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An audit of the labour epidural analgesia service at a regional hospital in Gauteng

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An audit of the 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, in partial fulfillment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology

Johannesburg 2017

Declaration

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

_____

Tristan Gavin Alexander Leonard

21st day of September 2017 in Johannesburg

Abstract

Background

Neuraxial analgesia in the form of continuous epidural infusion has been shown to be the most effective analgesic strategy for the labouring mother. In developed countries data are readily available as to the number of women receiving labour epidural analgesia as well as the complication rates of labour epidurals. Data for South Africa on labour epidural analgesia services are limited and there was no published data for Rahima Moosa Mother and Child Hospital (RMMCH).

Methods

A retrospective audit using consecutive convenience sampling was done reviewing all epidural records at RMMCH from 1 January to 31 December 2014.

Results

During the study period labour epidural analgesia was administered for 187 (1,6%) of 11 853 deliveries. Epidural records were collected for all labour epidurals administered. The most common indications documented were labour analgesia (41,7%) and primigravida (28,9%). Labour epidurals were not administered for specific medical conditions. The incidence of complications was 22,6% and these complications were minor and self-limiting. Hypotension was the most common complication (12,3%). Patient satisfaction with labour epidural analgesia, where documented, was high (98,4%).

Conclusions

This audit revealed a low incidence of labour epidural analgesia at RMMCH during the study period. The incidence of complications was in keeping with that seen in developed countries. Poor documentation was noted to be a problem.

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List of abbreviations

LOR: loss of resistance

RMMCH: Rahima Moosa Mother and Child Hospital

SAJAA: South African Journal of Anaesthesia and Analgesia

TENS: transcutaneous electrical nerve stimulation

TL: Tristan Leonard

USA: United States of America

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Section 1: Literature Review

1.1 Introduction

In this section the literature regarding labour and labour analgesia will be reviewed.

1.2 Labour

In this section the anatomy any physiology of labour pain as well as its severity and effects on maternal and foetal wellbeing will be discussed.

1.2.1 Anatomy and physiology of labour pain

Pain is defined by the International Association for the Study of Pain as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." (1) The pain of labour is likely to be the most severe that a woman will experience in her lifetime (2). Knowledge of the anatomy and physiology of labour pain provides for the rational treatment of this pain (2).

Anatomically the female genital tract can be divided into internal and external organs. The internal female genital organs are the vagina, uterus, uterine tubes and ovaries. The vagina receives both somatic and visceral innervation. Somatic innervation is limited to the inferior one quarter of the vagina and is conveyed by the deep perineal nerve, a branch of the pudendal nerve, and has its cell body in the S2 to S4 ganglia. The remaining three quarters of the vagina and the entire uterus receive visceral innervation from the uterovaginal nerve plexus, which is part of the inferior hypogastric plexus. This plexus contains sympathetic, parasympathetic and visceral afferent fibres. (3)

The external female genital tract includes the mons pubis, labia majora and minora, clitoris, vestibule and vestibular glands. These are commonly called the vulva. The vulva receives innervation from the anterior and posterior labial nerves, derived from the ilioinguinal nerve, the genital branch of the genitofemoral nerve and the pudendal nerve. (3)

Pain in the first stage of labour, from onset of contractions to full cervical dilatation, is caused by physical distension of the lower segment of the uterus and cervical dilatation. This causes tissue injury, fascial stretching and tears. This pain is visceral in nature and is transmitted via C type pain fibres, which accompany the sympathetic nerve fibres. These fibres enter the spinal cord at T10 to T12 and L1 and terminate in the ipsilateral superficial and deep dorsal horn and the ventral horn of the spinal cord. They also cross the midline to the contralateral dorsal horn and undergo rostrocaudal extension. As a result of the nature of these synaptic connections this visceral pain is often poorly localised and is referred to the dermatomes supplied by these spinal segments. (2, 4)

During the second stage of labour, full cervical dilatation to delivery of the foetus, the presenting part of the foetus descends and now compresses structures in the pelvis as well as stretching the perineum and vagina. This causes additional somatic pain from the vagina and perineum. The pain is much sharper and more localised than the pain from the first stage and is transmitted via the pudendal nerves to the spinal cord at the level of S2 to S4 where they synapse in the superficial ipsilateral lamina of the dorsal horn. (2, 4)

1.2.2 Severity of labour pain

Lamaze (5) in 1970 promised women that with proper childbirth training they could have painless labour. Melzack (6) and subsequent authors have disproved this promise. Labour pain is acknowledged to be severe and distressing, however it is a subjective experience. This is owing to widespread variation in the reported severity

of pain as determined by age, parity, previous painful experiences, maternal and foetal weight, socioeconomic status, level of childbirth training and anaesthetic intervention. (6)

Studies from both developed and developing countries have noted the severity of labour pain. Data obtained from Canadian and British women in 1984 using the McGill Pain Questionnaire rated labour pain as more severe than the pain of cancer or having a digit amputated without anaesthesia (6, 7). Ranta et al (8) in 1995 conducted a prospective survey of the experiences of labour pain in 1091 Finnish parturients and found that 80% of women described their pain as very severe to intolerable. Furthermore, 51% of these women complained of inadequate analgesia during their labour.

In developing countries labour pain is consistently rated as moderate to severe. In Kuwait in 1991, 90% of the 275 women surveyed rated their pain as moderate to severe with 73% of these women saying that their maximal pain was intolerable (9). In a Chinese study in 1999, 157 out of 303 women described their pain as intolerable (10). A descriptive study of 300 parturients in Nepal during 2008 and 2009 used a visual analog scale of pain and found that 57% of women described their labour pain as moderate and 32% as severe (11) and in India, 47% of women surveyed described their labour pain as moderate with 21% describing it as severe to intolerable; furthermore 93% of these women said that they were fearful of the pain that would occur during their childbirth (12). In Nigeria, a study in 2014 on the perception of labour pain found that 52% of parturients rated their labour pain as severe (13).

In South Africa, Mugambe et al (14) investigated the knowledge and attitudes toward pain relief during labour of women attending the antenatal clinic at Cecilia Makiwane Hospital. Interviews were conducted on 151 women and of those who had previously experienced labour pain 85,6% described it as moderate or severe and 65,3% of these women found their pain experience to be unacceptable (14).

1.2.3 Effects of labour pain on maternal and foetal wellbeing

Labour pain has direct and indirect effects on the mother and foetus (2). Lederman et al (15) described, in 1977, the changes in catecholamine (adrenaline and noradrenaline) levels that occurred in 21 otherwise healthy parturients from the third trimester of pregnancy through labour and delivery. The authors found a statistically significant increase (doubling and up to tripling) in the levels of catecholamines during labour and immediately postpartum.

These increases in catecholamine levels have significant effects on maternal physiology. This includes an increase in heart rate and cardiac output and hence increases in myocardial oxygen demand. Labour pain is also a potent respiratory stimulant leading to hyperventilation and maternal respiratory alkalosis; this causes a left shift of the oxygen-haemoglobin dissociation curve and impairs oxygen delivery to the foetus. (2, 4, 16)

Lederman et al (17, 18) described further deleterious effects of pain and increased maternal catecholamine levels on foetal health. Increased levels of adrenaline and noradrenaline were associated with prolonged labour, stronger uterine contraction with decreased placental blood flow and decreases in foetal heart rate. Such adverse effects may not be tolerated in at risk foetuses and could lead to foetal distress and poor neonatal outcomes (2).

The physiological effects of labour pain are not the only deleterious effects that should be considered. Harmful psychological outcomes following traumatic and painful childbirth have been described in the literature. In 2008 Eisenach et al (19) enrolled 1288 women in a survey to determine the impact of pain during childbirth on subsequent mental health. It was found that severe postpartum pain was independently associated with postpartum depression and that women who experienced severe postpartum pain had a threefold increased risk of postpartum depression. Indeed prior to this, in the 1990s, a series of case studies conducted by Ballard et al (20) and a cross sectional study by Wijma et al (21) showed that

traumatic childbirth can be a risk factor for the development of posttraumatic stress disorder.

1.3 Labour analgesia

1.3.1 History

The father of labour analgesia is considered to be James Young Simpson. He was a professor of midwifery at the University of Edinburgh and pioneered the use of diethyl ether during childbirth. On January 19, 1847, three months after the discovery of the anaesthetic properties of ether, he successfully used it for a woman with an abnormal pelvis during labour and delivery. This was initially met with severe criticism by the greater medical fraternity but gradually gained widespread acceptance. Under the care of another pioneer of anaesthesia, Jon Snow, Queen Victoria requested ether during the delivery of her eighth child, Prince Leopold; and this led to women all over Great Britain requesting analgesia more frequently during labour. In this way the spread of the use of ether as an analgesic in labour was patient, rather than physician, driven. (2, 22)

Early in the twentieth century two more advances were made in the practice of labour analgesia. Gauss of Freiberg popularised *Dämmerschlaff,* meaning “twilight sleep”. This combination of morphine and scopolamine was the first time that the use of opioids became widespread in obstetric practice. More importantly, the use of regional anaesthesia in obstetrics began to be described. Carl Koller, the father of regional anaesthesia, first used cocaine for eye surgery in 1884. In 1900 Oskar Kreis used cocaine for spinal anaesthesia in a pregnant patient for the first time. This spawned the investigation of various regional anaesthesia techniques for labour analgesia including local nerve blocks, spinal and epidural analgesia. (2, 22)

While James Young Simpson is regarded as the pioneer of labour analgesia, it is perhaps interesting to note that Oskar Kreis has not received the acclaim he

deserves for advancing regional analgesia in obstetrics for this is now accepted as the gold standard in labour analgesia.

1.3.2 Current methods of labour analgesia

Non-pharmacological and pharmacological methods of labour analgesia are discussed for background. The main focus of this study is labour epidural analgesia, which is discussed in detail.

Non-pharmacological

Numerous non-pharmacological modalities exist for the alleviation of labour pain; these include, but are not limited to:

- antenatal education
- partner or doula support
- massage
- intradermal water injections
- transcutaneous electrical nerve stimulation (TENS)
- acupuncture
- hypnosis (2).

Antenatal childbirth education consists of group or individual classes in which expectant mothers with or without a significant other are provided with information regarding pregnancy, labour and parenting (23). These classes are varied and data regarding their effectiveness is limited (2).

Continuous labour support is the non-medical physical and emotional support given to a woman throughout the childbirth process. This can be in the form of a significant other or trained professional called a doula. Two systematic reviews by Simkin et al (23, 24) showed that women who received continuous labour support had significantly less pharmacological requirements, needed fewer assisted

deliveries, had fewer cases of surgical intervention, shorter labour duration and better foetal outcomes than those women who laboured alone.

Massage therapy involves the systematic manipulation of the soft tissues of the body. It has been shown to reduce pain intensity during labour as reported on visual analogue scales but does not reduce maternal analgesic consumption. (2, 23, 24)

Intradermal water blocks are postulated to relieve lower back pain during labour (2). The blocks are performed by injecting 0,05 to 0,1 mL of sterile water subcutaneously into four locations on the lower back. Pain is experienced for approximately 20 to 30 seconds after the injection with lower back pain then subsiding for 30 to 120 minutes after injection. Systematic review agrees that intradermal water blocks decrease the need for other intrapartum analgesics. (23-25)

TENS is the use of a nerve stimulator to emit low voltage electrical impulses at varying frequencies and intensities. For labour pain relief specifically, electrodes are placed at the level of T10 to L1 and S2 to S4 paravertebrally. The parturient then controls the frequency and intensity of impulses delivered. Studies on the efficacy of TENS remain inconsistent. Patient perception of pain is decreased but there is no decrease in analgesic consumption. (2, 23, 24, 26)

Acupuncture is a part of traditional Chinese medicine where the body is divided in 12 channels of energy with 365 acupuncture points along each channel (2). Outcomes on the efficacy of acupuncture during labour are varied. Hantoushzadeh et al (27) found in a randomised controlled trial on 150 women that acupuncture had subtle influences on pain perception in labour.

Hypnosis refers to an altered state of consciousness in which perceptions do not reach conscious awareness. Hypnotherapy is the clinical use of suggestions in a person under hypnosis to achieve a specific goal, in this cause the lessening of pain perception. (28) Two systematic reviews in 2004 by Cyna et al (28) and by Simkin et al (23) and a Cochrane review in 2006 (29) concluded that analgesic consumption

was decreased in women undergoing hypnotherapy during labour. All three review articles stated that poor randomisation, lack of blinding and small samples sizes may have resulted in an overestimation of the efficacy of hypnotherapy and as such, larger randomised control trials are necessary to establish the true efficacy of this therapy (2, 23, 28, 29).

The experience of pain is, by definition, subjective and as such it is difficult to reliably determine the effectiveness of pain relief, especially non-pharmacological methods. These methods show promise but data is conflicting and more research is required to fully determine their efficacy.

Pharmacological

Systemic pharmacological analgesia takes the form of inhaled nitrous oxide or systemic opioids. Nitrous oxide has been used for more than 100 years as a labour analgesic and is still popular in the United Kingdom and parts of Europe (30). Entonox is a mixture of 50% nitrous oxide and 50% oxygen that is commonly used. The use of this mixture remains controversial because there is conflicting evidence regarding its efficacy and it is not widely used outside of the United Kingdom (2, 31).

Systemic opioids are used widely around the world for labour analgesia. Their effectiveness is limited and there is a high incidence of maternal and foetal side effects. When compared to regional anaesthesia they provide significantly poorer analgesia. (2, 32)

Regional anaesthesia

Regional nerve blocks can be performed with an understanding of maternal genital tract anatomy. Bilateral paracervical plexus or lumbar sympathetic blocks can alleviate pain in the first stage of labour and pain the second stage can be blocked with bilateral pudendal nerve blocks. These techniques are not widely employed. (2)

Neuraxial analgesia

Neuraxial analgesia is the most complete, reliable effective method for labour analgesia. Less commonly used forms are single shot spinal, caudal epidural and continuous spinal anaesthesia. Performed most commonly are continuous lumbar epidural and combined spinal-epidural analgesia and these have been validated by numerous randomised controlled trials. (2)

1.4 Epidural analgesia

Lumbar epidural analgesia involves the process of inserting an epidural needle into the lumbar, usually L3 to L4, region of a parturient to identify the epidural space. This can be done with the patient sitting or in the lateral position. A midline approach with loss of resistance to air or saline technique is employed in most patients. Once the epidural space is located a 20 gauge catheter is fed through the needle into the epidural space to the desired length, the needle is removed and the catheter is secured with a transparent dressing. (2, 16, 33)

Once the catheter is in situ a test dose of lignocaine or bupivacaine with adrenaline is used to determine whether the catheter is intrathecal or intravenous, rather than in the epidural space. When the anaesthetist is satisfied that the catheter is in the correct place analgesia is started with a bolus of local anaesthetic and maintained either by continuous infusion or bolus dosing of a mixture of dilute local anaesthetic and a low dose short-acting opioid. (2, 16, 33)

1.4.1 Current evidence

Numerous authors highlight the effectiveness of epidural analgesia for the alleviation of childbirth pain as being able to provide complete, reliable and effective analgesia with no maternal or foetal sedation (2, 33-35). A large trial in 2003 by Dickinson et al (36) was conducted on 992 women in which two groups were randomised; the first group received epidural analgesia and the second group

continuous midwifery support with supplemental pain relief. Pain scores were significantly reduced in the epidural analgesia group (p<0,001). In another study in 2004 by Sharma et al (32) 2703 women were assigned to either an epidural analgesia group or an intravenous pethidine group. Pain scores as measured by a visual analogue scale were significantly lower and patient satisfaction was significantly higher in the epidural analgesia group.

Not only is labour epidural analgesia effective in reducing pain and increasing maternal satisfaction with their childbirth process, it is also beneficial in terms of maternal health. Epidural analgesia in labour was been shown by Shnider at al (37) in 1983 to decrease maternal catecholamine levels and as such have beneficial effects of maternal heart rate, blood pressure and cardiac output. Epidural analgesia is often recommended for parturients with hypertension or underlying cardiac conditions (16, 38).

Epidural analgesia has also been shown to be beneficial for maternal mental health. Painful or traumatic labour was shown by Eisenach et al (19) , Ballard et al (20), Wijma et al (21) and to be associated with adverse psychological outcomes including postpartum depression and posttraumatic stress disorder and as such effective pain relief can prevent such. Indeed, Ding and Dong et al (39) showed in a prospective cohort study in 2009 that epidural labour analgesia is associated with a decreased risk of postpartum depression, odds ratio of 0,31 compared with no epidural.

1.4.2. Technique

There has been much debate about whether loss of resistance (LOR) to air or to saline should be used to locate the epidural space. Numerous reviews and trials have yielded conflicting evidence. A literature review by Shenouda and Cunningham (40) in 2002 found that LOR to air was associated with more cases of inadequate analgesia, segmental blocks and nerve root compression and suggested that LOR to a small amount of saline is the best technique. A study by Norman et al (41) in 2006 randomised 50 patients into two groups, namely LOR to air or to saline. No

difference in onset of pain relief and quality of pain relief was found between the two groups but again there was a significant increase in the incidence of segmental blockade with LOR to air (41). This is in contrast to a 2010 retrospective study by Segal and Arendt (42) that found no statistically significant difference between LOR to air and saline.

1.4.3 Safety and complications

Complications of epidural analgesia include minor and major complications related to maternal wellbeing as well as complications related to the effect of epidural analgesia on labour itself.

The incidence of minor complications of labour epidurals is varied. A prospective analysis of 10 995 epidurals in Australia by Paech et al (43) demonstrated hypotension, as defined by a greater than 30% decrease in systolic blood pressure, occurred in 4,9% of cases. In Tygerberg, hypotension, defined as a greater than 20% drop in systolic blood pressure was identified in 13,4% of women undergoing epidural (38). Accidental dural puncture occurred in 0,6% of women in Australia with no measure of postdural puncture headache (43) and an American study by Singh et al (44) showed an accidental dural puncture incidence of 0,73% with postdural puncture headaches occurring in 0,49% of parturients. Failed anaesthesia occurred in 1,7% and 0,65% of women respectively (43, 44).

In the late 1970s and early 1980s there was concern that labour epidural analgesia was associated with chronic backache post delivery (45, 46). This has not been supported by the literature and a randomised controlled trial by Howell et al (47) in 2001 concluded that “this study provided no evidence to support the suggestion of a direct association between the use of epidural anaesthesia in labour and the incidence of long term backache.”

The incidence of serious major complications from epidural anaesthesia is low. Serious complications are defined as: death, paraplegia, cardiac arrest, respiratory

failure, seizures and meningitis (48). In France, Auroy et al (48) identified five of these serious complications out of 29 732 epidurals in a one year period. In the Third National Audit Project of the Royal College of Anaesthetists Cook et al (49) found the incidence of permanent harm, including death, to be 0,6 per 100 000 cases.

Maternal fever is a potentially serious complication of labour epidural analgesia and requires more investigation. The mechanism of maternal pyrexia is unknown but is thought to involved thermoregulatory and inflammatory mechanisms. An incidence of 1 to 46% has been shown in various studies. (50)

The effect of labour epidural analgesia on the progress of labour has stirred much debate and controversy. Clear from the literature is that epidural analgesia is associated with prolonged labour, specifically the second stage of labour, and increases the risk of instrumental delivery. Labour epidural analgesia does not increase the incidence of caesarian section delivery. (51)

1.4.4 Guidelines

There are no published guidelines on the use of regional anaesthesia for the management of labour pain in South Africa however guidelines from the United Kingdom and United States are available.

In the United Kingdom the Association of Anaesthetists of Great Britain & Ireland and Obstetrics Anaesthetists' Association (52) and National Institute for Health and Care Excellence (53) guidelines on regional anaesthesia for women in labour provide for a consultant led service to provide epidural analgesia to all women in labour. There should be a 24 hour a day, seven days a week service to provide epidural analgesia to all women in the latent or active phase of labour. Informed consent is mandatory and full anaesthetic and resuscitation facilities must be available. Anaesthetic and nursing staff should be educated in the use and management of epidural analgesia. These guidelines also encourage the development of local hospital-based guidelines for the management of labour epidural analgesia.

The American Society of Anesthesiologists Task Force on Obstetric Anesthesia released practice guidelines for obstetric anesthesia in 2007. These guidelines advocate that maternal request is justification for pain relief and state that neuraxial analgesia is superior to other methods. Guidelines also recommend that neuraxial analgesia is provided by trained staff in a setting equipped to deal with all possible complications of neuraxial analgesia. They also recommend the use of the lowest possible concentration of local anaesthetic and opioid to achieve maternal pain relief. (54)

1.4.5 Labour epidurals in developed countries

The American Society of Anesthesiologists and American College of Obstetrics and Gynecology state that "in the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labour" (55). This view is reflected in the high incidence of labour epidural analgesia being given to laboring women. In the United Kingdom the rate of labour epidural analgesia has ranged from 16,5% to 24% over the last 20 years (56, 57). In North America the epidural rate is even higher with 58,3% of laboring women in Canada (58)and 61% of women in the USA receiving labour epidurals (59).

1.4.6 Labour epidurals in developing countries

Data on the incidence of labour epidural analgesia in developing countries is limited but in general there is low provision of analgesia in any form. In China, a study by Qian et al (10) on obstetric practice simply stated that "pain relief was rarely given" and no epidurals were performed on the 599 women interviewed. In Nigeria a study on the perception of labour pain among parturients revealed that only 27% of parturients received analgesia during their labour and this was exclusively in the form of parenteral opioids (13). A further study of the practices of health care providers in Nigeria revealed that none of the 95 respondents had placed a labour epidural in the four weeks before the study (60)

1.4.7 Patient satisfaction

Multiple studies have consistently shown high levels of patient satisfaction with labour epidural analgesia. Howell et al (47) in 2001 enrolled 369 primigravid women and allocated them to two groups receiving epidural or non-epidural analgesia, 85% of women in the epidural group were satisfied or very satisfied with their analgesia. Sharma et al (32) in 2004 found that 95% of patients who received epidural analgesia reported their satisfaction as good or excellent. Factors associated with dissatisfaction with labour epidural analgesia include incomplete analgesia, prolonged labour and epidural time and the need for instrumental delivery (2, 38, 61).

1.4.8 Tygerberg Hospital audit

Published data regarding the labour epidural services at South African public hospitals is limited but a 2014 audit by Jacobs-Martin et al (38) on the labour epidural analgesia service at Tygerberg Hospital has provided some insight. This was a retrospective audit of the labour epidural analgesia records over a period of 1 year from 1 January 2012 to 31 December 2012.

The aims of the audit were to "establish the incidence of epidural analgesia in women in labour, the indications for this approach, associated complications and overall patient satisfaction over a one year period in a tertiary referral hospital in the Western Cape." Study variables included "total number of women in labour, number of epidural analgesia procedures, patient demographics, indication, complications, epidural technique, experience of the anaesthesiologist and patient satisfaction." (38)

Out of a total of 7005 deliveries managed at Tygerberg Hospital during the study period, 3032 underwent caesarian section delivery and 3973 underwent normal or

assisted vaginal delivery. Epidurals were placed for 157 women, representing 2,2% of labouring women. (38)

Epidural analgesia in this unit at Tygerberg Hospital is not placed on patient request but rather for a medical indication as identified by the obstetrician on call. The main indications for epidural analgesia were preeclampsia, body mass index greater than 45kg/m^2 and cardiac conditions. Second year registrars performed the most epidurals with an equal split amongst the first, third and fourth year registrars. In terms of anaesthetic technique the midline approach with loss of resistance to saline was used most often. (38)

Follow up of patients was done within 24 hours in 47% and after 24 hours in 16% (24 patients) of cases. No time to follow up was recorded in the remaining cases. Of those cases followed up after 24 hours, 17 occurred within 48 hours, six within 72 hours and one after 74 hours post insertion. (38)

Complications were identified in 32,2% of patients. Hypotension as defined by the authors as a "greater than 20% decrease from a baseline systolic blood pressure taken before commencing epidural placement" occurred in 13,4% of patients. Lower back pain at the time of follow up was present in 7,4% of patients; unintentional dural puncture was defined as "cerebrospinal fluid observed or aspirated from the epidural needle or the epidural catheter" and occurred in 4% of epidurals. Other complications included post-dural puncture headache (3,4%) and nausea and vomiting (2,7%). There was one case of residual parasthesia, which resolved before discharge. A serious complication occurred in one patient who had undergone an uneventful vaginal delivery and whose epidural bupivacaine infusion was connected to an IV line post delivery. She developed seizures and went into cardiac arrest, which was treated with cardiopulmonary resuscitation and intravenous lipid emulsion. Resuscitation was successful and the patient was discharged home with no residual adverse effects. (38)

The majority, 86% of patients reported being happy or very happy with their epidural analgesia. (38)

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1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3-dimensional reconstruction by high-resolutional CT scanning. Otolaryngol Head Neck Surg. 2005 Mar;132(3):429-34.

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Section 3

An audit of the labour epidural analgesia service at a regional hospital in Gauteng

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Keywords

Epidural, analgesia, labour, indications for labour epidural, complications of labour epidural, patient satisfaction with labour epidural

Abstract

Background
Neuraxial analgesia in the form of continuous epidural infusion has been shown to be the most effective analgesic strategy for the labouring mother. In developed countries data are readily available as to the number of women receiving labour epidural analgesia as well as the complication rates of labour epidurals. Data for South Africa on labour epidural analgesia services are limited and there was no published data for Rahima Moosa Mother and Child Hospital (RMMCH).

Methods
A retrospective audit using consecutive convenience sampling was done reviewing all epidural records at RMMCH from 1 January to 31 December 2014.

Results
During the study period labour epidural analgesia was administered for 187 (1,6%) of 11 853 deliveries. Epidural records were collected for all labour epidurals administered. The most common indications documented were labour analgesia (41,7%) and primigravida (28,9%). Labour epidurals were not administered for specific medical conditions. The incidence of complications was 22,6% and these complications were minor and self-limiting. Hypotension was the most common complication (12,3%). Patient satisfaction with labour epidural analgesia, where documented, was high (98,4%).

Conclusions
This audit revealed a low incidence of labour epidural analgesia at RMMCH during the study period. The incidence of complications was in keeping with that seen in developed countries. Poor documentation was noted to be a problem.

Conflicts of interest

We declare that we have no financial or personal relationships, which may have inappropriately influenced the writing of this paper.

Introduction

All humans are faced with episodes of pain in their lifetime; the experience of pain can range from mild and self-limiting to severe and debilitating. The pain that a woman experiences during childbirth can arguably be described as the most severe pain that she will experience in her life.[1,2] This pain has been described as being worse than cancer pain or having a digit amputated without anaesthesia.[3]

Not only is this pain distressing for the mother but it can also have detrimental effects on maternal and foetal wellbeing. Activation of the sympathetic nervous system due to pain leads to large rises in circulating adrenaline and noradrenaline levels.[4] These increases in catecholamine levels have significant effects on maternal physiology, especially for mothers with cardiac conditions such as valvular heart disease, cardiomyopathy and ischaemic heart disease. This includes an increase in heart rate and cardiac output which leads to increases in myocardial oxygen demand, placing the myocardium at risk for ischaemia, as well as causing a decrease in placental blood flow.[5] This decrease in placental blood flow can cause foetal hypoxia and acidosis. Labour pain is also a potent stimulant of respiratory drive leading to hyperventilation, with a subsequent increase in minute ventilation and maternal respiratory alkalosis; this causes a left shift of the oxygen haemoglobin dissociation curve and impairs oxygen delivery to the foetus.[6]

Untreated labour pain can also have detrimental psychological effects on mothers. In the 1990s, a series of case studies conducted by Ballard et al[7] and a cross sectional study by Wijma et al[8] showed that traumatic childbirth can be a risk factor for the development of posttraumatic stress disorder with subsequent long term effects on maternal mental health and maternal-foetal bonding. Furthermore, in 2008, Eisenach et al[9] enrolled 1288 women in a survey to determine the impact of pain during childbirth on subsequent mental health. It was found that severe peripartum pain was independently associated with postpartum depression and that women who experienced severe peripartum pain had a threefold increased risk of posttraumatic stress disorder.

Due to these well described adverse effects of pain in labour, there is a worldwide effort toward ensuring mothers are offered adequate analgesia in the peripartum period. Studies and reviews have been conducted over a number of years and there is consensus that lumbar epidural analgesia is the gold standard for labour analgesia, by providing the most effective, reliable and flexible method of pain relief during labour.[1, 10, 11]

According to the American Society of Anesthesiologists and American College of Obstetrics and Gynecology, "in the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labour".[11] This is reflected in the number of women receiving epidural analgesia in developed countries with rates in the United Kingdom[12] and in large hospitals in the United States of America (USA)[13] being reported as 49,3% and 61% respectively.

Data regarding the number of women receiving labour epidural analgesia in developing countries is limited but is assumed to be much lower than in developed countries. Data for South Africa is also limited. A recent audit at a tertiary public hospital in the Western Cape revealed that only 2,2% of labouring mothers received labour epidural analgesia and that epidural placement was done for a medical indication upon obstetrician request and not on patient request.[14]

Epidurals are considered safe but when serious complications occur they can be fatal or lead to permanent harm.[6] An audit by the Royal College of Anaesthetists in 2009[15] found the incidence of permanent harm after epidural to be 0,6 per 100 000 cases (95% CI 0 – 3,4) and a survey in France found an incidence of serious events related to obstetric epidural to be less than 5 in 10 000.[16] Data on complications with respect to obstetric epidural analgesia is again limited in South Africa with the audit in the Western Cape showing a serious complication rate of 0,7%.[14]

There are no data on the labour epidural analgesia service at Rahima Moosa Mother and Child Hospital (RMMCH) and the aim of this study was to describe the labour epidural analgesia service at RMMCH over the period of one year.

Methods

A retrospective, contextual, descriptive research design was followed. Approval to conduct the study was obtained from the University of the Witwatersrand Human Research Ethics Committee (Medical) and other relevant authorities.

The standard, existing labour epidural service at RMMCH during 2014 was a Monday to Friday office hour service. An anaesthetist (medical officer or registrar) was on call for labour ward to administer epidurals in consultation with the obstetric staff. The anaesthestist was also able to identify patients during the day and offer an epidural after discussion with the responsible nursing sister. Informed, written consent for the epidural was obtained prior to insertion and the event recorded manually on a single page, pre-printed labour epidural chart. Once the patient had delivered her baby and the anaesthetist had removed the epidural, the epidural records were placed in a file on the epidural trolley. These completed records were collected by the consultant responsible for overseeing the epidural service and were stored in a secure site in the anaesthetic department.

An audit of the labour epidural analgesia service for the period 1 January to 31 December 2014 was conducted using consecutive convenience sampling. The labour ward admission book was used to determine the number of deliveries, including caesarean sections, during the study period.

Each epidural record was assigned a study number, which was recorded together with the patient's hospital number on a separate Microsoft Word® document. This would allow specific records to be identified if necessary. During data collection and analysis only study numbers were used to ensure anonymity.

Data were collected using standard data collection sheets adapted from an audit on the epidural analgesia service at Tygerberg Hospital.[14] Permission to use this instrument was obtained from the corresponding author. The data were collected by one author (TL). The data collected is summarised in Table I.

Table I Data collected at RMMCH

Variable
General demographics (total deliveries, caesarean sections, epidural analgesia records retrieved and records lost to follow up)
Patient demographics
Primary indication for labour epidural
Professional designation of the doctor inserting the epidural
Epidural technique
Complications
Patient satisfaction
Time to follow up after removal of the epidural catheter

All captured data was recorded and analysed on a Microsoft Excel® spreadsheet. Descriptive statistics were used. Categorical data was summarised using frequencies and percentages. Continuous variables that were normally distributed were summarised using means and standard deviations and variables that were not normally distributed were summarised using medians and interquartile ranges.

Results

The results of this study are summarised in Table II. During the study period there were 11 853 patients managed for labour and delivery at RMMCH. Normal vertex deliveries and Caesarean sections accounted for 7970 (67,2%) and 3883 (32,8%) of deliveries respectively. A total of 187 (1,6%) epidurals were administered in the labour ward during the year. Labour epidural records were collected for 100% of labour epidurals administered.

The mean age of patients who received labour epidural analgesia was 26 years (SD 5,4). There were 80 (42,8%) primigravida, 50 (26,7%) para two and 3 (1,6%) patients of greater parity. The parity of 34 (18,2%) patients was not recorded.

The most common recorded indications for epidural analgesia were labour analgesia in 78 (41,7%) patients and primigravida in 54 (28,9%) patients. One (0,5%) patient had augmentation of labour as an indication. There was no indication recorded for 54 (28,9%) of the patients. Registrars and medical officers administered 174 (93,0%) epidurals with 12 (6,4%) records having no identifying name recorded. One (0,5%) epidural was administered by a consultant. No details with regard to the epidural technique used (approach and loss of resistance) were recorded for any patients.

The majority of patients, 120 (64,2%), experienced no complications following labour epidural with data not recorded in 32 (17,1%) cases. There were no major complications. Minor complications occurred in 35 (18,7%) patients. Follow up was done within 24 hours of removal of the epidural catheter in 124 (66,3%) patients and there was no documentation of follow up for the remaining 63 (33,7%) patients.

Patient satisfaction with their epidural analgesia was recorded in 124 (66,3%) patients and was rated as very happy and happy in 122 (65,2%) patients, representing 98,4% of patients where documentation was complete. There were 2 (1,1%) patients who were not happy with the labour epidural analgesia.

Table II Summary of results obtained from RMMCH

Variable		n	%
Demographics	Total deliveries	11 853	
	Total Caesarean sections	3883	32,8
	Total epidurals performed	187	1,6
	Epidural records retrieved	187	100
Indication	Labour analgesia	78	41,7
	Primigravida	54	28,9
	Augmentation of labour	1	0,5
	Not recorded	54	28,9
Professional designation	Registrar	104	55,6
	Medical officer	70	37,4
	Consultant	1	0,5
	Not recorded	12	6,4
Epidural technique	Not recorded	187	100
Complications	No complication	120	64,2
	Hypotension	23	12,3
	Incomplete analgesia	6	3,2
	Back pain	5	2,7
	Pyrexia	1	0,5
	Not recorded	32	17,1
Time to follow up	Within 24 hours	124	66,3
	Not recorded	63	33,7
Patient satisfaction	Very happy	64	34,2
	Happy	58	31,0
	Not happy	2	1,1
	Not recorded	63	33,7

Discussion

The epidural rate at RMMCH of 1,6% is low compared to rates in developed countries. In the United Kingdom the rate of labour epidural analgesia has ranged from 24% to 49,3% over the last decade,[12, 17] with rates in Canada[18] and the United States of America (USA)[13] of 58,3% and 61% respectively. Data on epidurals in developing countries is limited but there is a general low provision of labour analgesia and labour epidurals.[19-21] An audit at Tygerberg Hospital[14] showed an epidural rate of 2,2% which is in keeping with the findings of this audit.

The reasons in our study for this low epidural rate are multi-factorial and include a limited number of anaesthetists available to provide labour epidurals. During the study period there was a single anaesthetist on call for labour epidurals from Monday to Friday during the daytime (07:00 to 16:00) only. There was no after hours service. There is also an anecdotal perception among nursing staff that labour epidurals lead to higher Caesarean section rates, even though is not the case based on the literature,[22] and hence there is resistance amongst nurses to widespread insertion of labour epidurals in the labour ward.

At Tygerberg Hospital the indications for epidural analgesia were primarily for medical conditions that needed amelioration of the neuroendocrine stress response during labour.[14] Our audit has revealed that the primary indications for labour epidural were for labour analgesia or for primigravidas, who often experience severe pain in labour, which is more in line with The American Society of Anesthesiologists and American College of Obstetrics and Gynecology statement that "in the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labour".[11]The epidurals done at RMMCH during the study period were primarily for pain relief, albeit not at maternal request. It is also worth noting that at the time of the audit RMMCH was a regional hospital as compared to Tygerberg Hospital being a tertiary hospital and as such RMMCH does not manage cardiac patients or the morbidly obese, which could explain the differences in indications for labour epidurals.

The epidural technique used (approach and loss of resistance) was not recorded on any of the epidural records. There is no place on the current epidural record used at RMMCH to record the epidural technique, which would prompt the anaesthetist to complete this section. An unpublished MMed study done by Jacobs et al in South Africa on the characteristics of an ideal epidural record has shown that this is essential data that should be recorded for all epidurals done.

Major complications, defined as death, paraplegia, cardiac arrest, respiratory failure, seizures and meningitis from labour epidurals are rare.[16] Two large audits in France and the United Kingdom revealed serious major complications of 5 in 29 732 and 0,6 in 100 000 cases respectively.[15, 16] There were no major complications during the study period at RMMCH. Maternal fever is a potentially serious complication of labour epidural analgesia and requires more investigation. The mechanism of maternal pyrexia is unknown but is thought to involve thermoregulatory and inflammatory mechanisms. An incidence of 1 to 46% has been shown in a review by Segal in 2010.[23] There was one patient who experienced pyrexia in this study and this was mild and resolved without treatment within 24 hours after the epidural.

Minor complications occurred in 18,7% of patients. These were all self-limiting. Hypotension as indicated by the anaesthestist performing the epidural, reflecting a drop in systolic blood pressure of more than 20% from baseline, occurred in 12,3% of patients. The other complications were incomplete analgesia (3,2%) and back pain (2,7%). This is in keeping with the findings on complications of labour epidural analgesia by Paech et al[24], which in a prospective study of 10 995 labour epidurals in Australia found an incidence of hypotension of 4,9% and of failed (incomplete) analgesia of 1,7%. Singh et al[25] in the United States showed a failed (incomplete) analgesia incidence of 0,65%. The incidence of hypotension in our study is similar to that found by Jacobs-Martin et al[14] at Tygerberg Hospital who reported an incidence of 13,4%. However, these authors reported a higher incidence of back pain (7,4%) in their study as compared to 2,7% in our study. The five patients who reported back pain in

this audit all experienced the pain at the time of epidural catheter insertion. There was no incidence of back pain reported at the 24-hour follow up in any patients. Evidence with respect to lower back pain from epidural analgesia is conflicting with Macarthur et al[26] reporting an incidence of lower back pain on day one following labour epidural analgesia of 56%. However, Howell et al[27] in 2001 concluded that "this study provided no evidence to support the suggestion of a direct association between the use of epidural anaesthesia in labour and the incidence of long term backache." The lack of lower back pain in our audit could be due to the lack of adequate follow up as well as differences in patient demographics from those in Europe and the USA.

There was no incidence of unintentional dural puncture and postdural puncture headache in our study. The Australian study by Paech et al[24] showed an incidence of unintentional dural puncture of 0,6%. In the study by Singh et al[25] in the USA the incidence of unintentional dural puncture and postdural puncture headache was 0,73% and 0,49% respectively, while at Tygerberg Hospital they were 4% and 3,4% respectively.[14] The lack of these complications at RMMCH could be due to the low number of epidurals administered and as such the study is not powered to detect them but could also be due to poor documentation. The section for complication on the epidural record was not completed in 18,9% of cases and it cannot be assumed that these patients did not experience any complication following labour epidural analgesia.

It is concerning that there was no documentation of follow up after removal of the labour epidural catheter in 33,7% of cases with the remaining 66,3% all being followed up within 24 hours. RMMCH is a very busy hospital with thousands of deliveries each year and as such the majority of patients are discharged six hours after normal vaginal delivery. This could explain some of the difficulty with regard to patient follow up but is also an example of the failure of adequate documentation of cases as well the failure to apply hospital protocols.

A high level of patient satisfaction with epidural analgesia has been consistently demonstrated.[27-29] Satisfaction in this audit was in three categories "very happy", "happy" and "not happy". The majority of patients reported being very happy (34,2%) or happy (31,0%) with only two patients (1,1%) reporting being not happy. Both of these patients had experienced incomplete analgesia. When taking into account the lack of documentation of patient satisfaction in 63 (33,7%) the patients reporting being happy and very happy reflect 98,4% of those where documentation was complete. These findings are in keeping with research by Howell et al[27] and Sharma et al[29] who reported high levels of patient satisfaction with labour epidural analgesia of 85% and 95% respectively.

There was a consistent problem with lack of adequately completed epidural records at RMMCH. For each variable that was assessed there was data that was not recorded. This poor documentation is a reflection of inadequate application of protocol and could have medicolegal consequences if there were to be any future litigation regarding a labour epidural that was inserted at RMMCH.

A 24-hour labour epidural service has been introduced at RMMCH subsequent to this study. There has also been increased education of nursing staff and efforts to enhance awareness regarding labour epidurals in the labour ward and it would be prudent to investigate the change that this has had on the epidural rate. This is an avenue for future research.

A limitation of this study would be that in determining the percentage of patients receiving labour epidural analgesia it would be ideal to exclude patients who had elective caesarean section deliveries, as these patients would never have been in labour nor been candidates for labour epidural analgesia. The information on how many caesarean sections during the study period were elective is not available from RMMCH. This is a limitation of the study.

Conclusion

This audit investigated the labour epidural analgesia service at RMMCH. There was a low incidence of labour epidural analgesia of 1,6%. This is much lower than international standards. There were no major complications during the study period and the incidence of minor complications was in keeping with complication rates identified in large studies in developed countries as well as one study in South Africa. Furthermore a failure of adequate documentation was identified. This is an area for future education and changes in practice at RMMCH.

The introduction of a 24-hour epidural service at RMMCH provides a research opportunity to assess the impact of this intervention and the new incidence of labour epidural analgesia.

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Section 4: Appendices

Post graduate approval

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
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Reference: Ms Thokozile Nhlapo
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16 April 2015
Person No: 0501010M
PAG

Dr TGA Leonard
P O Box 145318
Brackendowns
1454
South Africa

Dear Dr Leonard

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *An audit of the 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

Ethics clearance

R14/49 Dr Tristan Gavin Alexander Leonard

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150112

NAME: (Principal Investigator)	Dr Tristan Gavin Alexander Leonard
DEPARTMENT:	Anaesthesiology Rahima Moosa Mother and Child Hospital Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	An Audit of the Labour Epidural Analgesia Service at a Regional Hospital in Gauteng
DATE CONSIDERED:	30/01/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Helen Perrie
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	08/06/2015

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 Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Approval from RMMCH Clinical Manager

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

RAHIMA MOOSA MOTHER AND CHILD HOSPITAL

Enquiries : Dr Edward Hank
Tel : (011) 470 9030/1
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Department of Anaesthesiology
University of the Witwatersrand

Dear Dr Leonard,

RE: AN AUDIT OF THE LABOUR EPIDURAL ANALGESIA SERVICE AT A REGIONAL HOSPITAL IN GAUTENG

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
Clinical Manager
2015:04:17

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

Approval from RMMCH Head of Clinical Unit: Anaesthesiology



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Department of Anaesthesiology
Rahima Moosa Mother and Child Hospital

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07 November 2014

Attention: Dr T Leonard

Dear Dr Leonard

ACCESS TO EPIDURAL RECORDS

With reference to your communication on the 7th November 2014, regarding access to the labour epidural records at RMMCH, I am happy to permit you to have access to these records for the purpose of data collection for your MMed, provided that to are granted approval by the Human Research Ethics Committee of the University of the Witwatersrand and the CEO of the hospital.

Kind Regards

Sean Chetty

Dr S Chetty

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

Section 5: Annexure

An audit of the labour epidural analgesia service at a regional hospital in Gauteng

Tristan Gavin Alexander Leonard

0501010M

Supervisor: Helen Perrie
Department of Anaesthesiology

Co-supervisor: Juan Scribante
Department of Anaesthesiology

Co-supervisor: Sean Chetty
Department of Anaesthesiology

1. Introduction

All humans are faced with episodes of pain in their lifetime; the experience of pain can range from mild and self-limiting to severe and debilitating. The pain that a woman experiences during childbirth can arguably be described as the most severe pain that she will experience in her life (1, 2). This pain has been described as being worse than cancer pain or having a digit amputated without anaesthesia (3).

Not only is this pain distressing for the mother but it can also have detrimental effects on maternal and foetal wellbeing (1). Activation of the sympathetic nervous system due to pain leads to large rises in circulating adrenaline and noradrenaline levels (4). These increases in catecholamine levels have significant effects on maternal physiology, especially for mothers with cardiac conditions. This includes an increase in heart rate and cardiac output and hence increases in myocardial oxygen demand as well as a decrease in placental blood flow (5). Labour pain is also a potent respiratory stimulant leading to hyperventilation and maternal respiratory alkalosis; this causes a left shift of the oxygen haemoglobin dissociation curve and impairs oxygen delivery to the foetus (6).

Untreated labour pain can also have detrimental psychological effects on mothers. In the 1990s, a series of case studies conducted by Ballard et al (7) and a cross sectional study by Wijma et al (8) showed that traumatic childbirth can be a risk factor for the development of posttraumatic stress disorder. Furthermore, in 2008, Eisenach et al (9) enrolled 1288 women in a survey to determine the impact of pain during childbirth on subsequent mental health. It was found that severe postpartum pain was independently associated with postpartum depression and that women who experienced severe postpartum pain had a threefold increased risk of posttraumatic stress disorder.

Due to these well described adverse effects of pain in labour, there is a worldwide move toward ensuring mothers are offered adequate analgesia in the peripartum period. Studies and reviews have been conducted and there is consensus that lumbar epidural analgesia is the gold standard of labour analgesia, by providing the most effective, reliable and flexible method of pain relief during labour. (1, 10, 11)

According to the American Society of Anesthesiologists and American College of Obstetrics and Gynecology, "in the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labour" (11).
This is reflected in the number of women receiving epidural analgesia in developed countries with rates in the United Kingdom and in large hospitals in the United States of America (12) being reported as 16,5% and 61% respectively.

The number of women receiving epidural analgesia in developing countries is unknown but is assumed to be much lower. Data for South Africa is also limited. A recent audit at a tertiary public hospital in the Western Cape revealed that only 2,2% of labouring mothers received labour epidural analgesia and that epidural placement was done for a medical indication upon obstetrician request and not on patient request (13).

Epidurals are considered safe but when serious complications occur they can be fatal or lead to permanent harm (6). An audit by the Royal College of Anaesthetists in 2009 (14) found the incidence of permanent harm after epidural to be 0,6 per 100 000 cases (95% CI 0 – 3,4) and a survey in France found an incidence of serious events related to obstetric epidural to be less than 5 in 10 000 (15). Data on complications with respect to obstetric epidural analgesia is again limited in South Africa with the audit in the Western Cape showing a serious complication rate of 0,7% (13).

2. Problem statement

Neuraxial analgesia in the form of continuous epidural infusion has been shown to be the most effective analgesic strategy for the labouring mother (1, 10). In developed countries data is readily available as to the number of women receiving labour epidural analgesia as well as the complication rates of labour epidurals. In the United Kingdom 16,5% of parturients receive labour epidural analgesia (16); with rates in the United States of up to 61% (12). Complication rates of labour epidurals in developed countries are very low with an incidence of 0,6 per 100 000 cases in the United Kingdom (14).

Data for South Africa on labour epidural analgesia services is limited and a recent audit at Tygerberg Hospital showed that epidurals were performed for only 2,2% of labouring women and that these epidurals were placed exclusively for medical indications and not patient request (13). Furthermore there are no data on the labour epidural analgesia service at Rahima Moosa Mother and Child Hospital (RMMCH).

3. Aim

The aim of this study is to describe the labour epidural analgesia service at Rahima Moosa Mother and Child Hospital over the period of one year.

4. Objectives

The 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 catheter
- describe the technique of labour epidural insertion
- 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.

5. Research assumptions

The following definitions will be used in the study.

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

Medical Officer: a qualified doctor practicing anaesthesia under specialist supervision. A medical officer with more than 10 years experience is regarded as a career medical officer.

Registrar: a qualified doctor who is registered with the HPCSA as a registrar in the specialty of anaesthesiology.

Consultant: any anaesthetist who has completed the required South African Colleges of Medicine examinations, or equivalent, and all other criteria to become a specialist in anaesthesiology. Career medical officer will be included in this category.

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

6. Demarcation of the study field

This study will be conducted on the labour epidural analgesia service of RMMCH. RMMCH is a regional academic hospital located in Coronationville, Gauteng. It is a dedicated maternity and paediatric hospital with 338 beds. There are, on average,

12 000 deliveries per year at the hospital. It is affiliated to the University of the Witwatersrand.

7. Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Postgraduate Committee of the University of the Witwatersrand. Approval will be obtained from the CEO of RMMCH (Appendix B). Approval to access stored epidural records was obtained from the gatekeeper at RMMCH (Appendix C).

This is a retrospective study and the name of the patient and anaesthetist for each record will not be recorded on the data collection sheet. Each patient will be allocated a study number. A list with the patients names and corresponding study numbers will be generated and filed separately. Confidentiality will be maintained as only the researcher and supervisors will have access to the raw data.

All data collected will be kept and stored securely for six years after completion of the study.

This study will be conducted according to the principles of the Declaration of Helsinki (17) and the South African Guidelines for Good Clinical Practice (18).

8. Data collection

8.1 Research design

The design of a study is the template whereby the study aims to obtain valid answers (19). It determines the methods by which data is collected, analysed and interpreted (19, 20).

The research design used in this study is that of a retrospective, contextual, descriptive study.

A retrospective study measures variables that have occurred in the past (20). This study will obtain data from epidural records that have already been completed.

A contextual study focuses on a particular group or a "small scale world" (21). This study is contextual in that it will examine the labour epidural analgesia service at RMMCH.

A descriptive study is intended to describe variables; the researcher defines the sample and does not manipulate any variables (20). This study will describe the labour epidural analgesia service at RMMCH.

8.2 Study population

The study population will be the labour ward admission book and the epidural records of the women who have received labour epidural analgesia at RMMCH in 2014.

8.3 Study sample

Sample size

The sample size will be determined by the number of women who have received labour epidural analgesia at RMMCH for the period of 1 January 2014 to 31 December 2014. It is estimated that there will be approximately 200 epidurals.

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. Convenience sampling collects the most readily available subjects in a non-random manner. (22)

In this study consecutive, convenience sampling means that every labour epidural record available for the entire study period will be collected.

Inclusion and exclusion criteria

The epidural record of every woman who has received a labour epidural from 1 January to 31 December 2014 will be included in the study.

Illegible records will be excluded from the study.

8.4 Data collection

Once the relevant approvals have been received, data will be collected from RMMCH.

The labour ward admission book will be used to determine the number of patients that were admitted and the number of deliveries, including caesarean sections, in 2014.

RMMCH uses a single page, pre-printed epidural record that is completed manually by the anaesthetist performing the epidural (Appendix A).

Once the patient has delivered her baby and the anaesthetist has removed the epidural, the epidural record is placed in a file on the epidural trolley. These completed records are collected by the consultant responsible for overseeing the epidural service and are kept in a secure site in the anaesthetic department.

Each epidural record will be assigned a study number, which will be recorded together with the patient's hospital number on a separate Microsoft Excel®

spreadsheet. This will allow specific records to be identified if necessary. During data analysis only study numbers will be used.

Data will be collected according to the data collection sheets (Appendix D and E) adapted from an audit on the epidural analgesia service at Tygerberg hospital (13). Permission to use this instrument has been obtained from the author (Appendix F).

The data collection sheets will include the following information:

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

Data capturing will be done in the Department of Anaesthesiology at RMMCH and records will not be removed from the hospital premises.

8.5 Data analysis

All captured data will be recorded and analysed on a Microsoft Excel® spreadsheet. Descriptive statistics will be used to analyse the data. Categorical data will be summarised using frequencies and percentages. Continuous variables that are normally distributed will be summarised using means and standard deviations and those that are not normally distributed will use medians and interquartile ranges.

9. Significance of the study

Labour is an extremely painful process for a woman to endure and this pain can have multiple adverse effects for both the mother and foetus (1-9). Epidural analgesia for labour is regarded as the current gold standard for labour pain relief and is widely practiced in developed countries (1, 10-12, 16, 23, 24).

Data regarding labour epidural analgesia in developing countries is limited. An audit of the labour epidural service at Tygerberg hospital revealed an epidural rate well below that of the developed world but showed no differences in the incidence of complications from labour epidurals (13).

It is important that any service rendered to patients is continually evaluated for effectiveness and safety. This audit will establish information on the labour epidural analgesia practices of RMMCH, a service that has not been audited previously. The results of this study will provide insight into the labour epidural service at RMMCH. This is with the goal of identifying possible deficiencies in our labour epidural service in order to improve patient care.

10. Validity and reliability of the study

The validity of a study is the extent to which it accurately reflects the variables being measured and the reliability is the consistency and repeatability of the instrument being used to measure variables (19).

Measures to ensure the validity and reliability of this study are:

- the use of an appropriate study design
- a retrospective design ensures that anaesthetists are not able to change their practice in response to the study
- a single researcher will collect data
- every tenth data entry will be checked for accuracy of capture
- data analysis will be done in consultation with a biostatistician.

11. Potential limitations of the study

Limitations are restrictions or problems that weaken the assumptions that can be made from the findings of a study (20).

This study is contextual in that the population is limited to the labour epidural analgesia service at RMMCH. The results therefore may not be generalisable to the labour epidural analgesia services at other teaching hospitals affiliated to the University of the Witwatersrand or to other hospitals in South Africa.

Convenience sampling may be a limitation. However consecutive, convenience sampling is used in this study and it is the strongest form of such sampling. All records collected over the period of one year will be analysed.

A further potential limitation is the reliance on completed epidural records for data analysis.

12. Project outline

	Oct 2014	Nov 2014	Jan 2015	Feb 2015	Mar 2015	Apr 2015	May 2015	Jun 2015	Jul 2015
Proposal									
Chapter 1-3									
Proposal submission									
Ethics committee submission									
Postgraduate committee submission									
Data collection									
Data analysis									
Chapter 4, 5									
Editing									
Submission									

13. Financial plan

The Department of Anaesthesiology at the University of the Witwatersrand will bear the costs of printing and paper for the study.

	Price per page	Number of pages	Copies	Total
Proposal	R1	20	10	R200
Ethics form	R1	10	25	R250
Post graduate form	R1	1	6	R6
Completed report	R1	100	4	R400
Binding		R150	3	R450
			Grand total	R 1306

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LABOUR EPIDURAL CHART
RHM&CH

PATIENT DETAILS	**TIME** XXhXX	0	5	10	15	20	25	30	*	*	*	60	*	*	*	90	*	*	*	120	*	*	*	150	*	*	*	180	*	*	*	210	*	*	*	240	*	*	*	*	*	*	300	*	*	*	330	*	*
	min																																																	
NAME:	TOP-UPS																																															
	Drugs Ropiv (%)																																															
HOSPITAL No:	Ligno (%)																																															
	Fent (ug/ml)																																															
AGE:	Adren (ug/ml)																																															
	Volume (ml)																																															
ASSESSMENT:																																																
	MAINTENANCE INFUSION																																															
	Drugs Ropiv (%)																																															
	Ligno (%)																																															
	Fent (ug/ml)																																															
	Adren (ug/ml)																																															
	Rate (ml/hr)																																															
	LEVEL OF BLOCK																																															
	VITALS 240																																															
	(mm Hg) 200																																															
	(beats/min) 180																																															
	160																																															
	140																																															
	120																																															
INDICATION:	100																																															
	80																																															
ASA STATUS: 1 2 3 4 5	60																																															
	40																																															
FBC	RESP RATE (breaths/min)																																															
U+E	LEVEL OF SEDATION																																															
INR/PTT	SpO2																																															
	FOETAL HEART RATE																																															
	URINE OUTPUT																																															

CONSENT:	**INSERTION:**	**DELIVERY:**	**COMPLICATIONS:**	**ANAESTHETIST IN CHARGE**
I, the undersigned, agree to having an epidural catheter inserted for the purpose of analgesia during labour. The benefits and complications have both been explained to me.	BP: Local infiltration:	Unassisted:		
	HR: Needle type/size:	Assisted:		
	RR: Distance to space:	Forceps:		
	Pt position: Catheter fed in (cm):	Ventouse:		**MIDWIFE IN CHARGE**
	IV access: G Test dose:	Caesarian Section:	**DAY 1 POST-PARTUM:**	
Signature	Site:		FULL REGRESSION OF BLOCK:	
	Preload:			
Date			COMPLICATIONS	
	Aseptic field: IV/IT injection excluded:			**DATE**
Witness			PT SATISFACTION	

Appendix B: Request to the CEO of Rahima Moosa Mother and Child Hospital

Dr Tristan Leonard
Department of Anaesthesiology
University of the Witwatersrand

Attention: The CEO of Rahima Moosa Mother and Child Hospital

Re: An audit of the labour epidural analgesia service at a regional hospital in Gauteng

Dear Sir or Madam

I am a registrar in the Department of Anaesthesiology. The research component of my MMed is a non-human study. I propose to do a retrospective audit of the labour epidural analgesia service at Rahima Moosa Mother and Child Hospital. The study has been approved by the Human Research Ethics Committee (Medical) (number XXX) and Postgraduate Committee of the University of the Witwatersrand.

This audit will involve reviewing the epidural records collected for the period 1 January 2014 to 31 December 2014. The records will be the focus of the study and no identifying patient or medical staff information will be recorded. Records will be reviewed where they are stored and will not be removed from the premises.

There will be no financial implications for RMMCH or the Gauteng Department of Health. A copy of the final report, should you request it, will be made available to you.

Yours sincerely

Dr Tristan Gavin Alexander Leonard
0838635855
tristanleonard@hotmail.com

Appendix C: Permission from the Head of Clinical Unit and gatekeeper at RMMCH



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Department of Anaesthesiology
Rahima Moosa Mother and Child Hospital

Tel: (011) 470-9303
Fax: 0866 170 530
E-mail seanchetty@gmail.com

07 November 2014

Attention: Dr T Leonard

Dear Dr Leonard

ACCESS TO EPIDURAL RECORDS

With reference to your communication on the 7th November 2014, regarding access to the labour epidural records at RMMCH, I am happy to permit you to have access to these records for the purpose of data collection for your MMed, provided that to are granted approval by the Human Research Ethics Committee of the University of the Witwatersrand and the CEO of the hospital.

Kind Regards

Sean Chetty

Dr S Chetty

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

Appendix D: General demographics

This will be recorded on the Microsoft Excel™ spreadsheet

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

Appendix E: Data collection sheet

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	Approach Midline Paramedian Loss of resistance technique Saline Air
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
Patient satisfaction	Not happy Happy Very happy
Time to follow up post epidural removal	Within 24 hours Later than 24 hours

Appendix F: Request for use of the data collection instrument

From: **Tristan Leonard** tristanleonard@hotmail.com
Subject: Article:LabourepiduralanalgesiaauditinatertiarystatehospitalinSouthAfrica
Date: 16 October 2014 at 12:54 PM **To:** gillian.jacobsmartin@gmail.com
Cc: seanchetty@gmail.com, juan.scribante@wits.ac.za, helen.perrie@wits.ac.za

Dear Dr Jacobs-Martin

My name is Tristan Leonard and I am an anaesthetic registrar at the University of the Witwatersrand.

I read with interest your article published in SAJAA recently. I noted your conclusion regarding the need for this sort of audit to be performed in other South African hospitals.

I would like to do an audit of the labour epidural service at either Chris Hani Baragwanath Academic Hospital or Rahima Moosa Mother and Child Hospital as the research component of my MMed and request your permission to use the instrument (Table 1 in the article) for my research.

I have Cc'd my co-supervisor and research co-ordinators in the email.

Dr Sean Chetty
Head: Clinical Unit - Anaesthesiology Rahima Moosa Mother and Child Hospital
Juan Scribante Helen Perrie

Please contact me if you have any queries.

Kind regards
Dr Tristan Leonard MBBCh (Wits) DA (SA)

From: **Gillian Jacobs-Martin** gillian.jacobsmartin@gmail.com **Subject:** Re: Audit
Date: 31 October 2014 at 12:33 PM
To: Tristan Leonard tristanleonard@hotmail.com

Hi Tristan

That's fine. You can use the table, then it will be easier to compare. Just an update, since my study was completed, TBH now has a dedicated registrar on call as part of the epidural team (more nurses were appointed in labour ward as well).

If I can give you a tip, that made a big difference to me: speak to the person who will do your stats, long before you start collecting data, so that your data will be in a format that is easy for them to analyse.(eg tickboxes instead of handwritten details)

Good luck with your study. Let me know if I can help.

Kind regards
Gillian Jacobs-Martin