 39.3	68 $\pm$ 51	0.56

* p value calculated using Fischer exact test.

Table 13 reflects the fetal outcomes based on maternal, epidural and labour factors. Despite the average maternal age in pregnancies with adverse outcomes being lower than those of pregnancies with no adverse outcomes it was of no significant value (23.1 vs 26.1; p value >0.05). Neither parity, gravidity nor gestational age showed any significance in terms of fetal outcome. A greater decrease in MAP was noted in women who delivered neonates without adverse outcomes in comparison to those with adverse outcomes (21.9 vs 14.7; p value >0.05)

The majority of women, 45 (16.8%) who experienced intra epidural complications, delivered neonates without any adverse outcomes vs 4 (1.4%) with adverse outcomes.

The most common complication experienced by the study population was that of hypotension, and despite having a larger number of adverse fetal outcomes in women who developed hypotension, it reflected no statistical significance.

5.0 DISCUSSION

The percentage of women receiving intrapartum epidural analgesia during the study period was 3.24%, which is below the reported rates in developed countries. In a 2012 audit of epidural services at a tertiary hospital in the Western Cape, the rate of intrapartum epidural analgesia was 2.2%, whilst in the United States of America and European countries its 50% and 25%, respectively.^{1,16} The epidural rate of 3.24% is only applicable to CHBAH, and does not reflect incidences of surrounding tertiary institutes. The limited usage of intrapartum epidural in developing countries in comparison to developed countries reflects the wide variation in health care provision globally.

In a study performed in the Western Cape, the low epidural rate of 2.2% was attributed to limited time and a shortage of staff, as there was only one anaesthesiologist for both epidural and emergency services.¹⁶ During the 6-month period of this study however, there was a dedicated anaesthesiologist for epidural services, and the low rates were mostly due to reservations from women and medical staffs based on perceptions that epidural analgesia prolongs the first and second stage of labour. This finding is in keeping with studies performed in other developing countries, suggesting that reservations from medical personal, low socioeconomic status and lower educational levels of women contribute to lower intrapartum epidural use.^{16,17;18}

The mean maternal age of patients in this study was 26.1 years. This is in keeping with the reported ranges of 21.2 to 32.7 years.^{41,42,43} The mean gestational age at the time of delivery was 38.9 weeks, and therefore allowed for adequate assessment of fetal outcome, alleviating complications of prematurity. The median parity within this study was 0, in

keeping with studies conducted by Dickson J,et al. and Halpern S,et al. who reported that nulliparous women are more likely to request epidural analgesia.^{40,41} Suggesting that nulliparous women in who the primary indication for caesarean sections is fetal distress and dystocia are more likely to choose epidural analgesia.

5.1 Maternal Outcomes

Epidural complications were seen in 48 women, with a complication rate of 17%, in keeping with the complication incidence of 14,1% globally as reflected in a recent ACOG Practice Bulletin.³ These complications consisted of 16.3% minor complications and 0.3% major complications with no recorded mortality. Scott D,et al. and others, despite having a larger cohort found a similar incidence of severe long-term complication rates.^{27,28}

Maternal factors were stratified against presence of complications, and no clear risk profile was identified, and therefore benefit of epidural analgesia outweighs the potential associated risk.

The most common complication was that of hypotension 13.4%, with an average decline in mean arterial pressure of 30%. This is slightly higher than the global incidence of 9% but in keeping with local data where the incidence was reported at 13.5%.^{16, 31} The decline in blood pressure and subsequent hypotension (MAP<65mmHg or decline more than 10%), was not associated with age, baseline MAP, race or presence of comorbidities and occurred despite fluid preloading of the women. Kinsella S,et al., Dryer R,et al. and Hofmyer G,et al., reported similar incidence of hypotension with epidural use despite pre loading with fluids.^{32,33,34} These trials mentioned above were similar in nature as each used 1000ml of crystalloid fluid as their preloading. In this study no standard protocol was available and different anesthesiologists used different fluids, including crystalloids and colloid at differing amount. However due to the impact of maternal hypotension on placental blood flow and the transient risk of fetal heart rate decelerations measures need to be instituted early to correct this potential complication.

The incidence of pyrexia within this study was 0.6%, and demonstrated no change in baseline temperature post epidural. The majority of the women were nulliparous. Apantaku O,et.al conducted a study assessing risk of pyrexia in nulliparous labour and reported a 33% incidence.³⁶ Anim-Somuah M,et al. reported a three times greater incidence of pyrexia associated with epidural use.¹ While this study consisted of both nulliparous and multiparous women, there was no control group to assess relative risk between epidural use versus non-epidural use. Also this study cohort was smaller than Anim-Somuah, et al. 258 vs 150000 respectively. Therefore the incidence of pyrexia with epidural use cannot be commented on.

The incidence of post epidural headaches was 1% in this study and the global incidence has been shown to range from 1.3% to 30%.³

Other complications included failed epidural of 1.4%, which was lower than the reported incidence of 13.5%.²⁸ Apart from a single episode of a high spinal which was adequately managed, with complete recovery there was no associated maternal morbidity or mortality recorded. This is in keeping with the proposed rarity of major fatal complications associated with epidural as discussed in a French survey.^{27,28}

5.2 Labour Outcomes

Ninety-six (33.9%) women had features of poor progress of labour prior to the placement of the epidural catheter. This number decreased to 84 (29.7%) after epidural placement. Thirteen (4.6%) women had features of poor progress of labour only after the placement of the epidural catheter. These findings are similar to the meta analysis conducted by Anim-Somuah,et al. which concluded that epidural analgesia has no significant effect on the duration of the first stage of labour with a mean difference of 13.66 minutes and a confidence interval of 95%.¹

There were 97(32.8%) women who received oxytocin for augmentation of labour, similar to the international findings of 40% incidence of oxytocin use related to epidural analgesia.¹⁹ This study, while consisting primarily of nulliparous women did not compare the use of augmentation of labour pre and post epidural analgesia.

Lewis,et al. found that 60% of women who request epidural analgesia had oxytocin augmentation of labour commenced prior to epidural placement (95%CI 0.33-0.42).⁴⁷ Similar findings have been reported that augmentation of labour is a common practice in nulliparous women who are more likely to request analgesia.^{7,19}

Therefore the relationship of epidural analgesia and the incidence of oxytocin use is an associative rather than a causal one.

There were a total of 142(50.2%) women that had a normal vaginal delivery. There were 118 women that delivered via caesarean section and 23 that had assisted vaginal deliveries. The incidence of caesarean sections and assisted vaginal deliveries was 41.7% and 8.1% respectively. The incidence of caesarean section deliveries at CHBAH is 38.5%, which is only slightly lower than the incidence found within this study. Within the study cohort 50.2% delivered vaginally and 41.7% by caesarean section. A regression analysis was not performed on the data and therefore a causation relationship could not be established between epidural analgesia and risk of caesarean section. The statistic in table 7 reflects no relative risk of caesarean section deliveries with epidural analgesia. These finding are in keeping with data performed by Anim-Somuah,et al. who reported a relative risk of 1.07 with a confidence interval of 95%.¹ Dickson, et al. reported that when given the choice of analgesic regime, obstetric factors like painful labour, oxytocin usage and cervical dystocia are more likely to influence women's choice.⁴⁰ Similarly, in the CHBAH cohort, women requested epidural analgesia.

Of the 118 women who delivered via caesarean section the main indication (55%) was that of fetal distress. Epidural analgesia is associated with CTG changes post epidural in

particular changes in baseline fetal heart rate, as a result of either maternal hypotension or uterine hypotonicity^{40,50,51} A significantly higher decrease in MAP was noted in women who received epidural analgesia and delivered via caesarean section in comparison to the NVD group, p value <0.05 . This resultant hypotension and therefore fetal heart rate changes could account for the higher incidence of caesarean sections. Studies however have shown that despite prolonged episodes of fetal bradycardia, there were no associated adverse neonatal outcomes.^{50,51,52} One study looked at CTG changes post epidural analgesia, in women who had hypotension post epidural placement versus women with intravenous analgesia. A 24% increase in variable and late deceleration was noted within the epidural group, but the neonatal outcomes were similar within the two groups. Most attending physicians opted for conservative measures and this resulted in no increase incidence of caesarean section rates.⁵¹

Therefore any changes in CTG post epidural analgesia may be treated conservatively if there is no evidence of a pathological trace pattern though this is not part of the protocol at CHBAH and most suspicious tracing post epidural was managed actively and a caesarean section was performed. This could be a causal effect to the relative increase in caesarean section rates seen in this study however no formal conclusion can be drawn as no statical evaluation was performed.

There were 23(8.1%) women who delivered via assisted vaginal delivery, all of which were vacuum assisted deliveries. This is out of keeping with the relative increased risk associated with epidural analgesia and assisted vaginal delivery.^{1,38,40,41,42} An explanation for the decreased incidence of assisted vaginal deliveries could be that CHBAH, is a low resource academic setting and at times there is a lack of availability of vacuum devices and/or poor skills of attending physicians and therefore decreased use of assisted delivery methods. Poor documentation of assisted vaginal deliveries could also explain the relatively low incidence, however this study did not include such confounding factors.

The average duration of the second stage of labour was 63 minutes ± 33 , which is contrary to studies that suggest that epidural analgesia prolongs the second stage of labour by an

average of 25 minutes.^{1,38,40,41,42} However when the population group was divided into primigravid versus multigravid women, the average duration of the second stage was 79 minutes ± 39 and 40 minutes ± 35 , respectively. This correlates with findings by Zhang who observed that the median duration of the second stage of labour in nulliparous versus multiparous women with epidural analgesia was 70 minutes and 35 minutes respectively.⁴³

The incidence of prolonged second stage of labour beyond 60 minutes was 26.9%, which is slightly higher than the general prevalence of 20% of all live births irrespective of analgesia.⁴⁹ This could be explained by the fact that the majority of the study population was nulliparous women at term, which in itself is a risk factor for a protracted second stage of labour.³⁸ This is in accordance with the risk stratification that showed a longer duration of the second stage of labour within the nulliparous population. It was always shown that the mean age of women who had prolonged second stage of labour was younger than those who had a second stage less than 60 minutes, 24.0 years vs. 27.6 years.

In terms of epidural complications, in particular hypotension and its effect on the second stage of labour, no studies could be identified and therefore requires further investigation to draw a formal conclusion.

5.3 Fetal and neonatal outcomes

There were 62 women who had changes in the CTG pattern from reactive to suspicious post epidural analgesia in this study. Of those 10 (3.5%) were born with an Apgar score <7 (p value >0.23), while 52 (18.4%) had Apgars >7 (p value <0.05). This may be attributed to the low positive predictive value of CTG tracings. However women in labour who have received epidural analgesia should still receive CTG monitoring, as it is still the best available tool to anticipate poor fetal outcomes.

There were a total of 258 (91.2%) neonates born with Apgars >7 and 95% of them had no adverse outcome. This is in keeping with studies performed on neonatal outcomes of women who receive epidural analgesia intrapartum.^{1,21,51} It has also been shown that despite changes in CTG patterns post epidural analgesia, neonates of mothers who received epidural analgesia had fewer Apgar scores <7 and decreased requirements for naloxone.^{51,52}

6.0 LIMITATIONS

Further studies would need to be done to assess the views of medical professionals on offering epidural services to women in labour and the impact of such views. The study cohort consisted primarily of Black women (98.6%), but cannot be used as a representation of racial variation in epidural use locally, as it does not clearly illustrate use in other races within South Africa. No studies were identified that showed any preference to epidural usage based on race within the South African population.

7.0 CONCLUSION

An evaluation of the intrapartum epidural analgesia service at the CHBAH yielded results that are beneficial to women and their neonates compared to the associated risk of intrapartum epidural analgesia. The maternal complication rate was 17% with no associated morbidity or mortality. There was no increased incidence of caesarean section deliveries considering that 50.2% of women had normal vaginal deliveries and 41.7% delivered via caesarean section, with mode of delivery proving no benefit or risk to the neonate. Despite the incidence of hypotension and CTG changes post epidural analgesia 91.2% of the neonates were born with Apgar scores > 7 and an adverse neonatal outcome rate of 4.2%.

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APPENDIX A: DATA SHEET

Maternal factors

Study no			
Age in years			
Parity			
Booking Status	booked	1	
	unbooked	0	
Gestational age at booking in weeks			
Gestational age at delivery in weeks			
Co morbidities	Diabetes	1	
	Gestational hypertension	2	
	Preeclampsia	3	
	Chronic hypertension	4	
	Cardiac disease	5	
	HIV	6	If positive CD4 count
			ViralLoad (copies)
			Anteretroviral
			1
			0
			2
	Epilepsy	7	
	Other 1	8	
	Other 2	9	
Race	Black	1	
	Coloured	2	
	Indian	3	
	White	4	
	Other	5	
Last recorded weight on Antenatal card			

Epidural Factors

Baseline Observations	Blood pressure	systolic			
		diasystolic			
		Hypertension		yes	1
				no	0
	Heart rate				
	Respiratory rate				
	Temperature				
Post epidural Observation	Blood pressure	systolic			
		diasystolic			
		hypertension		yes	1
				no	0
		hypotension		yes	1
				no	0
	Heart rate				
	Respiratory rate				
	Temperature				
Intra epidural significant event	Blood pressure	1	increase	1	
			decrease	0	
	Heart rate	2	Increase	1	
			decrease	0	
	temperature	3	Increase	1	
			decrease	0	
	other	4			
ASA Status					
Difficulty with placement	yes	1			
	no	0			
Level of epidural	L3/L4	1			
	L4/L5	2			
Density of block	Sensory only	1			
	Motor only	2			
	Sensory and motor	3			
Other medication	yes	Name/s			
	no				
Complications	Hypotension	1			
	Spinal analgesia	2			
	Failed Epidural	3			
	Fever	4			
	Headaches	5			
	Respiratory distress	6			
	High Spinal	7			
	Other	8			

Labour factors

Total duration of labour in hours				
Total duration of latent phase of labour in hours				
Total duration of active phase of labour in hours				
Rate of cervical dilatation post epidural placement	<1cm/hr	1		
	1-1.5cm/hr	2		
	>1.5cm/hr	3		
Use of Syntocinon	Yes	1	Duration in hours	
			Duration pre epidural	
			Duration post epidural	
	No	0		
Duration of second stage of labour in minutes				

Delivery factors

Mode of delivery	NVD	1		
	Caesarainsection	2		
	Instrumental delivery	3	Vacuum delivery	1
			Forcep delivery	2
			episiotomy	3
Indication for caesarain section	Prolonged latent phase of labour	1		
	Poor progress	2		
	Fetal distress	3		
	Antepartum haemorrhage	4		
	Failed operative delivery	5		
	Delayed second stage of labour	6	>1hour	1
			1-2 hours	2
			>2hours	3
	Cephalopelvic disproportion	7		
	Other 1	8		
	Other 2	9		
Complications	PPH	1	500-1000ML	1
			>1000ML	2
			Blood transfusion required	3
	TAH	2	Atonic Uterus	1
			PPH	2
			Cervical tear	3

			Other	4
	Vaginal tear	3	NVD	1
			Vacuum delivery	2
			Forceps delivery	3
	Other	4		

Fetal factors

Antepartum fetus alive	yes	1			
	no	0			
Corticosteroids required	yes	1	Received 2 doses of steroids	1	
			Received 1 doses of steroids	0	
	No	0			
Fetal heart rate prior to epidural					
Fetal heart rate post epidural					
Change in fetal heart rate	yes	1			
	no	0			
NST prior to epidural	Reactive	1	Baseline	1	
	Suspicious	2	Variability	2	
	Pathological	3	Accelerations	yes	1
				no	0
			Decelerations	yes	1
				no	0
			type		
NST after epidural	Reactive	1	Baseline		
	Suspicious	2	Variability		
	Pathological	3	Accelerations	yes	1
				no	0
			Decelerations	yes	1
				no	0
			type		
NST during the second stage of labour	Reactive	1	Baseline		
	Suspicious	2	Variability		
	Pathological	3	Accelerations	yes	1
				no	0
			Decelerations	yes	1
				no	0
			type		
Birth weight in grams					
Apgars at 1 minute	<7	1			
	>7	2			
Fetal Outcomes	Alive	1			
	Cephaloha	2			

	emotoma				
	Birth trauma	3			
	MSB	4			
	FSB	5			
	Hypoxic ischemic encephalopathy	6			
Neonatal outcomes	Early neonatal death	yes	1	No of days alive	
				Cause of death	
		no	0		
	Neonatal ICU admission	yes	1	Duration of stay	
				Outcome	
		no	0		
	TICU admission	yes	1	Duration of stay	
				Outcome	
		no	0		

APPENDIX B: ETHICS CLEARANCE FORM



R14/49 Dr Veneshree Padayachee

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M151120

NAME: Dr Veneshree Padayachee
(Principal Investigator)
DEPARTMENT: Obstetrics and Gynaecology
Chris Hani Baragwanath Academic Hospital

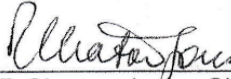
PROJECT TITLE: Pregnancy Outcomes in Patients Receiving Intrapartum
Epidural Analgesia at the Chris Hani Baragwanath
Academic Hospital : A 6 Month Review

DATE CONSIDERED: 27/11/2015

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Poovangela Naidoo

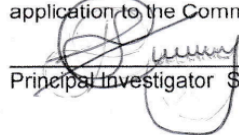
APPROVED BY: 
Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 03/02/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

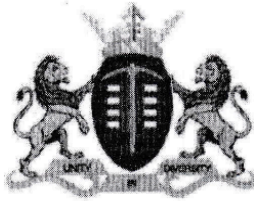

Principal Investigator Signature

Date

12/2/2016

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX C: PERMISSION LETTERS



GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 27 Jan 2016

TITLE OF PROJECT: Pregnancy outcomes in women receiving intrapartum epidural analgesia at Chris Hani Baragwanath Academic Hospital: a 6 month review

UNIVERSITY: Witwatersrand

Principal Investigator: V Padayachee

Department: Obstetrics and Gynaecology

Supervisor (If relevant): P Naidoo

Permission Head Department (where research conducted): Yes

Date of start of proposed study: Jan 2016

Date of completion of data collection: Dec 2017

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

Recommended
(On behalf of the MAC)
Date: 27 January 2016

Approved/Not Approved
Hospital Management
Date: 2016/01/28

11 JANUARY 2016

To Whom It May Concern

RE: PERMISSION TO CONDUCT RESEARCH AT YOUR INSTITUTION.

I, Dr. Veneshree Padayachee, MP 0730300, am a third year Obstetric and Gynaecology registrar currently at Chris Hani Baragwanath Hospital.

As part of my course requirements I am conducting an MMED research entitled: *Pregnancy outcomes in women receiving intrapartum epidural analgesia at the Chris Hani Baragwanath Hospital over a six month period.*

The study design is a retrospective study, where the required woman's details will be collected from an Epidural Registry held at the Department of Anesthesia and the necessary information sought from their files held at Chris Hani Baragwanath Records Department. As a result, I would like to request permission to conduct the study at this institute/department and obtain the necessary data to complete my study. All details obtained will be kept confidential at all times.

My supervisors' details are as follows:

Supervisor 1: Dr Poovangela Naidoo - 082 926 9077 (Department of Obstetric & Gynaecology)

Supervisor 2: Dr Estie Mostert - 076 421 0277 (Department of Anaesthesiology)

I have enclosed my research proposal for your perusal and should you require further information on my study please feel free to contact either my supervisors on the details above, or myself on the details below:

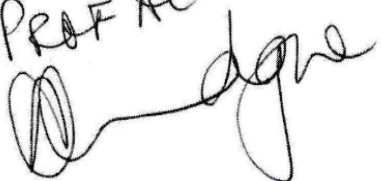
Researcher: Dr Veneshree Padayachee - 081 360 3097

Your assistance and co-operation will be highly appreciated.

Thanking you



Dr. Veneshree Padayachee

Supported.
Prof AE WARDEN


11 JANUARY 2016

To Whom It May Concern

RE: PERMISSION TO CONDUCT RESEARCH AT YOUR INSTITUTION.

I, Dr. Veneshree Padayachee, MP 0730300, am a third year Obstetric and Gynaecology registrar currently at Chris Hani Baragwanath Hospital.

As part of my course requirements I am conducting an MMED research entitled: *Pregnancy outcomes in women receiving intrapartum epidural analgesia at the Chris Hani Baragwanath Hospital over a six month period.*

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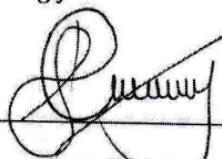
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Researcher: Dr Veneshree Padayachee - 081 360 3097

Your assistance and co-operation will be highly appreciated.

Thanking you



Dr. Veneshree Padayachee

Permissi - Graham
Be - Graham
19/1/2016

APPENDIX D: CANDIDATE SUBMISSION FORM

CERTIFICATE OF SUBMISSION FOR EXAMINATION OF MASTERS RESEARCH REPORT / DISSERTATION OR PHD THESIS SIGNED BY HIGHER DEGREES CANDIDATES

Full name	VENESHREE PADAYACHEE		
Student number	0400576N		
Title of submitted Research Project: <i>Pregnancy outcomes in women receiving intrapartum epidural analgesia at the Chris Hani Baragwanath Academic Hospital: a 6 month review.</i>			
Contact no	0813603097	E-mail	Dr.vnashp@gmail.com

- If you are likely to move in the next 6-12 months, please give the anticipated date of move:
n/a
- I hereby submit my **Masters (research report) / Masters (dissertation) / PhD thesis for examination**
(Select whichever is applicable)
- I have checked all copies of my research report / dissertation / thesis and declare that no pages are missing or poorly reproduced.
- I have submitted 2(TWO) bound copies and 1 (ONE) copy on CD.
- I confirm that I have:**
 - A signed declaration indicating my understanding of the concept of plagiarism and a denial of plagiarism in my research document.
 - A report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document included as an appendix.
- I confirm that I have:**
 - Not used either human or animal tissue or records **Yes/No**
 - If yes: I have included the ethics waiver letter pertinent to my research as an appendix **Yes/No**
 - Done research using animals **Yes / No**
If yes: I have included a copy of the animal ethics committee clearance certificate as an appendix in this document **Yes/No**
 - Done research using human subjects, human tissue or patient records **Yes / No**
If yes: I have included a copy of the human ethics clearance certificate as an appendix to the research document **Yes/No**
- I understand that I may not graduate unless my University fees have been paid in full.
- My Supervisor(s) names, departments, telephone numbers and email addresses are as follows:

Name	POOVANGELA NAIDOO		
Department	OBSTETRICS AND GYNAECOLOGY		
Telephone	0829269077	E-mail	poovanela@gmail.com
Name	ESTIE MOSTERT		
Department	ANAESTHETICS		
Telephone	0764210277	E-mail	estiemostert@yahoo.com

List all publications, which you have published in peer-reviewed journals from your postgraduate research report/dissertation/thesis during the course of your studies in the Faculty of Health

Sciences (Include authors, year, title of paper, name of journal, volume number and page numbers). This information is mandatory.

Signature of candidate: _____

A handwritten signature in black ink, appearing to be 'S. M. M.', written over a horizontal line.

_____ Date: 30/12/2016 _____

APPENDIX E: PLAGIARISM DECLARATION



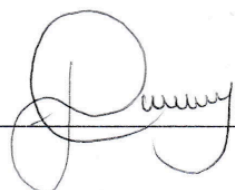
PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I VENESHREE PADAYACHEE (Student number: 0400576 N) am a student registered for the degree of MASTERS OF MEDICINE in the academic year 2017.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: 

Date: 30/12/16

APPENDIX F: TURNITIN REPORT

Turnitin Originality Report

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<1% match (publications) SHIV K. SHARMA. "Regional Analgesia and Progress of Labor", Clinical Obstetrics and Gynecology, 09/2003

APPENDIX G: SUPERVISORS ACQUIESCENCE FORM



CERTIFICATE OF SUBMISSION FOR EXAMINATION SIGNED BY SUPERVISORS OF HIGHER DEGREES CANDIDATES

Full name	VENESHREE PADAYACHEE		
Student number	04005760		
Candidate for the degree of: <u>MASTER OF MEDICINE</u> has submitted his/her thesis/dissertation/research report			
Entitled: <u>PREGNANCY OUTCOMES IN WOMEN RECEIVING</u> <u>INTRAPARTUM EPIDURAL ANALGESIA AT THE CHRS</u> <u>HANI BARAGWANATH HOSPITAL: A 6 MONTH REVIEW</u>			
Contact no	0813603097	E-mail	dr.vnashp@gmail.com

Mark with an X on appropriate box	Yes	No
Has this thesis/dissertation/research report been submitted with the acquiescence of the supervisor?	☒	☐
To the best of your knowledge are you able to verify that this is the candidate's work, except as otherwise stated by the candidate?	☒	☐
The substance (nor any part of it) has not been submitted in the past nor is being submitted for a degree in any other university?	☒	☐
The candidate has acknowledged wherever any information used in the thesis, dissertation or other work has been obtained by him/her while employed by, or working under the aegis of, any person or organization other than the University or its associated institutions?	☒	☐
Have examiners been nominated and approved?	☒	☐

I certify that this thesis/dissertation/research report has the approval of the Animal Ethics Committee / Committee for Research on Human Subjects and the Number of the Certificate of Approval is:

M151120

List all publications, which your student has published in peer-reviewed journals from his/her postgraduate research report/dissertation/thesis during the course of his/her studies in the Faculty of Health Sciences (Include authors, year, title of paper, name of journal, volume number and page numbers). This information is mandatory.

Name of Supervisor 1: Poovangela Nadda
 Telephone: 0829269077 Email: poovangela@gmail.com
 Signature:  Date: 12/01/17

Name of Supervisor 2: E. Mostert
 Telephone: 076 421 0277 Email: estiemostert@yahoo.com
 Signature:  Date: _____

Name of Supervisor 3: _____
 Telephone: _____ Email: _____
 Signature: _____ Date: _____

=====

IMPORTANT NOTICE WITH REGARD TO THE SENATE STANDING ORDERS:

A.22 Submission against advice of Supervisor

If the Supervisor is not prepared to agree to the submission of a thesis, the candidate shall still be entitled, if he or she wishes, to submit it for examination. When a thesis is submitted against the advice of the Supervisor, this should be recorded in the minutes of the Faculty Graduate Studies Committee. In such a case, no internal examiners are appointed but a Supervisor's report will still be required. After the examination process, the external examiner(s) will be advised by the Chairperson of the Faculty Graduate Studies Committee that the thesis was submitted against the advice of the Supervisor.

A.24 Nomination of Examiners:

Nomination of examiners should take place at least six weeks before submission of the thesis or dissertation. (The Postgraduate Office will not accept any submission for examination without the confirmed appointment of the nominated examiners.)

A.25 Confidentiality of names of examiners (both external and internal)

The names of the examiners should be confidential during the examination process and may only be revealed to the candidate with the acquiescence of the examiner once the final version of the thesis has been submitted to the Faculty and the process has been completed.

26/05/2015