A follow-up study of the extended labour epidural analgesia service at a regional hospital in Gauteng

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

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Declaration

I, Andrea Lynne Murphy declare that this research report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

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Abstract

Background

In 2014 an audit was performed at Rahima Moosa Mother and Child Hospital (RMMCH) on the daytime labour epidural analgesia service, prior to extension of the service to 24 hours. Since implementation of the extended service, no follow-up audit has been performed. Services based on pain management require regular auditing in order to determine safety, efficiency, and practices in keeping with current evidence.

Methods

A retrospective audit using consecutive convenience sampling was done reviewing all epidural records at RMMCH from 1 June 2017 to 31 May 2018.

Results

During the study period 658 labour epidurals were inserted for a total of 12 600 deliveries, from which 637 (96.8%) records were recovered. The labour epidural rate was 5.2%, a statistically significant improvement from 1.6% ($p<0.0001$) in 2014. The major complication rate was 0.4% with one respiratory arrest and one cardiac arrest. The most common minor complication was multiple attempts (15.1%). Odds ratios for caesarean section and assisted deliveries in this study were 0.8422 and 0.5020 respectively. The majority of epidurals were maintained by continuous infusion (52.8%). Patient satisfaction was 97.2%. Documentation improved significantly from 2014 to our study ($p<0.001$).

Conclusion

In this study the labour epidural rate increased from 1.6% to 5.2%. However, this still falls well below international rates.

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Abbreviations

AM	Andrea Murphy
AMB	Automated manadatory bolus
CEI	Continuous epidural infusion
C/S	Caesarean section
CSE	Combined spinal epidural
LCLA	Low concentration local anaesthetic
LOR	Loss of resistance
NVD	Normal vaginal delivery
PCEA	Patient-controlled epidural analgesia
PDPH	Post-dural puncture headache
PIEB	Programmed intermittent epidural bolus
RCT	Randomised control trial
RMMCH	Rahima Moosa Mother and Child Hospital
TBH	Tygerberg Hospital
USA	United States of America

Statement

The Research Report consists of a literature review, draft article, study proposal and appendices. The study proposal is included for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The formatting of the draft article may differ from the rest of the Research Report in order to comply with the author guidelines of the South African Journal of Obstetrics and Gynaecology, the journal to which it is intended to be submitted.

Section 1: Review of the literature

1.1 Introduction

"Behind every beautiful thing, there's some kind of pain"
- Bob Dylan

In this section the literature regarding the history, the definition, the physiology of pain and labour pain, and the impact and complications thereof will be discussed. This will be followed by a discussion of non-pharmacological and pharmacological management of labour pain, with a focus on epidural analgesia.

1.2 Background of pain and labour pain

In this section pain and labour pain, as well as the adverse effects of labour pain will be discussed.

1.2.1 History of pain and labour pain

The earliest documentation of pain dates back to the eighth century BC. Homer (1) wrote about "Oedipus of many pains" and the Iliad's (2) representation of *odunai*, the pain caused by a weapon. The ancient book of oriental medicine (3) which was originally written 3000 years ago, documents pain as an imbalance between yin and yang.

Hippocrates described the pain of separation of the pelvic girdle during pregnancy in the fifth century BC (4). Opiates, potions and herbal mixtures were used in ancient China and Egypt to alleviate the pain of labour (5). In the mid-1800s Sir James Young Simpson, a Scottish physician, demonstrated the first successful use of labour analgesia when he administered ether to a woman with a contracted pelvis (6,7). Six years later, Sir John Snow, an English physician, administered chloroform to Queen Victoria for the birth of her eighth child. This resulted in the

widespread use of inhalational anaesthetic agents for pain-free and successful deliveries (7).

1.2.2 Definition of pain

The definition of pain has evolved as the understanding of pain pathways and mechanisms have become better understood. The most widely accepted definition is from the International Association for the Study of Pain from 1994 where pain is defined as “an unpleasant sensory and emotional experience; associated with actual or potential tissue damage, or described in terms of such damage” (8). This definition makes mention of emotional factors, but does not take into consideration cultural, non-verbal, and cognitive influences (9,10). The term “unpleasant” may also undermine the experience of severe pain (11). The criticism of the 1994 definition of pain is pertinent when describing the pain of labour. While it can be severe, it may not necessarily be a negative pain; with some women describing it as “empowering” and a “positive pain” (12). When labour pain is viewed as a productive form of pain, it can be interpreted as a transformative event in a woman’s life (10). The phrase “actual or potential tissue damage” may also be misleading as the tissue changes occurring in the process are of a normal physiological basis (13).

1.2.3 Physiology of pain

Nociceptors are pain receptors that are found throughout the body in skin, muscle, connective tissue, blood vessels and viscera. Thick myelinated A-delta nerve fibres and thin unmyelinated C-type nerve fibres are responsible for the transmission of stimuli from nociceptors to the spinal cord. Tissue damage results in the release of multiple inflammatory cytokines and leukotrienes that stimulate nociceptors. Stimulation of nociceptors results in activation of multiple voltage-gated ion channels throughout the nerve fibres, resulting in the transmission of the painful stimulus along the fibres. The dorsal horn in the spinal cord is the site of termination of the primary afferent fibres. (14)

1.2.4 Physiology of labour pain

The first stage of labour is defined as the period from the onset of labour to full cervical dilatation (15). Pain experienced in the first stage of labour is visceral and poorly localised (16), but becomes more localised to the perineum towards the end of the first stage (17). The second stage of labour is defined as the period from full cervical dilatation to delivery of the foetus (15). It is characterised by somatic pain that is well localised and sharp. It is due to traction on, and distension of, the perineum, pelvic floor, pelvic structures and the vagina (17). The third stage of labour is the delivery of the placenta and is not associated with much pain. Afterpain follows delivery of the placenta and is caused by powerful contractions of the myometrium (15).

1.2.5 Impact and complications of labour pain

The pain of childbirth is one of the most severe types of pain a woman might experience in her lifetime (18). Pain induces a physiological stress response in the human body that results in increased catecholamine release (17,19,20). An increase in catecholamine production has the following maternal effects.

- Shunting of blood from non-vital to vital organs, resulting in a decrease in uterine blood flow and therefore perfusion (17,20,21).
- Alterations in respiratory patterns: hyperventilation resulting in a respiratory alkalosis, which further decreases uterine blood flow and thus perfusion (17).
- Prolonged labour (20,21) and inefficient uterine contractions (17).
- Increases in peripheral vascular resistance, blood pressure and cardiac output (17).
- Increased gastroparesis and gastric acid secretion (17).

An increase in maternal catecholamine production results in increased foetal catecholamine production. The implications of this for the foetus are vagal stimulation resulting in bradycardia, respiratory and metabolic acidosis, and increased risk of necrotising enterocolitis (20,21).

1.3 Treatment of labour pain

In this section the non-pharmacological and pharmacological treatment of labour pain will be discussed.

1.3.1 Non-pharmacological

In 2007 the consumers group of the Cochrane Pregnancy and Childbirth Group identified pain relief in labour as a topic of importance. As such, a series of Cochrane reviews was conducted between 2009 and 2012, a few of which were aimed at addressing the value of alternate therapies in the treatment of labour pain (22).

Hydrotherapy or immersion in water is defined as the complete submergence of a parturient in any body of water during any stage of labour (23). A 2017 systematic review by Shaw-Batista (24) concluded that hydrotherapy can facilitate the process of labour and delivery in a benign fashion, reduce the incidence of labour augmentation and improve patient satisfaction with the birthing process. This is in keeping with a 2018 systematic review by Cluett et al (23).

Transcutaneous electrical nerve stimulation uses alternating current to stimulate cutaneous afferent nerve fibres to inhibit pain transmission to the cortex (25). A systematic review by Dowswell et al (26) concluded that there was limited evidence for the use of transcutaneous electrical nerve stimulation for labour pain relief. Two randomised control trials (RCTs) by Shahoei et al (27) and Santana et al (28) subsequent to the 2009 systematic review by Dowswell et al (26) established that transcutaneous electrical nerve stimulation offered statistically significant pain relief in the first and second stages of labour, and post-delivery. The results of these RCTs should be interpreted with caution as both had small sample sizes.

Hypnosis is an alteration in consciousness that heightens response to suggestion (22). A RCT in 2015 by Downe et al (29) found no reduction of epidural or other

analgesic use in the intrapartum period by parturients utilising hypnosis. A systematic review by Madden et al (30) in 2016 came to the same conclusion.

Continuous support through labour and delivery has proven to be beneficial for mother and foetus by significantly shortening labour duration, decreasing the rate of assisted and caesarean deliveries, and improving maternal satisfaction with the birthing process. It also decreased the need for intrapartum analgesic intervention. (31,32)

Acupuncture is the ancient Chinese practice whereby acupuncture needles are inserted into acupuncture points (meridians) to aid the flow of energy through the body (33). A meta-analysis by Koyyalamudi et al (34) in 2016 and another by Schlaeger et al (33) in 2016 identified that acupuncture may reduce labour pain. Smith et al (35) reported insufficient evidence for recommendation of acupuncture for the treatment of labour pain in a systematic review in 2017.

An experimental study in 2017 with a small sample size by Erdogan et al (36) found that lower back massage during labour had a significant impact on reducing labour pain. A systematic review by Smith et al in 2018 (37) observed that massage may assist in treating labour pain, based on low quality evidence.

The systematic review by Smith et al (38) found that yoga helps to reduce pain, improve maternal satisfaction, decrease analgesic interventions and decrease the rate of assisted deliveries. A subsequent RCT by Jahdi et al (39) with a small sample size reported that yoga contributes to a reduction in labour pain and a reduction in risk of delivery by caesarean section.

In summary, there is inconsistent evidence with regards to the efficacy of non-pharmacological techniques in the management of labour pain.

1.3.2 Pharmacological

Non-opioid analgesia

Non-opioid analgesia includes agents such as paracetamol, non-steroidal anti-inflammatories, antispasmodics and dexamethasone. These drugs have been found to be effective in treating mild to moderate pain when used as exclusive analgesic agents, but demonstrate a ceiling effect where increasing the dosage does not increase the effect (22). This limits their use as exclusive analgesia, and they should be used as adjunctive treatment or as treatment for breakthrough pain (22). The side effects of these drugs are minimal when used in the acute pain setting (40,41). Dexamethasone has little analgesic effect when used in isolation but can reduce local anaesthetic requirements when given intravenously in combination with epidural analgesia (42).

Opioid analgesia

Epidural analgesia has been established as the gold standard for the management of labour pain (43). There are certain instances where neuraxial analgesia is contra-indicated. For these patients opioids form part of the management of labour pain (44).

Remifentanil is an ultra-short acting synthetic opioid with potent mu opioid receptor agonist activity (45). Remifentanil has organ-independent metabolism via hydrolysis by non-specific tissue and plasma esterases (43,46). Due to its rapid onset and its short duration of action, remifentanil should be administered via an infusion, or patient-controlled analgesia (46). Remifentanil is superior to other parenteral opioids in the treatment of labour pain, but is inferior to epidural analgesia (47).

Pethidine is a synthetic opioid with an active metabolite, norpethidine (48). Norpethidine is a potent respiratory depressant with a long half-life and causes significant maternal sedation (22,48,49) as well as being proconvulsant (48). For these reasons, pethidine is not an ideal analgesic agent in labour. Despite its poor analgesic qualities and significant side-effect profile, pethidine is the most commonly used opioid in the labour ward environment (44). The common use of

pethidine in the labour ward setting is due to staff familiarity with the drug, midwife administration without the need for medical practitioner prescription, the ease of intramuscular administration, and cost (22).

Morphine is a phenanthrene derivative from the poppy plant and has an active metabolite – morphine-6-glucuronide (46). With regular doses, morphine-6-glucuronide accumulates and causes profound maternal respiratory depression. Due to its long duration of action and active metabolite, morphine is not suitable for use in the acute labour pain setting. It is also the most emetogenic opioid (48).

Fentanyl is a synthetic pure mu opioid receptor agonist (45) that is highly protein-bound and lipid soluble, making it more potent than morphine (46). It can be administered either in on-demand boluses or via patient-controlled pump on demand. Fentanyl is preferable to pethidine when administered subcutaneously or intra-nasally (50) but is not the first line opioid of choice in the treatment of labour pain due to it causing poor foetal heart rate variability (46,48).

Inhaled agents

Inhalational anaesthetic agents such as nitrous oxide and flurane gases can be used at sub-anaesthetic concentrations to bring about analgesia during the labour process (51).

The analgesic qualities of nitrous oxide are mediated by stimulation of mu and gamma opioid receptors via methionine encephalin and beta-endorphins (46). The amnesic qualities are mediated by n-methyl-d-aspartic acid receptor antagonism (46). Nitrous oxide is effective in reducing pain intensity and offering pain relief to labouring women but has a larger side effect profile (nausea and vomiting, drowsiness, diffusional hypoxia, aplastic anaemia and leukopaenia, sympathetic nervous system stimulation and diffusion into air-filled body cavities (46)) when compared with flurane derivative inhaled agents (51). The cost of nitrous oxide and its ease of use in the labour ward setting mean it is still a widely-used agent for labour analgesia (52).

Volatile agents are gases with variable molecular groups structured around a central carbon atom which act centrally to bring about sedation, amnesia and anaesthesia (46). Sevoflurane is the volatile agent of interest due to its non-pungent smell and fast onset and offset of action, as well as its smaller side-effect profile when compared with nitrous oxide (51). A small pilot study by Toscano et al (53) reported an improvement in pain scores in patients using intermittent inhaled sevoflurane, with no adverse APGAR scores for the neonate. A later study by Yeo et al (54) found that sevoflurane at sub-anaesthetic levels offered adequate analgesia to labouring women. Klomp et al (51) identified that sevoflurane was slightly more effective in labour pain management than nitrous oxide and had fewer side-effects. These findings should be interpreted with caution as the studies quoted had small sample sizes, and the systematic review by Klomp et al (51) found low level evidence.

Neuraxial analgesia and anaesthesia

Neuraxial analgesia and anaesthesia refer to the use of anaesthetic agents (local anaesthetic or opioids alone, or in combination, with or without adjunct drugs) instilled into either the subarachnoid or epidural space of the spinal canal to inhibit the transmission of pain (55,56). Drugs can be instilled by a single-shot technique where a single dose of medication is given, or via insertion of a catheter (16). The catheter then allows for a continuous infusion of medication, or for multiple boluses to be given (16).

Spinal anaesthesia is the use of a single-shot neuraxial technique where a spinal needle is inserted into the subarachnoid spinal space. Cerebrospinal back flow in the needle confirms the correct position of the needle. Anaesthetic agents are then instilled intrathecally (56). This technique is usually reserved for patients with imminent vaginal delivery or delivery via caesarean section (16).

A combined spinal epidural (CSE) is a single-shot intrathecal injection combined with an epidural catheter insertion. The intrathecal component can contain an opioid only or an opioid-local anaesthetic combination. The benefit of combining spinal and epidural anaesthesia is the fast onset of pain relief, with the epidural being used for pain management as labour advances and pain becomes more

somatic in nature (57). Simmons et al (56) compared CSE with traditional dose and low dose epidural analgesia alone. The findings were that CSE showed no added benefit over epidural only. Patient satisfaction was the same across the CSE and epidural-only groups. CSE had a slightly faster onset but there was less reported pruritus with the low-dose epidural group. There was no increased risk of maternal or foetal adverse outcomes, no increase in reduced mobility or incidence of post-dural puncture headache (PDPH), and no increased risk of caesarean section in either group. Increases in rare complications were unknown as study groups were small (56).

The dural puncture epidural technique is a modified version of CSE (58-60). As with CSE, the dura is punctured with a spinal needle, with the difference being that no anaesthetic agent is instilled into the subarachnoid space (58,60). The principle of dural puncture epidural analgesia is that the punctured dura creates a conduit for translocation of anaesthetic agents from the subdural space into the subarachnoid space (58,60). A RCT by Chau et al (61) concluded that the dural puncture epidural technique had improved quality of block over standard epidural technique. The dural puncture epidural technique had fewer maternal and foetal side effects than CSE. CSE, however, had the fastest onset (61).

1.4 Epidural analgesia

Epidural analgesia is the insertion of a Tuohy needle into the epidural space followed by insertion of a catheter. Anaesthetic agents are then instilled into the epidural space via continuous infusion or boluses doses. (56)

1.4.1 Incidence of labour epidural analgesia

International data for the incidence of epidural administration is well established. According to the 2018 National Health Services Maternity Statistics (a collaboration of Hospital Episode Statistics and Maternal Services Data Set), 61% of normal deliveries in England are facilitated by anaesthetic intervention (no incidence of epidural incidence specifically) (62). In 2016 in the United States of

America (USA), 49 – 71% of parturients received epidural analgesia depending on the level of the health care facility. Of these, 75 – 86% are patient-controlled (63). In Australia in 2017, epidural analgesia was performed in 36% of deliveries (64). In Flanders in Belgium in 2016, an epidural rate of 62% was found (65). In China, an epidural rate of less than 1% was identified prior to the implementation of the 'No Pain Labour and Delivery' public health initiative. After implementation of the initiative, the epidural rate increased to more than 50% (66). A cross-sectional study by Narayanappa et al (67) identified a 12.5% labour epidural rate in government medical colleges and a 3% labour epidural rate in government hospitals in India in 2018.

In contrast, epidural statistics for South Africa are not well documented in the literature. A study done at Tygerberg Hospital (TBH) in the Western Cape in 2012 found an epidural incidence of 2.2% (68). Following upgrading of the epidural services offered at TBH, a follow-up study was done in 2014, with an epidural incidence of 5.2% (69). An audit of the labour epidural analgesia service at Rahima Moosa Mother and Child Hospital (RMMCH) in Gauteng in 2014 found an epidural rate of 1.6% (70).

1.4.2 Indications for labour epidural analgesia

According to the American College of Obstetricians and Gynecologists Practice Bulletin No 209, "in the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labor" (16). In settings where resource limitations preclude maternal request as an indication, there are certain medical conditions that may necessitate labour epidural analgesia to ameliorate the neuroendocrine response to labour pain. These indications include, but are not limited to hypertensive disorders of pregnancy (68-71), obesity (68,69,71), cardiac disease (68,69,71) and multiple pregnancies (71).

1.4.3 Contraindications to labour epidural analgesia

Abnormal coagulation and patients on anti-coagulation

The Multicenter Perioperative Outcomes Group (72) and the American College of Obstetricians and Gynecologists Practice Bulletin Number 207 (73) recommends that a minimum platelet count of 70 000 mm^{-3} be used as the minimum cut-off for neuraxial analgesia and anaesthesia administration. Further to this, the Practice Bulletin recommends platelet trends and function should guide the decision for neuraxial analgesia and anaesthesia, in conjunction with an absolute platelet count (73). Inherited disorders of coagulation include diseases such as von Willebrand disease, Haemophillia A and B, and Factor XI deficiency (14). Katz and Beilin (74) recommend that patients with these coagulopathies be treated on an individual basis with necessary coagulation studies to determine a clotting profile before neuraxial anaesthesia or analgesia is administered. Recommended guidelines for testing and safety ranges have not been established due to the scarcity in case number (74). The American Society for Regional Anaesthesia (75) and the European Society of Anaesthesiologists (76) recommend that neuraxial anaesthesia be performed no less than 12 hours after the administration of prophylactic low-molecular weight heparin and 24 hours after therapeutic low-molecular weight heparin. Catheter removal should occur at least 4 hours after low-molecular weight heparin administration. (75,76)

Intracerebral space-occupying lesions

Patients with a space-occupying lesion that have no mass effect, no hydrocephalus and no clinical or imaging symptoms or signs suggestive of raised intracranial pressure, have minimal to no increased risk of brain herniation during neuraxial anaesthesia and analgesia (77).

1.4.4 Complications of labour epidural analgesia

Minor complications

Labour epidural analgesia has previously been thought to have an association with an increased risk of delivery via caesarean section – a belief that Grant et al (55) labelled a fallacy in their 2014 review article. A later systematic review by Anim-

Somuah et al (78) determined no increased risk of caesarean section associated with the administration of labour epidural analgesia (55,78).

A meta-analysis by Sultan et al (79) in 2013, identified no increased risk of assisted delivery with labour epidural administration. A subsequent systematic review and meta-analysis by Wang et al (80) in 2017, concluded no association between labour epidural analgesia administration and an increased risk of assisted vaginal delivery, or prolonged second stage of labour. An RCT by Shen et al (81) in 2017, found no increase in the duration of the second stage of labour with labour epidural administration. The relationship between no prolongation of labour and no increased risk of assisted vaginal delivery, and the administration of labour epidural analgesia is likely due to the evidence-based practice of the use of low concentration local anaesthetic (LCLA) agent in the epidural mix (79-81).

Pruritus can be described as “a subjective unpleasant and irritating sensation that provokes an urge to scratch” (82). Pregnant women are more prone to opioid-induced pruritus than their non-pregnant counterparts due to an opioid receptor-oestrogen interaction (83). The incidence of opioid-induced pruritus is variable, and is experienced by 1 – 10% of women receiving neuraxial analgesia and anaesthesia, with neuraxial morphine having the highest incidence (83).

Intrapartum fever is defined as a maternal temperature of greater than 38^{o}C (84). In the USA, approximately 20% of all labouring women who receive an epidural experience fever (85). The exact pathophysiological mechanism resulting in maternal fever following labour epidural insertion is largely unknown. Research has ruled out the fever being derived from an infectious aetiology (84). Hypotheses are that it is an inter-play between pregnancy-induced up-regulation of the inflammatory response and the release of damage-associated molecular patterns from sterile tissue damage, resulting in a sterile systemic inflammatory response (86).

Intrinsic obstetric neurological injury refers to neurological fallout, whether permanent or transient, as a direct result of nerve damage from the labour process alone. In a retrospective study by Wong et al (87) the incidence of postpartum

neuropathy was approximately 1%. Risk factors for postpartum neurology were identified as a prolonged second stage of labour, instrumental delivery, short stature and nulliparity. Lateral femoral cutaneous nerve injury is the most common nerve injury. Neuraxial analgesia and anaesthesia were not listed as a contributing factor. A review by Birnbach et al (88) concluded that neurological injuries following labour epidural analgesia were associated with pregnancy and delivery and not the neuraxial analgesia or anaesthesia itself.

The International Classification of Headache Disorders describes a PDPH as “a headache occurring within five days of a lumbar puncture, caused by cerebrospinal fluid leakage through the dural puncture.” (89). A meta-analysis by Choi et al (90) identified accidental dural puncture to occur once in every 100 labour epidurals inserted, with a PDPH occurring in 50% of these patients. Birnbach et al (91) were in agreement with Choi et al (90) that the risk of developing a PDPH after accidental dural puncture was up to 50% (91). The Serious Complications Repository Project of the Society for Obstetric Anesthesia and Perinatology found a 0.7% incidence of PDPH (92).

Pregnancy and the labour process can result in lower back pain (91). In a retrospective questionnaire study by MacArthur et al (93) in 1990, an incidence of backache of 18.9% was found amongst labouring women who had received labour epidural analgesia, versus 10.5% in their non-epidural counterparts. The authors thus concluded a causal link between epidural analgesia and an increase in long-term lower back pain. A retrospective study by Russell et al (94) in 1993, had similar findings to that of MacArthur et al (93), with an incidence of 17.8% in the epidural analgesia respondent group. Both studies suggested that lower back pain following labour and delivery is multifactorial and could not exclusively attribute backache to the use of epidural analgesia. A follow up after RCT was conducted by Howell et al (95) in 2002, which found a high incidence of backache amongst the parturients who participated in the RCT: 76% in the epidural group and 72% in the non-epidural group. The majority of these patients (58% and 54% respectively) had backache prior to epidural administration. Howell et al (95) concluded no difference in the incidence of backache amongst those receiving labour epidural analgesia and those not.

Birnbach and Ranasinghe (91) define hypotension as a systolic blood pressure of less than 90 - 100mmHg or a drop in baseline blood pressure of more than 20 - 30%. The incidence of hypotension after labour epidural analgesia insertion varies from 10 - 20% (96). Transient hypotension or hypotension that is treated with vasopressors should have no adverse maternal or foetal effect (88).

Pan et al (97) conducted a retrospective study in the USA to determine the overall labour epidural failure rate of 19 259 parturients that received labour epidural analgesia between 2000 and 2002 . The definition they used was “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, intravenous epidural catheter, or any technique requiring replacement or alternative management”. Their failure rate was reported as 14% (97). Thangamuthu et al (98) conducted a retrospective study in 2011 to establish an epidural failure rate with the use of a standardised definition that they derived during the same study. “The definition of epidural failure included one or more of the following: lack of adequate pain relief by 45 minutes from the start of epidural placement, dural puncture, re-siting or abandoning the epidural and maternal dissatisfaction with analgesia at the follow-up visit.” (98). Using this definition, the authors identified an epidural failure rate of 23% amongst 1521 women who received labour epidurals. From these two studies it is evident that the incidence of failed epidurals is variable, and is based on the definition used.

Major complications

Major complications from epidural administration have been identified as epidural haematomas, spinal abscesses, nerve and spinal cord injuries and infarction, cardiorespiratory arrest and death. In 2009, The Third National Audit Project of the Royal College of Anaesthetists (99) identified four major complications from a total of 320 425 obstetric central neuraxial blocks (no differentiation between spinal versus epidural complications): one epidural haematoma, two nerve injuries, and one cardiac arrest. From this study, the incidence of permanent harm was 0.6 per 100 000 epidurals inserted (99).

A retrospective audit in 2014 by Rosero and Joshi (100) identified 3 703 755 epidural procedures performed in the USA from 1998 – 2010. Of these, 2 320 950 were for obstetric patients. The incidence of epidural haematomas amongst the obstetric population was found to be 0.6 per 100 000 epidural insertions. There were no cases of epidural abscess formation, and no deaths in the obstetric population. Obstetric patients were found to be the lowest risk population for major epidural complications, with vascular patients having the highest risk. The authors stated that the duration of admission, duration of epidural catheterisation, surgical procedure, comorbidity score and teaching status of hospital were related to an increased risk of major epidural complications (100). The Serious Complications Repository Project of the Society for Obstetric Anesthesia and Perinatology (92) found the following incidence of complications: myocardial infarction 1:128 398, epidural abscess/meningitis 1:62 866, epidural haematoma 1:251 463, serious neurological injury 1:35 923, respiratory arrest in labour suite 1:10 000, and cardiac arrest 1:128 398. In the United Kingdom the incidence of anaesthetic-related cardiac arrest in pregnancy is 0.7 per 100 000 deliveries (101) and in Canada the incidence is 1 per 100 000 deliveries (102).

1.4.5 Technique of epidural insertion

Loss of resistance technique

Correct identification of the epidural space is paramount in the insertion of an epidural catheter. Evidence is equivocal as to which loss of resistance (LOR) technique is superior when finding the epidural space – LOR to air or saline. A 2014 systematic review by Antibas et al (103) concluded that there is no significant difference between saline and air for LOR technique. Brogly et al (104) came to the same conclusion as Antibas et al (103) in a RCT in 2018.

The role of ultrasound

Landmark identification for insertion of labour epidural catheters has been the most common technique employed since the inception of epidural analgesia (105). In non-obese, non-pregnant patients the landmark technique is adequate for insertion (106). The physiological changes that occur during pregnancy (107,108), together with obesity (109), spinal deformities (110) and previous spinal surgery

(111), may result in difficult lumbar epidural catheterisation for analgesia. Pre-procedural ultrasonography is the use of ultrasound prior to insertion of the epidural catheter, to identify the correct vertebral space, needle depth and angle, to facilitate easier insertion (106). A systematic review and meta-analysis by Shaikh et al (110) revealed that pre-procedural ultrasonography was associated with a reduction in failed epidural, traumatic insertion, number of needle adjustments and attempts. Limitations to this systematic review were the methodological variation and the skill of the persons performing the ultrasonography (experienced obstetric anaesthesiologists or proficient ultrasound technicians). In line with these limitations, a RCT performed by Arzola et al (112) found that pre-procedural ultrasonography conferred no benefit over the landmark technique when performed by anaesthesia trainees. Chin et al (105) concluded in a review that ultrasonography should not be included as part of the basic standard of care for labour epidural insertion, but rather as a valuable adjunct for difficult neuraxial access.

1.4.6 Maintenance of epidural analgesia

Infusion versus bolusing

The maintenance of epidural analgesia can take the form of a continuous infusion or bolus dosing of anaesthetic agent. Programmed intermittent epidural bolusing (PIEB) or automated mandatory bolusing (AMB) is the process whereby a fixed bolus of anaesthetic agent is delivered through an epidural catheter by a pre-programmed drug delivery pump system at regular intervals (60,113,114). Continuous epidural infusion (CEI) is the process whereby a continuous infusion of anaesthetic agent is given via an epidural catheter, driven by an infusion pump (113). PIEB and CEI can be supplemented by patient-controlled epidural analgesia (PCEA) – anaesthetic agent boluses self-administered by the patient via a drug delivery pump (114).

The last decade of research into epidural analgesia maintenance has focused on the comparison of infusion versus bolus dosing, and which is superior.
PIEB has been found to be superior to CEI in the following aspects.

- Patient satisfaction (115,116)
- Reduced local anaesthetic consumption (115-118)
- Less breakthrough pain and fewer PCEA bolus requirements (114,119)
- Less occurrence of motor block (115,118,120)
- Improved labour and neonatal outcomes (115,116,118).

A systematic review by Sng et al (121) concluded that AMB and CEI were comparable when maintaining epidural analgesia, but AMB had the benefit of decreased risk of breakthrough pain, increased maternal satisfaction, and decreased local anaesthetic consumption.

When comparing infusion versus bolus dosing, anaesthetic agents are more widely distributed and therefore provide better nerve bathing when administered intermittently under a greater driving pressure than the lower continuous pressure of an infusion (122,123).

Low concentration local anaesthetic versus high concentration local anaesthetic

The choice of which long-acting local anaesthetic agent (bupivacaine, ropivacaine, or levobupivacaine) to use in epidural analgesia has no significant effect on maternal (122,124), neonatal (122,125) or labour outcomes (122,126). LCLA is defined as a concentration of bupivacaine (or equipotent ropivacaine or levobupivacaine) of 0.1% or less (127). LCLA has been associated with a decreased risk of local anaesthetic toxicity (113), reduced haemodynamic effects (113), less placental drug transfer (113), and reduced incidence of motor block resulting in a decreased incidence of assisted deliveries (79,80,113). A systematic review by Simmons et al (56) found in favour of the use of LCLA as the best practice for labour epidural analgesia.

Adjunct drugs

Short-acting opioids have traditionally been the adjunct drugs of choice for addition to labour epidural analgesia (128). The resurgence of drugs such as neostigmine, and the development of alpha-2-agonists have challenged the use of opioids as the mainstay for adjunct use in labour epidural analgesia in the last decade (128).

A systematic review in 2015 by Cossu et al (129) found that neostigmine reduced local anaesthetic consumption and resulted in no serious adverse effects for mother and foetus when compared with local anaesthetic alone, or local anaesthetic in combination with other adjunct agents. Of the alpha-2-agonists, dexmedetomidine has been proven to have superior efficacy over opioids (130,131) when used as an adjunct in labour epidural mixtures in combination with local anaesthetic agents. Clonidine has not been proven to be superior to opioids in labour epidural analgesia (132,133). Literature is scant with regards to the comparison of dexmedetomidine to clonidine as adjuncts in labour epidural analgesia. In non-labour epidural analgesia, dexmedetomidine has been proven superior to clonidine (134).

1.4.7 Patient satisfaction

After conducting a prospective observational study to evaluate maternal satisfaction with labour neuraxial analgesia, Clivatti et al (135) stated that "the assessment of the effectiveness of neuraxial analgesia encompassing the entire process of labour and delivery, including maternal satisfaction, may unveil problems, identify opportunities for improvement of clinical practice, and raise new research perspectives." (135). In 2003, Dickinson et al (136) conducted a prospective RCT comparing epidural and non-epidural analgesic techniques to determine parturient birthing experience and satisfaction with the allocated analgesic regimen. Maternal satisfaction was significantly higher amongst the group who received epidural analgesia (90 – 95%). A retrospective cohort study by Tan et al (137) in 2018, which included 10 146 parturients, investigated the factors determining parturient satisfaction with labour epidural analgesia. The following risk factors for low patient satisfaction were identified: breakthrough pain after epidural insertion, having an assisted delivery, re-siting of epidural catheter, epidural insertion at an advanced cervical dilatation, complications such as backache, headache, urinary retention, neural deficit, multiparity and Chinese ethnicity (137). The incidence of patient satisfaction in Tan et al's (137) study was 68.1%.

1.4.8 Labour epidural analgesia services in South Africa

Tygerberg Hospital 2012

Jacobs-Martin et al (68) conducted the first retrospective audit of labour epidural analgesia in South Africa in 2012, at TBH. They identified a labour epidural rate of 2.2%. The majority (72.3%) of labour epidurals were inserted for medical reasons (pre-eclampsia, cardiovascular disease, and morbid obesity). There was one major complication of cardiac arrest following inadvertent intravenous infusion of bupivacaine. The most common minor complication was hypotension (13.4%). Patient satisfaction was high at 86%.

Tygerberg Hospital 2014

Van Zyl and Burke (69) performed a follow-up labour epidural audit to Jacobs-Martin et al (68) at TBH in 2014 following extension of the labour epidural analgesia service. The authors found an increase in the rate of labour epidural insertion from 2.2% to 5.2%. Primary indications for labour epidural insertion were the same as that found by Jacobs-Martin in 2012. There was one major complication of cardiac arrest following inadvertent intravenous infusion of bupivacaine. The most common minor complication was also hypotension (14.2%). Patient satisfaction was high at 88.4%.

RMMCH 2014

Leonard et al (70) conducted a retrospective audit of the labour epidural services at RMMCH in 2014 when the service was limited to the daytime. They attained a labour epidural rate of 1.6%. The most common indication for labour epidural insertion was for labour analgesia (41.7%). There were no major complications during the study period, and minor complications occurred in 18.7% of patients, with hypotension being the most common (12.3%). Patient satisfaction was found to be high at 98.4%. The inadequacy of completed epidural records was identified as a problem in the study. (70)

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Section 3: Draft article

A follow-up study of the extended labour epidural analgesia service at a regional hospital in Gauteng

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Key words: Epidural, labour, analgesia.

Abstract

Background
In 2014 an audit was performed at Rahima Moosa Mother and Child Hospital (RMMCH) on the daytime labour epidural service, prior to extension of the service to 24 hours. Since implementation of the extended service, no follow-up audit has been performed. Services based on pain management require regular auditing in order to determine safety, efficiency and practices in keeping with current evidence.

Methods
A retrospective audit using consecutive convenience sampling was done reviewing all epidural records at RMMCH from 1 June 2017 to 31 May 2018.

Results
During the study period 658 labour epidurals were inserted for a total of 12 600 deliveries, from which 637 (96.8%) records were recovered. The labour epidural rate was 5.2%, a statistically significant improvement from 1.6% ($p<0.0001$) in 2014. The major complication rate was 0.4% with one respiratory arrest and one cardiac arrest. The most common minor complication was multiple attempts (15.1%). Odds ratios for caesarean section and assisted deliveries in this study were 0.8422 and 0.5020 respectively. The majority of cases were maintained by continuous infusion (52.8%). Patient satisfaction was 97.2%. Documentation improved significantly from 2014 to our study ($p<0.001$).

Conclusion
In this study the labour epidural rate increased from 1.6% to 5.2%. This still falls well below international rates.

Introduction

The sensation of pain is a universal phenomenon which no human being can be immune to. Documentation of pain dates back to the eighth century BC where Homer wrote about "Oedipus of many pains" [1], and the fourth century BC where Hippocrates described the pain of pelvic girdle separation during pregnancy and labour [2].

The most widely accepted definition of pain is from the International Association for the Study of Pain from 1994 where pain is defined as "an unpleasant sensory and emotional experience; associated with actual or potential tissue damage, or described in terms of such damage"[3].

The pain of labour is one of the most severe types of pain that can be experienced by a woman in her lifetime [4-8]. At its extreme, it has been compared to digit amputation without anaesthesia [19]. Labour pain results in multiple physiological and psychological changes which can be harmful to both mother and child, both short term and long term [7-13]. Increased levels of circulating catecholamines can result in prolonged and dysfunctional labour, and decreased uterine blood flow [5,14,15]. Maternal respiratory alkalosis can result in impaired oxygen offloading to the foetus [5,6,16]. Emotionally, poorly managed labour pain can result in poor mother-child bonding, impaired breastfeeding, and increased risk of developing post-partum depression and post-traumatic stress disorder [11-13].

While there are multiple treatment modalities for labour pain, epidural analgesia is well established as the gold standard thereof [17,18]. Statistics from developed countries with regards to the rate of labour epidural analgesia, side effects, complications, and patient satisfaction are well documented. In contrast, epidural analgesia statistics for developing countries are not well established. A study done at Tygerberg Hospital (TBH) in the Western Cape in 2012 found an epidural rate of 2.2% [4]. Following upgrading of the epidural analgesia services offered at TBH, a follow-up study was done in 2014, with an epidural analgesia rate of 5.2% [20]. A study of the rate of labour epidural analgesia insertion at Rahima Moosa Mother and Child Hospital (RMMCH) in Gauteng in 2014 found an epidural analgesia rate of 1.6% [21]. The epidural analgesia service at RMMCH has subsequently been extended to a 24 hour service. However, the impact of this extended service is not known. The aim of this study was to conduct a follow-up survey using epidural records from 1 June 2017 to 31 May 2018 to assess the labour epidural analgesia service at RMMCH following the extension of the service.

Methods

Approval to conduct this study was obatined from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand and other relevant authorities. The research design used in this study was retrospective, contextual and descriptive.

Following the extension of the labour epidural analgesia service from a daytime service to a 24 hour service, an anaesthetist (medical officer or registrar) was assigned for a 24 hour period to the service for the sole purpose of insertion of labour epidurals. The responsible anaesthetist, in collaboration with the obstetric team covering labour ward, would identify and discuss suitable patients and then insert the epidural and monitor the patient for the duration of labour and delivery, and then follow up and remove the catheter after delivery,

and assess patient satisfaction. The labour ward admissions book was used to determine the total number of patients in the specified study period.

The study population was the epidural analgesia records of the women who had received labour epidural analgesia at RMMCH from 1 June 2017 to 31 May 2018. Consecutive, convenience sampling was used. The sample size was determined by the number of women who had received labour epidural analgesia during the study period. The exclusion criteria was illegible epidural records.

The data collection sheet used in the epidural analgesia audit in 2014 [21] was adapted and used in this study. Permission to use and adapt the data collection sheet was obtained from the author. The data sheet contained the following information: overall delivery statistics, patient-specific demographics, primary indication for labour epidural insertion, professional designation of the doctor inserting the epidural, loss of resistance technique for finding the epidural space, method of epidural maintenance, complications, time to follow-up, and patient satisfaction.

RMMCH uses a pre-printed single page epidural record that is manually completed by the anaesthetist administering the epidural. Once the patient has completed the delivery process and the epidural catheter has been removed, the epidural record is placed in a file in the epidural sleep room (the room utilised by the anaesthetist to rest between cases). These completed records are then handed in to the consultant in charge of the epidural analgesia service and are kept in a secure office in the anaesthetic department. Only one author (AM) collected all the data. Epidural records did not leave the hospital premises.

Data were captured directly on to a Microsoft Excel spreadsheet and analysed in consultation with a biostatistician using Stata version 15 (StataCorp, USA). Categorical variables were described using numbers and frequencies. Continuous variables were described using means and standard deviations. Comparisons with the previous study were done using Chi-squared or Fisher's exact test. A p value ≤ 0.05 was considered stasticially significant. Not all the information collected was the same between this study and the 2014 study. Grey shaded blocks in the results are a reflection of this.

Results

The delivery statistics of the 2014 study and this study are shown in Table 1. There was a significant difference in the total number of epidurals inserted between the two studies ($p<0.0001$), with this study having the greater number. Of the 658 labour epidurals inserted, 637 (96.8%) records were recovered and were included in this study.

Table 1: RMMCH delivery statistics for 2014 and 2017/18

Demographics	2014		2017/18	
	n	%	n	%
Total deliveries	11 853		12 600	
Normal vaginal delivery (NVD)	7 970	67.2	7 725	61.3
Assisted deliveries			242	1.9
Total caesarean section (C/S)	3 883	32.8	4 875	38.7
Total epidurals inserted	187	1.6	658	5.2
Epidural records recovered	187	100	637	96.8

The patient demographics of the 2014 study and this study are shown in Table 2. There was a significant difference in documentation of parity ($p<0.0001$), with less documentation occurring in this study. The risk of having a C/S following epidural insertion was significantly lower than the risk in the general RMMCH maternity population. (OR 0.8422, 95% CI 0.7145 – 0.9930, p=0.0451). The risk of having an assisted delivery following labour epidural insertion was significantly lower than the risk in the general RMMCH maternity population (OR 0.5020, 95% CI 0.3170 – 0.7948, p=0.0076).

Table 2: Patient demographics for 2014 and 2017/18

Demographic	2014		2017/18	
	Mean	SD	Mean	SD
Age	26	5.4	25	5.5
Parity	**n**	**%**	**n**	**%**
0	80	42.8	153	24.0
1	20	10.7	82	12.9
2	50	26.7	44	6.9
≥3	3	1.6	22	3.5
Not documented	34	18.2	336	52.8
Total	**187**	**100**	**637**	**100**
Mode of delivery			**n**	**%**
NVD unassisted			326	51.2
NVD assisted			21	3.3
C/S			260	40.8
Not documented			30	4.7
Total			**637**	**100**

The indications for labour epidural insertion in the 2014 study and this study are shown in Table 3. There was a significant difference in documentation of indications for epidural insertion between the two studies (p=0.0161) with more documentation occurring in this study. Of the 153 documented primigravidas, 123 (80.4%) received a labour epidural for labour analgesia.

Table 3: Indications for labour epidural insertion in 2014 and 2017/18

Indication	2014		2017/18	
	n	%	n	%
Labour analgesia	78	41.7	419	65.7
Primigravida	54	28.9	0	0
Augmentation of labour	1	0.5	70	11
Hypertension	0	0	2	0.3
Vaginal birth after C/S	0	0	6	0.9
Patient request	0	0	1	0.2
Cardiac lesion	0	0	1	0.2
Prolonged labour	0	0	1	0.2
Induction of labour	0	0	1	0.2
Twin pregnancy	0	0	1	0.2
Poor progress	0	0	3	0.5
Termination of pregnancy	0	0	2	0.3
Foetal anomaly	0	0	1	0.2
Not documented	54	28.9	129	20.2
Total	**187**	**100**	**637**	**100**

Table 4 shows the professional designation of the anaesthetist inserting the epidural in the 2014 study and this study. There were significantly more registrar-inserted epidurals in this study (p=0.0010).

Table 4: Professional designation of the anaesthetist inserting the epidural in 2014 and 2017/18

Profession designation	2014		2017/18	
	n	%	n	%
Registrar total	104	55.6	458	71.9
Registrar – 1st year			226	35.5
Registrar – 2nd year			172	27.0
Registrar – 3rd year			50	7.9
Registrar – 4th year			10	1.6
Medical officer	70	37.4	168	26.4
Consultant	1	0.5	1	0.2
Not documented	12	6.4	10	1.6
Total	**187**	**100**	**637**	**100**

Complications of the labour epidurals for the 2014 study and this study are shown in Table 5. Where comparisons could be made, no significant differences were found between the occurrence of complications: hypotension (p=0.1594), incomplete analgesia (p=0.4111), back pain (p=0.5823), none (p=0.4100). There was no significant difference in the documentation between the two studies (p=0.1903).

Table 5: Complications in 2014 and 2017/18

Complications	2014		2017/18	
	n	%	n	%
Major	**0**	**0**	**2**	**0.4**
Respiratory arrest	0	0	1	0.2
Cardiac arrest	0	0	1	0.2
Minor with insertion	**0**	**0**	**131**	**25.3**
Multiple attempts	0	0	78	15.1
Failed insertion	0	0	16	3.1
Pain on insertion	0	0	15	2.9
Bloody tap	0	0	11	2.1
Dural tap	0	0	8	1.6
Parasthesia on injection	0	0	3	0.6
Minor post-insertion	**35**	**22.6**	**112**	**21.7**
Hypotension	23	12.3	57	11.0
Incomplete analgesia	6	3.2	14	2.7
Back pain	5	2.7	14	2.7
Headache	0	0	11	2.1
Failed block	0	0	4	0.8
Motor block	0	0	4	0.8
Pruritus	0	0	3	0.6
Nausea and vomiting	0	0	2	0.4
Tachycardia	0	0	1	0.2
Catheter dislodged	0	0	2	0.4
Pyrexia	1	0.5	0	0
None	120	64.2	352	68.1
Not documented	32	17.1	80	13.4
Total	**187**	**100**	**677**	**100**

The follow-up information of the 2014 study and this study are shown in Table 6. There was a significant difference in the documentation of follow-up ($p<0.0001$) with significantly more follow-ups being documented in this study. There was no significant difference in patient satisfaction between the 2014 study and this study ($p=0.7469$). There was a significant difference in documentation of patient satisfaction ($p=0.0006$), with more documentation occurring in this study.

Table 6: Follow up information in 2014 and 2017/18

Variable	2014		2017/18	
	n	%	n	%
Time to follow-up				
Within 24 hours	124	66.3	532	83.5
After 24 hours	0	0	0	0
Not documented	63	33.7	105	16.5
Total	**187**	**100**	**637**	**100**
Patient satisfaction	**n**	**%**	**n**	**%**
Happy	122	65.2	490	76.9
Not happy	2	1.1	13	2.0
Not documented	63	33.7	134	21.0
Total	**187**	**100**	**637**	**100**

The methods of labour epidural maintenance for this study are shown in Table 7. This was not recorded in the 2014 study.

Table 7: Method of maintenance of labour epidural analgesia

Method	n	%
Manual boluses	158	24.8
Programmed intermittent epidural bolus (PIEB)	7	1.1
Continuous epidural infusion (CEI)	336	52.8
Patient-controlled epidural analgesia (PCEA)	4	0.6
CEI + manual boluses	84	13.2
CEI + PCEA	5	0.8
PIEB + PCEA	4	0.6
No maintenance	24	3.8
Not documented	15	2.4
Total	**637**	**100**

Discussion

The labour epidural analgesia rate at RMMCH following the extension of the epidural service was 5.2%. This is a significant increase ($p<0.0001$) from 1.6% when the service was limited to the daytime [21]. The findings in this study are comparable with a similar follow-up study conducted at TBH in the Western Cape where the labour epidural rate increased from 2.2% [19] to 5.2% [20] following extension of the labour epidural service. While a statistically significant increase was found in our study, it has very little clinical significance as it still falls far below the established statistics found in developed countries. The USA's Obstetric Anesthesia Workforce survey reported an epidural incidence of 49 – 71% in 2016 [22], the Australian Institute of Health and Welfare's 'Australia mothers and babies 2017 – in brief' had an epidural rate of 38% in 2017 [23], and a nationwide survey in the Netherlands had an epidural rate of 22% in 2016 [24].

The only evidence identified for labour epidural analgesia in developing countries comes from South Africa, India and China. The Chinese labour epidural rate is currently over 50% [25], in line with statistics in developed countries. Over the course of a 10 year period, a nationwide multi-collaborative public health initiative involving large-scale education and service funding was implemented. "No Pain Labour and Delivery" resulted in the epidural rate increasing from 1% to over 50% [25]. The modest increase in labour epidural rate in our study and in the TBH study, and the Chinese public health collaboration, are indicators that improving labour epidural services in developing countries is complex and multifactorial. Addressing only one arm of the service delivery chain (increasing the availability of anaesthesiology staff to cover a 24 hour service) is not adequate to bring services in line with international standards, and points to a need for multidisciplinary (obstetric and nursing) buy-in and improved resource allocation on a provincial and national level.

The perception that labour epidural analgesia increases the risk of having a delivery via C/S has long-since been allayed in the literature [18,26-28]. The finding from this study was that parturients who received labour epidurals were 16% less likely to deliver via C/S than their counterparts in the general maternity population at RMMCH.

The increased risk of having an assisted vaginal delivery as a complication of labour epidural insertion has been an area of debate within the labour analgesia literature in the past. A systematic review by Anim-Somuah in 2018 [18] concluded that there was no link between labour epidurals and an increased risk of assisted vaginal delivery, and that the evidence-based practice of low concentration local anaesthetic (LCLA) was the most plausible reason for this. In our study, patients who received a labour epidural were 50% less likely to have an assisted delivery than their counterparts in the general maternity population at RMMCH. The reason for a lower likelihood of assisted delivery following labour epidural insertion at RMMCH could be related to the practice of LCLA.

The American College of Obstetricians and Gynecologists advocates for the insertion of labour epidurals based on maternal request for analgesia rather than for medical indications alone [4]. The indications in this study are in keeping with this sentiment. The most common indication in this study was for analgesia (65.7%), with the second most common indication being augmentation of labour (11%). There was one (0.2%) epidural inserted in a 27 year old woman with a cardiac lesion. Two (0.3%) epidurals were inserted for termination of pregnancy. The appropriateness of the use of epidurals in the termination of

pregnancy is debatable. Primigravidity was never documented as an indication for labour epidural insertion in this study. Due to the lack of documentation of parity and indication, there may have been more primigravidas who received labour epidurals than what was found in this study.

A study in the USA found the incidence of maternal pyrexia to be 20% [29]. There were no cases of maternal pyrexia reported in this study. The reason for this could be that patients never developed pyrexia, or that the pyrexia was not documented.

Two (0.4%) major complications occurred in this study. A 23 year old patient developed respiratory arrest following administration of a 3ml test dose of 2% lignocaine following uneventful epidural insertion and a 31 year old patient had a cardiac arrest when a second bolus dose of LCLA was given. In both cases, accidental intrathecal injection was excluded. The cause of the events was not documented in the patient notes, therefore making it difficult to draw conclusions. These epidurals were inserted by junior anaesthetists which may have played a role. Following resuscitation, both patients underwent emergency C/S and both made a full recovery. Data on the incidence of labour epidural-related respiratory and cardiac arrest is limited. In the USA the incidence for anaesthetic-related respiratory and cardiac arrest is 1 per 10 000 deliveries [30] and 0.7 per 100 000 deliveries [31] respectively. In the United Kingdom the incidence of anaesthetic-related cardiac arrest in pregnancy is 0.7 per 100 000 deliveries [32] and in Canada 1 per 100 000 deliveries [33]. The incidence of anaesthetic-related respiratory arrest and cardiac arrest in our study were 1 per 500 deliveries respectively. These major complication incidences are in excess of the incidence in developed countries, but should be interpreted with caution based on the study number and the time period that this study was conducted over. There are no established incidences of anaesthetic-related respiratory and cardiac arrests in developing countries to compare our study to.

Epidural failure rates vary across studies as there is no standardised definition. There are multiple complications in this study that could be combined under the single complication of 'failed epidural'. The overall epidural failure rate in this study was 22.3% - multiple attempts (15.1%), failed insertion (3.1%), incomplete analgesia (2.7%), bloody tap (2.1%), dural tap (1.6%), failed block (0.8%), and catheter dislodgement (0.4%). The epidural failure rate from our study is comparable to that found by Thangamuthu et el [34] in the United Kingdom in 2011. Pan et al [35] documented an overall epidural failure rate of 14% in the United States in 2002.

The incidence of hypotension in this study was 11%. This is in keeping with Birnbach et al [36] who described an incidence of hypotension of 10 – 20%, but well below the incidence of 30 – 40% described by Hoefnagel et al [37]. There was no significant difference between the incidence found in this study and that in the 2014 RMMCH study [21].

Patient satisfaction with labour epidural analgesia is usually high. Tan et al [38] described a 68.1% satisfaction rate in their cohort study of 10 170 parturients. Jacobs-Martin et al [19] described a satisfaction rate of 64% at TBH in 2012, and van Zyl et al [20] described a satisfaction rate of 88.4% in a TBH follow-up study. The patient satisfaction rate in the 2014 RMMCH study was 98.4% [21]. Patient satisfaction in our study was not documented in 134 (21%) charts. In charts where satisfaction was documented in our study, 97.4% of patients were "happy" with their labour epidural.

In our study, the majority of epidurals were maintained with CEI (52.8%). PIEB has been proven to be superior to CEI, yet a number of developed countries still use CEI as the mainstay of labour epidural maintenance [39-41]. The reasons for the low incidence of PIEB maintenance in our study could be due to limited stock of consumables for the PIEB pumps. This resulted in infrequent use and a lack of familiarity with the pumps, and therefore reluctance to use PIEB. It is encouraging that PIEB was used, albeit very occasionally. There was also a high incidence of manual boluses in our study (24.8%). This could be due to multiple factors, and highlights the need for continuous education of anaesthetists inserting epidurals on the current evidence for practice.

There was a significant improvement in the documentation of indications ($p=0.0161$), documentation of patient follow-up ($p<0.0001$), and documentation of patient satisfaction ($p=0.0006$) between our study and the 2014 RMMCH study. These improvements in documentation could be due to the implementation of a new tickbox epidural chart. While our study has shown an improvement in documentation from the 2014 RMMCH study, it is still concerning that there is a consistent lack of complete documentation as this has potential medico-legal and ethical consequences for the anaesthetist involved.

A limitation to this study was that it was retrospective, with 3.2% of records missing, and incomplete documentation. For example, more than 50% of the records had no parity documented. A quality improvement project for physical record keeping and documentation is a recommendation based on the findings from this study.

Conclusion

This was a follow-up study after the implementation of an extended labour epidural analgesia service at RMMCH where the labour epidural rate increased from 1.6% to 5.2%. While this is a statistically significant increase, it still falls well below international standards.

Conflict of interest

The authors declare that we have no financial or personal relationships which may have inappropriately influenced us in writing this paper.

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Section 4: Proposal

A follow-up study of the extended labour epidural analgesia service at a regional hospital in Gauteng

Andrea Lynne Murphy
0504486K

Supervisor	Helen Perrie Department of Anaesthesiology
Co-supervisor	Juan Scribante Department of Anaesthesiology
Co-supervisor	Tristan Leonard Department of Anaesthesiology

4.1 Introduction and problem statement

The sensation of pain is a universal phenomenon which no human being can be immune to. Documentation of pain dates back to the eighth century BC where Homer wrote about “Oedipus of many pains” (1), and the fourth century BC where Hippocrates described the pain of pelvic girdle separation during pregnancy and labour (2).

The most widely accepted definition of pain comes from 1994 from the International Association for the Study of Pain (3) and is defined as “an unpleasant sensory and emotional experience; associated with actual or potential tissue damage, or described in terms of such damage”.

The pain of labour is one of the most severe types of pain that can be experienced by a woman in her lifetime (4-8). At its extreme, it has been compared to digit amputation without anaesthesia and cancer pain (8). Labour pain results in multiple physiological and psychological changes which can be harmful to both mother and child, both short term and long term (7-13). Increased levels of circulating catecholamines can result in prolonged and dysfunctional labour, and decreased uterine blood flow (5,14,15). Maternal respiratory alkalosis can result in impaired oxygen offloading to the foetus (5,6,16). Emotionally, poorly managed labour pain can result in poor mother-child bonding, impaired breastfeeding, and increased risk of developing past-partum depression and post-traumatic stress disorder (11-13).

While there are multiple treatment modalities for labour pain, epidural analgesia is well established as the gold standard thereof (17,18). Statistics from developed countries with regards to the rate of labour epidural analgesia, side effects, complications, and patient satisfaction are well documented. According to the National Health Services (19), 80% of normal deliveries in England are facilitated by anaesthetic intervention. In the United States of America, 49 – 75% of parturients receive epidural analgesia depending on the level of the health care facility. Of these, 75 – 86% are patient-controlled (20). A 2011 survey in Canada

comparing routine labour interventions between 1993 and 2007 found that the overall labour epidural analgesia rate increased from 55% to 87% (21). The Australian Institute of Health and Welfare gives an epidural analgesia rate of 35% (22). A retrospective audit by Rosero et al (23) found the major complication incidence of labour epidural analgesia to be 0.6 per 100 000 epidurals for epidural haematoma. There were no cases of epidural abscess formation.

In contrast, epidural analgesia statistics for developing countries are not well established. A study done at Tygerberg Hospital in the Western Cape in 2012 found an epidural rate of 2.2% (24). Following upgrading of the epidural analgesia services offered at this hospital, a follow-up study was done in 2014, with an epidural analgesia rate of 5.2% (25). A study of the rate of epidural analgesia at Rahima Moosa Mother and Child Hospital (RMMCH) in Gauteng in 2014 found an epidural analgesia rate of 1.6% (26). The epidural analgesia service at RMMCH has subsequently been extended to a 24 hour service. However, the impact of this extended service is not known.

4.2 Aim and objectives

4.2.1 Aim

The aim of this study is to conduct a follow-up survey using epidural records from 1 June 2017 to 31 May 2018 to assess the labour epidural analgesia service at RMMCH following the extension of the service.

4.2.2 Objectives

The primary objectives of this study are to:

- describe the total number of deliveries at RMMCH
- describe the number of labour epidurals inserted
- describe the indications for labour epidural analgesia
- describe the professional designation of the doctor inserting the labour epidural
- describe the technique of labour epidural insertion
- describe the mode of labour epidural analgesia maintenance

- describe the complications following labour epidural analgesia
- describe patient satisfaction with the labour epidural analgesia
- describe the time to follow up after removal of the labour epidural catheter.

The secondary objective of the study is to compare all the results obtained from this study to the results obtained from the labour epidural analgesia audit done in 2014 at RMMCH.

4.3 Research assumptions

The following definitions will be used in the study**.**

Anaesthetist: a qualified doctor working in the Department of Anaesthesiology including medical officers, registrars and consultants**.**

Medical officer: a qualified doctor practising in the Department of Anaesthesiology under specialist supervision. Medical officers with more than 10 years of experience are career medical officers and are regarded as consultants.

Registrar: a qualified doctor who is registered with the Health Professions Council of South Africa as a trainee anaesthetist**.**

Specialist anaestheist: a qualified doctor who has completed training time and exams and is registered with the HPCSA as a specialist.

Consultant: a specialist anaesthetist or career medical officer**.**

Epidural record: a pre-printed record used at RMMCH that is completed manually by the anaesthetist performing the epidural (Appendix 1).

4.4 Demarcation of study field

The study will be conducted at RMMCH, a regional academic hospital with 338 beds and an average of 12 000 deliveries per year. The hospital is affiliated to the University of the Witwatersrand.

4.5 Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of the University of the Witwatersrand. Approval to access stored records has been obtained from the gatekeeper of the records at RMMCH (Appendix 2). Approval to conduct the study has been obtained from the Clinical Head of Unit at RMMCH (Appendix 3) and the Head of Department of Anaesthesiology of the University of the Witwatersrand (Appendix 4). Approval will be obtained from the Research Committee at RMMCH (Appendix 5).

A list with patient name, hospital number and study number will be generated and filed separately. The data collection sheet will only contain a study number and no other identifying features. Confidentiality will be maintained as only the researcher and supervisors will have access to the raw data. The data collected from this study will be stored securely on a password protected database for six years after completion of the study.

This study will be conducted according to the principles of the Declaration of Helsinki (27) and the South African Guidelines for Good Clinical Practice (28).

4.5.1 Research design

The design of a study according to Burns and Grove (29) is a predetermined plan to elicit the best information from the data that is collected. It determines the best method to be implemented for data collection, analysis and interpretation (29).

The research design used in this study is retrospective, contextual and descriptive.

A retrospective study measures variables that have already occurred (30). This study design will obtain data from already-completed epidural records from RMMCH.

A contextual study extracts data from a particular group relevant to the study design in order to have the most accurate results (31). This study is contextual as it will examine the labour epidural analgesia service at RMMCH only.

A descriptive study explores the characteristics of variables when little is known about the variables involved. There is no manipulation of variables and no attempt to determine relationships between variables (32). This study will describe the labour epidural analgesia service at RMMCH.

4.5.2 Study population

The study population will be the epidural analgesia records of the women who have received labour epidural analgesia at RMMCH from 1 June 2017 to 31 May 2018.

4.5.3 Study sample

Sample size

The sample size will be determined by the number of women who had received labour epidural analgesia at RMMCH for the period of 1 June 2017 to 31 May 2018. On average, 80 labour epidurals are performed per month.

Sampling method

Consecutive, convenience sampling will be used in this study. Consecutive sampling refers to the attempt by the researcher to include all accessible subjects into the sample and convenience sampling collects the most readily available subjects in a non-random manner (31). In this study, consecutive, convenience sampling means that every labour epidural record available for the study period will be collected and analysed.

Inclusion and exclusion criteria

The inclusion criteria for this study are the records of every woman who received labour epidural analgesia at RMMCH from 1 June 2017 to 31 May 2018. The exclusion criteria in this study are illegible epidural records.

4.5.4 Data collection

Data collection sheet

The data collection sheet used in the intial epidural analgesia study in 2014 at RMMCH will be adapted and used in this study. Permission to use and adapt the data collection sheet was obtained from the author (Appendix 6).

The data sheet contains the following:

- general demographics (Appendix 7)
    - total deliveries
    - total caesarean sections
    - epidural analgesia records retrieved
    - epidural analgesia records lost to follow up
- patient demographics (Appendix 8)
    - age
    - parity
    - mode of delivery
- primary indication for labour epidural
- professional designation of the doctor inserting the epidural
- epidural technique
    - loss of resistance technique
- method of epidural maintenance
- complications
- patient satisfaction
- time to follow up post-epidural removal.

Data collection process

Data will be collected from RMMCH once all relevant authorities have given the necessary approval. The labour ward admissions book will be used to determine the total number of patients in the specified study period. RMMCH uses a pre-printed single page epidural record that is manually completed by the anaesthetist administering the epidural (Appendix 1). Once the patient has completed the delivery process and the epidural catheter has been removed, the epidural record is placed in a file in the epidural sleep room. These completed records are then handed in to the consultant in charge of the epidural analgesia service and are kept in a secure office in the anaesthetic department.

The researcher only will collect data. Epidural records will not leave the hospital premises.

4.5.5 Data analysis

Data will be captured directly onto a Microsoft Excel spreadsheet and analysed in consultation with a biostatistician using Stata version 15 (StataCorp, USA). Descriptive and inferential statstics will be used. Categorical variables will be described using numbers and frequencies. Continuous variables will be described using means and standard deviations or medians and interquartile ranges, depending on the distribution of the data. Comparisons with the previous study will be done using Chi-squared or Fisher's exact test. A p value of 0.05 or less will be considered stasticially significant.

4.6 Significance of the study

The pain of labour is one of the most extreme types of pain a woman might experience in her lifetime (4-8). When poorly treated, it can have multiple deleterious effects for mother and child (5,7-16). It is well established that epidural analgesia is the gold standard for treating labour pain (17,18,33). Brennan et al (34) are of the opinion that pain management is a basic human right. As such, any health care service that is offered with the function of treating pain should have regular monitoring to ensure international standards are met as far as is possible, and that safety and efficiency are maintained. When RMMCH offered a 07:00 to

16:00 epidural analgesia service the epidural analgesia rate was 1.6%, the minor complication incidence was 22.6% and patient satisfaction was high at 98.4%. The service has been extending to a 24 hour service and it is important that the impact of this extension is now assessed.

4.7 Validity and reliability of the study

The validity of a study is the degree to which it accurately represents the variables being measured and the reliability of a study refers to its ability to be consistent and reproducible across a range of variables (32).

The following are measures to ensure validity and reliability:

- appropriate study design
- use of a retrospective design to prevent anaesthetists from changing their practice in response to study results
- a single researcher to collect data
- 1 in 10 data entries to be checked for accuracy of data capture
- data analysis in consultation with a biostatistician.

4.8 Potential limitations

Limitations refer to restrictions that may reduce the generalised applicability of a study (29).

The limitations of this study are as follows:

- the study is contextual to the patient population receiving care at RMMCH and may not be generalisable to other labour epidural analgesia services
- reliance on completed epidural records for data analysis.

4.9 Project outline

4.9.1 Time frame

Activity	July 2018	Aug 2018	Sept 2018	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	Mar 2019	Apr 2019
Proposal preparation										
Literature review										
Proposal submission										
Ethics approval										
Postgraduate approval										
Data collection										
Data analysis										
Draft article										
Submission										

4.9.2 Budget

Item	Price per page	Number of pages	Copies	Total
Proposal	1	20	10	R 200
Ethics	1	10	25	R 250
Post graduate form	1	2	6	R 12
Complete report	1	100	4	R 400
Grand total				**R 812**

The Wits Department of Anaesthesiology will incur the costs of paper and printing.

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4.11 Appendices

Appendix 1: Epidural record from RMMCH

LABOUR EPIDURAL CHART - RMMCH

Midwife (Contact number)

Anaesthsetist (Contact number)

Obstetrician (Contact number)

Date

Staring time

PATIENT DETAILS
- Name
- Hospital No.
- Age/d.o.b.
- Height
- Weight

ASSESSMENT
- Past Ø
- Past medical Hx
- Current medical
- Allergies
- Family Hx:
- NPO? Y ☐ N ☐
- A/W
- Prior allnalgesia
- Absence of C/I: Y ☐ N ☐
  Hypotension / Refusal / Bleeding anti-coagulation / ↑ CP / Fixed cardiac output
- Indication
- ASA Status 1 2 3 4 5
- Bloods
- FBC
- U & E
- INR/PTT

CONSENT (verbal + written)
I, the undersigned, agree to having an epidural catheter inserted for the purpose of analgesia during labour. The benefits, complications and risks, have both been explained to me.

Signature:

Witness:

Date:

Language translated: ☐Y ☐N

TIME XXhXX

TOP-UPS

Drugs: (Concentration and volume)

MAINTENANCE INFUSION

Drugs: (Concentration and volume)

LEVEL OF SENSORY BLOCK

L1/L2 ☐
L2/L3 ☐
L3/L4 ☐
L5/L6 ☐
L6/ST ☐
T12/L1 ☐

FOETAL HEART RATE
SpO_2 / suppl O_2

BP (mm Hg) + HR (bpm)

0 5 10 15 20 25 30 * * * 60 * * * 90 * * * 120 * * * 150 * * * 180 * * * 210 * * * 240 * * * 270 * * * 300 * * * 330 * * * 360

180 170 160 150 140 130 120 110 100 90 80 70 60 50 40

INSERTION
Loss of resistance to saline vs. air:
IV access:
Gauge + Site
Test dose: ☐
Preload/fluids given (specify type & amount):
Resuscitation equipment ☐
Aseptic field:
Gloves ☐ Gown ☐
Skin ☐ Mask ☐
Level of insertion
Local infiltration:
Needle type/size:
Distance to space:
Catheter fed in (cm):

DELIVERY
- Unassisted ☐
- Assisted ☐
  Forceps ☐
  Venthouse ☐
- Caesarian section ☐
- Spinal Anaesthetic epidural top-up ☐

Name of theatre:

Anaesthetist:

COMPLICATIONS OF INSERTION
- Multiple attempts ☐
- Bloody tap ☐
- Dural tap ☐
- Pain ☐
- Paraesthesia ☐

DAY 1 POST-PARTUM
Catheter out & tip visualised ☐
Patient satisfaction/pain relief:
in labour ☐ for delivery ☐ post-op ☐

POST DELIVERY COMPLICATIONS
- Pruitis ☐
- Backache ☐
- Nausea ☐
- Headache ☐
- Vomiting ☐
- Neurological ☐
- Hypotension ☐

Appendix 2: Permission from the gatekeeper of the records at RMMCH to access the epidural analgesia records

Re: Permission for research at RMMCH
Monday, July 16, 2018 3:46 PM
From: "Janine Wagner" <drjaninewagner@gmail.com>
To: "Andrea Duigan" <duigana@yahoo.com>
Raw Message Printable View

Hi
You are welcome anytime. The files are either in the epidural sleep room or in the consultants office.

Janine

On Mon, Jul 16, 2018 at 1:32 PM, Andrea Duigan <duigana@yahoo.com> wrote:
Good day Drs Kleyenstuber and Wagner

Please see attached requests for permission to conduct research at Rahima Moosa Mother and Child Hospital.

Kind regards,

Andrea Murphy

Appendix 3: Permission from the Head of the Clinical Unit of Anaesthesiology at RMMCH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Department of Anaesthesiology
Rahima Moosa Mother and Child Hospital

Tel: (011) 470-9303
Fax: 0865194183
E-mail: kleyenstuber@hotmail.com

17 July 2018

Attention: The Chair of the Human Research Ethics Committee

Permission to collect data in the Department of Anaesthesia at Rahima Moosa Mother & Child Hospital

I hereby grant permission for data to be collected in the Department of Anaesthesia at Rahima Moosa Mother & Child Hospital for the following MMED research project: A follow-up study of the extended epidural analgesia service at a regional hospital in Gauteng.

Kind Regards

Dr T Kleyenstuber

Head: Clinical Unit - Anaesthesiology
Rahima Moosa Mother and Child Hospital

Appendix 4: Permission from the Head of the Department of Anaesthesiology

WITS UNIVERSITY

DEPARTMENT OF ANAESTHESIOLOGY
UNIVERSITY OF THE WITWATERSRAND,
JOHANNESBURG
Tel.(011)933-9334/5 / Fax (011)933-1843

FACULTY OF HEALTH SCIENCES

18 July 2018

Ms Zanele Ndlovu
Administrative Officer
Human Research Ethics (Medical)

RE: DR ANDREA LYNNE MURPHY STUDENT NUMBER 0504486K

I herewith grant permission to Dr Andrea Lynne Murphy to conduct the study titled "A follow-up of the extended labour epidural analgesia service at a regional hospital in Gauteng" in the University of the Witwatersrand Department of Anaesthesiology.

Yours sincerely,

Prof Christina Lundgren
Head of Department of Anaesthesiology
University of the Witwatersrand

Clinical Head, Department of Anaesthesiology
Chris Hani Baragwanath Academic Hospital

Phone: +27 825574605
Fax: +27 865532529

Appendix 5: Request to the RMMCH Research Committee

Dr Andrea Lynne Murphy
Department of Anaesthesiology
University of the Witwatersrand

Attention: The Research Committee at Rahima Moosa Mother and Child Hospital

Re: A follow-up study of the extended epidural analgesia services at a regional hospital in Gauteng

To Whom it May Concern

I am a registrar in the Department of Anaesthesiology. As part of the research component for my MMed, I would like to conduct a follow-up study of the labour epidural analgesia services at Rahima Moosa Mother and Child Hospital.

Dr Tristan Leonard conducted the original audit in 2014, entitled "An audit of the labour epidural analgesia service at a regional hospital in Gauteng". At the time of his study the labour epidural analgesia service was only offered on weekdays from 7am to 4pm. Subsequent to this, the service has been extended to a 24 hour service.

My research would require permission to access completed labour epidural analgesia records from 1 July 2017 to 31 June 2018. Data collection will take place in a secure location on the hospital premises and no charts will be removed from the hospital premises.

This study has been approved by the Human Research Ethics Committee (Medical) (number xxx) and the Graduate Studies Committee of the University of the Witwatersrand.

Yours sincerely,

Dr Andrea Murphy
0738284172
duigana@yahoo.com

Appendix 6: Permission to use the data collection instrument

16/07/2018

Dear Dr Murphy

Re: request to use data collection tool

You may use the data collection tool from my study "An audit of the labour epidural analgesia service at a regional hospital in Gauteng".

Kind regards
Dr TGA Leonard
MBBCh (WITS) DA (SA) FCA (SA) MMed (Anaes)
Specialist anaesthetist
Chris Hani Baragwanath Academic Hospital

Appendix 7: Data collection tool – general demographics

General demographics	Total deliveries during study period Total caesarean sections performed Epidural labour analgesia records retrieved Epidural labour analgesia records lost to follow up

Appendix 8: Data collection tool – patient demographics

Study number	
Variable	
Patient demographics	Age Parity Mode of delivery
Primary indication for epidural	BMI > 45kg/m^2 Cardiac condition Preeclampsia Augmentation of labour Primigravida Other
Professional designation of doctor inserting epidural	Registrar – year 1/2/3/4 Medical officer Consultant
Epidural technique	Loss of resistance technique Saline Air
Epidural maintenance	Continuous infusion Bolus dosing (manual or pump-driven) PCEA
Complication	Back pain Hypotension Pruritus Local anaesthetic toxicity Nausea and vomiting Post-dural puncture headache or unintentional dural puncture Incomplete or patchy block Residual paraesthesia Other
Patient satisfaction	Not happy Happy
Time to follow up post epidural removal	Within 24 hours Later than 24 hours

Section 5: Annexures

5.1 Ethics approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Andrea Murphy et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M180802

NAME: (Principal Investigator)	Dr Andrea Murphy et al
DEPARTMENT:	Anaesthesiology Rahima Moosa Mother and Child Hospital
PROJECT TITLE:	A follow-up study of the extended labour epidural analgesia service at a regional hospital in Gauteng
DATE CONSIDERED:	31/08/2018
DECISION:	Approved Unconditionally
CONDITIONS:	
SUPERVISOR:	Helen Perrie
APPROVED BY:	Doctor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	

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 on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, 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**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **August** and will therefore be due in the month of **August** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.2 Graduate studies approval

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

05 November 2018
Person No: 0504486K
PAG

Dr AL Murphy
24 Agapanthus Street
Brackenhurst
1449
South Africa

Dear Dr Andrea Murphy

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *A follow-up study of the extended labour epidural analgesia service at a regional hospital in Gauteng* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

5.3 Turnitin report

0504486k:Turnitin.docx

ORIGINALITY REPORT

19%	12%	10%	13%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Submitted to University of Witwatersrand Student Paper	1%
2	journals.lww.com Internet Source	1%
3	sajog.org.za Internet Source	1%
4	repo.lib.tokushima-u.ac.jp Internet Source	<1%
5	painrelief-doc.com Internet Source	<1%
6	es.scribd.com Internet Source	<1%
7	onlinelibrary.wiley.com Internet Source	<1%
8	almacen-gpc.dynalias.org Internet Source	<1%
9	soap.org Internet Source	<1%

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | FACULTY OF HEALTH SCIENCES

29th July, 2019

The Chairperson
Graduate Studies Committee
Faculty of Health Sciences
University of the Witwatersrand

Dear Madam,

Re: M Med: **A follow-up study of the extended labour epidural analgesia service at a regional hospital in Gauteng**

Dr Andrea Murphy, student number: 0504486K, has submitted her research report to Turnitin which revealed a similarity index of 19%. These similarities appear not to be plagiarism but mainly the use of common terminology and phrases specific to the topic of the research. Despite the filter being set to exclude short phrases of less than five word, this has not been done.

Yours sincerely,

H CPerrie

Helen Perrie
Supervisor

1

5.4 RMMCH Research committee approval

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

RAHIMA MOOSA MOTHER AND CHILD HOSPITAL

RAHIMA MOOSA MOTHER AND CHILD HOSPITAL
Enquiries : Karen Marshall
Tel : (011) 470 9284
Fax : 086 553 4623
Email : Karen.Marshall@wits.ac.za

TITLE OF RESEARCH PROJECT:
"A follow-up study of the extended epidural analgesia service at a regional hospital in Gauteng"

PRINCIPAL INVESTIGATOR:
Dr Andrea Murphy
Department of Anaesthesiology
Faculty of Health Sciences
University of the Witwatersrand

SUPERVISOR:
Ms. Helen Perrie/Prof Juan Scribante/Dr Tristan Leonard
Department of Anaesthesiology

NHRD REF NO: GP_201811_015

Dear Dr. MURPHY,

Permission is granted for you to conduct the research as indicated in the title above.

The terms under which this permission is granted is contained in the Researcher Declaration form that you have signed. Failure to comply with these conditions will result in the withdrawal of such permission.

It is crucial for you to inform the Research Coordinator, Karen Marshall of the actual start and end dates of your study. This could be done by e-mail.

Should the study commence more than 12 months after receipt of this approval letter you will have to go through the process of applying again.

You are strongly advised to keep a signed copy of the declaration form so as to ensure that the terms of this agreement are complied with at all times.

Yours sincerely,

DR EDWARD HANK
ACTING CHIEF EXECUTIVE OFFICER
2018:12:13

ADDRESS: Cnr FUEL & OUDSTHOORN STREET CORONATIONVILLE 2093 / PRIVATE BAG X20 NEWCLARE 2112 JHB