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Mode of delivery, analgesic, and neuromusculoskeletal profile of women developing new onset lower back pain postpartum

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MODE OF DELIVERY, ANALGESIC, AND NEUROMUSCULOSKELETAL PROFILE OF WOMEN DEVELOPING NEW ONSET LOWER BACK PAIN POSTPARTUM

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A research report for a master's degree by coursework submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree Master of Science in Physiotherapy field of Orthopaedic Manipulative Physiotherapy.

Johannesburg, 2024

DECLARATION

I, Joretha Steyn, declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Master of Science in coursework for orthopaedic manual therapy in physiotherapy at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



_____

(Signature of candidate)

_____20th ____day of __May_____2024_____in_East London_____

DEDICATION

To everyone, Mom, Dad, my staff at the office, and my dear friends, you know who you are, who has supported and encouraged me during the most difficult time in my life and to God that brought me this far. What was supposed to be a great academic journey started with a great loss and a void that will never be filled. To a legendary physio colleague, trusted friend, older sister, and loving aunt, all in one, who entrusted me with everything she worked for.

In loving memory of my Aunt

Gerda Bence

1968 – 2019

“But by the grace of God I am what I am, and his grace toward me was not in vain. On the contrary, I worked harder than any of them, though it was not I, but the grace of God that is with me.”

1 Corinthians 15:10

ABSTRACT

The aim of this cohort study, a longitudinal study that follows participants over a period, was to establish the profile of women developing lower back pain (LBP) postpartum by investigating the association between LBP and the mode of delivery, analgesia used and the neuromusculoskeletal structures involved. A baseline assessment was done on 16 participants, four were excluded as per the exclusion criteria, with outcome measures such as the Oswestry LBP disability questionnaire and the visual analogue scale (VAS) at 24 weeks gestation and a follow up assessment at six- and 12-weeks postpartum. Irrespective of the analgesia used during labour (epidural, combined spinal and epidural (CSE), general anaesthesia or no analgesia) or the mode of delivery, be it natural, an elective caesarean section or an emergency caesarean section, 50% (n=6) had pain at six weeks postpartum and 14% (n=7) at 12 weeks postpartum. The VAS and Oswestry LBP disability questionnaire averaging 4/10 and 12.6% respectively. It should be noted that the 14% (n=7) that had pain at 12 weeks had a scheduled caesarean section done under general anaesthesia which leads us to agree with Eisenach, et al., (2013) that labour itself does have a protective physiological mechanism against developing pain postpartum. It is recommended that a future study should extend the time frame of data collection to two to three years to ensure a larger sample size to get a more significant and clearer picture of the development of LBP postpartum and the factors or structures involved. This in turn can ensure a more comprehensive preventative strategy to be researched to decrease the development of LBP postpartum.

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LIST OF ABBREVIATIONS

COC	Coccygeus
CS	Caesarean section
ES	Erector spinae
GA	General anaesthesia
LA	Levator ani
LBP	Lower back pain
LBPP	Lower back pelvic pain
NDOH	National department of health
OI	Obturator internus
OLBPDQ	Oswestry lower back pain disability questionnaire
PGP	Pelvic girdle pain
PLBP	Pregnancy related lower back pain
PP	Postpartum
SA	Sphincter ani
SB	Spinal block
VAS	Visual analogue scale
WHO	World health organization

LIST OF OPERATIONAL DEFINITIONS

Lower back pain	Pain between the twelve rib and gluteal fold
Pregnancy related lower back pain	Lower back pain that starts at 18 weeks gestation and last up until labour
Lower back pain postpartum	Pain felt in the lower back six weeks or longer postpartum
Pelvic girdle pain	Pain between the posterior superior iliac spine and gluteal fold that could radiate into the posterior thigh
Epidural	Does not puncture the dura
Combined spinal block and epidural	Punctures the dura

CHAPTER 1

1. INTRODUCTION

1.1 Introduction

Chronic back pain has become one of the most debilitating conditions in our day and age and will affect many individuals at some point in their lives (Meucci, Fassa and Xavier Faria, 2015). One of the most common back pain conditions are those suffered by pregnant women. At least 80% of pregnant women will experience lower back pain (LBP) during their pregnancy (Martins and Silva, 2005). According to Tavares, et al., (2019) 2% – 75% of these women will continue to have LBP postpartum. Bergström, Persson and Mogren (2014) stated that pregnancy related LBP starts at about 18 weeks, peaks at 24 weeks gestation and then again at 36 weeks after which it decreases post-delivery and eventually resolves. However, eight percent of women end up with disabling pain and 25% with serious pain. Many young females who seek professional help for their chronic back pain postpartum believe that it is a direct result of having an epidural during labour, since it usually coincides with this event (Wong and To, 2007). Extensive research internationally has been done on this topic and contradicting evidence have been found over the years as to what the connection between the use of an epidural analgesia and the cause of long-term back pain postpartum is (Breen, Ransil, Groves and Oriol, 1994; Russel, Dundas, Reynolds, 1996; MacArthur, MacArthur and Weeks, 1997; Howell, et al., 2002; Loughnan, et al., 2002; Abassi, et al., 2014). There is a lack of research in South Africa and African women with regard to epidural use and lower back pain postpartum. The childbirth process itself should be considered as a contributing factor as well as the impact it has on the neuromusculoskeletal structures especially in the different modes of deliveries. Establishing the profile of these women can guide clinical practice for healthcare professionals to prevent the development and persistence of postpartum LBP.

1.2 Background

Eisenach, et al., (2013) stated that the childbirth process causes great physical trauma, both micro and gross injury, to a woman's body and having a caesarean section increases the trauma which could lead to chronic pain. The body of a pregnant

woman prepares itself for the labour process by cervical remodelling taking place just before labour. This is associated with the release of inflammatory substances that sensitizes the nociceptors. This physiological process alone will cause pain postpartum, but these women suffer less pain than women who had hysterectomies and other abdominal surgeries. Eisenach, et al. (2013) speculated that the puerperium is the protective biological factor that diminishes the risk for injury induced chronic pain. Women that have an elective caesarean section, compared to the other methods, are more prone to develop postpartum LBP possibly because they did not go into labour (Mogren, 2007; Mukkannavar, et al., 2013).

The trauma caused to the neuromusculoskeletal structures like muscles, joints, and ligaments is another factor that can contribute to LBP postpartum (Eisenach, et al., 2013; Mogren, 2007; Mukkannavar, et al., 2013). Shacklocks' study on neurodynamics in 1995 indicated that the spinal canal elongates by 7cm during flexion resulting in a longitudinal stress on the neuraxis and meninges (Shacklock, 1995). If a woman in labour is in a flexed position for extended periods, it may cause strain on the neural tissue. If she had an epidural, the pain signals of uncomfortable strain on the body are numbed and she is unable to relieve the strain on the anatomical structures which could lead to damage of joints, muscles, and ligaments in the short- or long-term increasing the potential for LBP postpartum (Mogren, 2007).

1.3 Problem Statement

There is a general concern among women that having an epidural during labour will cause long term LBP (Wong and To, 2007). Research has found an association between epidural analgesia and LBP postpartum since 1969 but findings still seem to be controversial (Malevic, Jatuzis and Paliulyte, 2019).

The administration of epidural techniques has changed over the years from point of insertion to different drugs used and the association seems to have become less (Silva and Halpen, 2010). The percentage of women suffering from long term LBP has however not decreased but rather increased, contrary to the expectation. Further research is therefore necessary to investigate interrelated factors that can contribute to the onset of LBP postpartum.

1.4 Research question

What is the profile of women developing new onset LBP postpartum regarding mode of delivery, analgesic, and neuromusculoskeletal structures, as well as the association between these factors?

1.4.1 Aim of the Study

This study aimed to investigate the mode of delivery, analgesic, and neuromusculoskeletal profile of women developing new onset LBP postpartum.

1.4.2 Objectives of the Study

The objectives for the study were:

- To determine the association between mode of delivery and onset of LBP postpartum.
- To determine the association between the type of analgesia used and the onset of LBP postpartum.
- To determine the association between the neuromusculoskeletal profile of the participant and the onset of LBP postpartum.
- To compare the participants' characteristics between the groups who developed pain and those who did not regarding the mode of delivery, type of analgesia received and neuromusculoskeletal profile.

1.5 Significance of the Study

Lower back pain seems to occur at an increasingly younger age, especially in pregnant women (Martins and Silva, 2005). Fifteen to twenty-one percent of women will develop long term lower back pain postpartum (Tavares, et al., 2019).

This study will help to clarify factors that might contribute to the development of new onset LBP postpartum. Should these factors be associated with LBP postpartum, preventative strategies should be emphasised in ante- and postnatal education in an effort to improve health and socio-economic wellbeing in women.

1.6 Outline of the research report



Figure 1.6.1 Outline of the research report

CHAPTER 2

2. LITERATURE REVIEW

2.1 Introduction

There are 140 million births worldwide per year (WHO, 2018). Eighty percent of women will have LBP during their pregnancy (Martins and Silva, 2005) of which 20% would have had LBP prior to their pregnancy. Forty percent will develop it in their first trimester, and 44% – 70% in their third trimester (Backhausen, et al., 2019). At least 8% – 25% of these women will end up with persistent LBP postpartum (Bergström, Persson, Mogren 2014).

A variety of factors such as hormonal changes, increased mobility of the pelvis, joint laxity, changes in the spinal curvature, and muscle dysfunction could cause the development of pregnancy-related LBP (Backhausen, et al., 2019), which could lead to persistent LBP postpartum. Other contributing factors that could lead to LBP postpartum is LBP prior to pregnancy, increased age and body mass index and urinary tract infections.

This chapter will provide a brief overview of contributing factors that could play a role in the development of LBP postpartum, such as the mode of delivery, the analgesia received and the impact of pregnancy and labour on the neuromusculoskeletal system.

2.2 Search strategies

Relevant literature was gathered by conducting an online search under the health science platform with the help of a librarian. Databases such as PubMed, Science direct, CINAHL, Google scholar and ClinicalKey were used to search for articles in both English, and articles translated into English, which were published between the year 2010 to January 2022. Mesh terms used were caesarean, emergency caesarean, natural birth, trauma, LBP, postpartum, epidural, spinal block, neuromusculoskeletal, and pain management. A wide range of articles were included, like narrative, systemic as well as meta-analysis review articles, randomised controlled

trials and observational studies. Since this study was a literature study and not a review, all relevant sources were included. These sources included studies focusing on baseline measurement at the start of pregnancy with a longitudinal follow up. Studies that did a retrospective measurement of the LBP prior to pregnancy was considered outside the scope and not aligned to the current study objectives.

2.3 Pregnancy related LBP

The first consideration to bear in mind is the pregnancy itself and the changes a woman's body undergo during those months. This includes changes such as the secretion of relaxin, which increases the laxity of the ligaments in the body, the increase in anterior abdominal weight, and the biomechanical shift that happens in the lumbar spine to compensate for the increased abdominal weight (Biviá-Roig, Lisón and Sánchez-Zuriaga, 2019). These changes lead to hyperlordosis and an anterior pelvic tilt, which the sacroiliac joints usually resist; but due to the increased laxity of the ligaments, the resistance from the sacroiliac ligaments decreases, thus increasing the strain on the lower back, pelvis, and sacroiliac joint itself (Borg-Stein and Dugan, 2007).

According to Biviá-Roig, Lisón and Sánchez-Zuriaga (2019), there is no correlation between waist circumference and available range for maximum lumbar flexion, which leads us to think that there must be more factors involved that would restrict the lumbar flexion ranges, which are lower in pregnant women. Pregnant women tend to flex more in the lower thoracic area, guarding the lumbar flexion movement like people with LBP pain normally would do. Increased trunk flexion overall, places a greater risk of injury to the spinal connective tissue because the erector spinae (ES) muscle is more activated. In normal pain-free subjects, the ES goes into a myoelectric silence when the trunk reaches 75% – 85% of the maximum flexion. This increases the load on the passive structures like ligaments and intervertebral discs, which then carry the stability load from the ES muscle (Biviá-Roig, Lisón and Sánchez-Zuriaga, 2019). Increase in weight extends this range before a state is reached where the passive structures can take over from the ES, and this leads to the ES being active for longer periods and in ranges where it is not normally active (Biviá-Roig, Lisón and Sánchez-Zuriaga, 2019).

Biviá-Roig, Lisón and Sánchez-Zuriaga (2019) stated that in pregnant women, the increase in weight causes the flexion range of the trunk to increase and the ES must be active for longer. With the secretion of relaxin and its effect on the passive structures, the ES must stay active for even longer before the passive structures are taut enough to take over from the ES and allow it to enter myoelectric silence. The laxity in the ligaments causes a delayed activation of the ES muscle to protect the spine when there is a sudden change in stability. This is due to altered afferent feedback through the mechanoreceptors in the ligaments, that are desensitised (Biviá-Roig, Lisón and Sánchez-Zuriaga, 2019). The desensitisation also causes the lumbar region to be exposed to further instability, which could lead to spinal injury (Biviá-Roig, Lisón and Sánchez-Zuriaga, 2019). Therefore, this may be one of the reasons pregnant women develop LBP during pregnancy and potential persistent pain postpartum.

There is currently little research on whether the ES activation returns to normal after the abdominal weight has been decreased, or when there is less relaxin being secreted.

2.4 Persistent LBP after pregnancy

Persistent pain is explained as “The failure of the body’s hyperalgesic state to return to the pre-injury or pre-surgical state after tissue healing has taken place” (Sun and Pan, 2019, page 81).

The two most common complications of pregnancy are pelvic girdle pain (PGP) and pregnancy-related lower back pain (PLBP), which usually starts at 18 weeks and peaks at 24 and 38 weeks (Bergström, Persson and Mogren, 2014). Bergström, Persson and Mogren, (2014) explain PGP as pain between the posterior superior iliac spine and gluteal fold that could radiate into the posterior thigh. The trigger point referral area for the pelvic floor muscles like the levator ani, sphincter ani, coccygeus, and the obturator internus muscles are over the coccygeal area, with the latter also referring to the posterior thigh, which is where PGP is felt (Simons, et al., 1992). Damage or trauma to these muscles during pregnancy or labour could lead to the activation of the trigger points and contribute to the persistent pain postpartum.

PLBP was defined as pain between the twelve rib and gluteal fold, which is felt more in forward flexion movements with restricted spine movements. It is also characterised by pain on palpation of the ES muscle (Bergström, Persson and Mogren, 2014).

2.4.1 Prevalence

As previously stated, 80% of pregnant women will suffer from LBP during pregnancy and it is therefore difficult to distinguish between PLBP and new onset of LBP that develops during or after delivery, or due to the different types of deliveries (Komatshu, Ando and Flood, 2020).

2.4.2 Causes of persistent LBP after pregnancy

Eisenach, et al., (2013) concluded that irrespective of the type of delivery, it is the severity of pain experienced during delivery that predicts the persistence thereof. Other important risk factors considered to be variables in developing chronic pain post-delivery was pain prior to delivery (7%) and the amount of trauma to the tissue during delivery (16.7%). Their study indicated that neither of these two variables showed any association to pain two months postpartum.

Sun and Pan (2019) support the above findings in their study, claiming that the severity and the duration of postoperative pain, and the management thereof, plays a role in the prediction of persistent pain developing postpartum. They explain that the greater the intensity of the pain, the more nociceptive input there is, that leads to an increase in peripheral and central sensitisation - which in turns amplifies the pain sensation and potentially leads to an increase in persistent pain (Sun and Pan, 2019).

2.5 Mode of delivery and persistent LBP

In both vaginal and caesarean deliveries, there is a fair amount of tissue damage (Bijl, et al., 2016).

During vaginal birth, the uterus contracts, and the cervix, as well as the lower uterine segment dilates, causing stretching and compression of the perineal and pelvic

structures (Bijl, et al., 2016). Vaginal birth also causes inflammation of cervical tissue, tears in the birth canal, and if an episiotomy was needed, these effects on the body will also cause nociceptive pain. Neuropathic pain can be attributed to pudendal neuropathy. All the above could lead to persistent postpartum pain (Bijl, et al., 2016; Komatshu, Ando and Flood, 2020). Therefore, it is important to distinguish where the participants feel their pain – perineum, vaginal, abdomen, lower back, or pelvis, as that will provide a better picture as to the cause or source of the pain.

According to Eisenach, et al., (2013) and as mentioned above, the delivery process causes microscopic and gross tissue injury to the mother. Tissue damage does not always lead to chronic, persistent pain due to the natural healing process of the body that takes place within a few weeks or months. If pain persists, it has a half-life of six to seven years, which could explain why young mothers still have pain five years after delivery. There are, however, a few physiological processes that take place that could explain or predict the development of chronic pain post-delivery. These processes include phenomena such as hypersensitivity to the distension and spontaneous activation of the sensory afferents to the uterine cervix and lower uterine segment that take place before labour (Eisenach, et al., 2013). Cervical remodelling and release of inflammatory substances like prostaglandins and cytokines, can sensitise the nociceptors in the cervical tissues just prior to labour (Eisenach, et al., 2013).

In the caesarean delivery population, 11% have persistent pain at 12 months postpartum (Eisenach, et al., 2013; Komatshu, Ando and Flood, 2020). Persistent pain is explained by Komatsu, Ando and Flood (2020) as pain lasting for longer than six weeks. Mothers who undergo caesarean deliveries have been reported to also suffer from perineal and vaginal pain, but it seems that the pain from the scar is the predominant reason for persistent pain (Komatshu, Ando and Flood, 2020). During caesarean procedures, there might be injury or traction to the neural tissue, like the ilio-inguinal and ilio-hypogastric, as well as the pudendal nerves, which could lead to neuropathic pain (Eisenach, et al., 2013; Komatshu, Ando and Flood, 2020). Borg-Stein and Dugan (2007) explains that compression, traction, ischaemia, and laceration of the nerves during pregnancy, labour, and postpartum can all lead to peripheral

nerve injury and potential persistent pain; the latter two compromising the lumbosacral plexus more than the peripheral nerves.

According to Mukkanavar, et al., (2013), 33.3% of women who had caesarean deliveries had PGP compared to 8.3% of vaginal deliveries. This seems contradicting when one takes into consideration that the consensus is that caesarean deliveries cause less tissue damage to the pelvic floor muscles. During delivery there is quite a bit of strain, stretch and injury to the pelvic floor muscles, especially the levator ani (LA), obturator internus (OI), and the coccygeus (COC) muscles (Lindo, et al., 2015). The lumbopelvic stability is actively assisted by these pelvic floor muscles and any deficit or injury to these muscles will influence the lumbopelvic stability, therefor causing LBP to develop (Chaitow, 2007). According to Simons and Travell (1999), trigger points develop in an ischaemic environment. They also develop when there is joint and ligament laxity as a stabilizing effect to support the hypermobility (Simons and Travell, 1999). This all influences the pelvic floor muscles both during pregnancy as well as labour and could contribute to persistent pain postpartum.

A study by Lindo, et al., (2015) on squirrel monkeys, which have a pelvic floor similar in structure to humans, was done to investigate the elimination of the adverse effects of vaginal delivery on the pelvic floor, especially the pelvic organ prolapses, by replacing it with scheduled caesarean delivery. They found that there were, however, less oedematous changes in the COC muscle of the caesarean group versus the vaginal group, the interpretation of this being that there was less trauma to the COC muscle in the caesarean group. The COC muscle volume was affected by both pregnancy and delivery, irrespective of mode of delivery (Lindo, et al., 2015).

The changes in the volume loss of the LA and OI muscles were the same in both groups and could be attributed to either stretching or atrophy of the muscles, but it returned to baseline three months postpartum (Lindo, et al., 2015).

Taking the above type of deliveries into consideration with regard to the tissue damage occurring during the labour process, one would think it would explain why women end up with chronic persistent pain postpartum. The phenomenon of the body naturally

preparing for the perceived increase in nociceptors and therefore pain according to Eisenach, et al., (2013) helps to prevent the development of persistent pain. Their study concluded that the tissue damage or physical trauma during labour, whether vaginally or by caesarean delivery, is inadequate to produce chronic pain, or that factors such as the puerperium post-delivery, or the protective biological, and psychosocial elements during pregnancy play a role in eliminating injury-induced chronic pain. This correlates with women who underwent other abdominal surgeries, including hysterectomies, who had more pain than women who underwent caesarean deliveries or that went into labour (Eisenach, et al., 2013).

Komatshu, Ando and Flood (2020) also found minimal association between caesarean delivery and the development of persistent LBP. Mogren (2007) and Mukkanavar, et al., (2013) found that women who had elective caesarean deliveries had an increased risk of developing lower back and pelvic pain.

Although it is thought that caesarean delivery will decrease the tissue damage to the pelvic floor muscles caused by the shearing forces of the foetal head during vaginal delivery, it seems that pregnancy itself causes changes in the connective tissue, ligaments and structures that cannot be prevented by caesarean delivery (Lindo, et al., 2015).

2.6 Analgesia/anaesthesia and persistent LBP

There is a general concern amongst women that having an epidural during labour will cause long-term LBP (Wong and To, 2007). Research has established an association between epidural analgesia and LBP postpartum since 1969, but findings still seem to be controversial (Malevic, Jatuzis and Paliulyte, 2019). In retrospective studies by MacArthur, et al., (1990, 1992, 1995), Breen, et al., (1994) and Russels, et al., (1993,1996), they found a correlation between epidural anaesthesia and chronic LBP postpartum, but in the prospective studies they later conducted, there was no distinct correlation between the two (MacArther, et al., 1997).

In high income countries, epidural anaesthesia seems to be the golden standard for analgesia during labour (Abbasi, et al., 2014; Chia, et al., 2014). Chia, et al., (2016) found in their study that women who had caesarean deliveries with epidural anaesthesia were more prone to develop LBP than women who had vaginal delivery. They also found that older age and urinary tract infections were further risk factors for developing LBP postpartum.

In Abbasi's, et al., (2014) study, the non-epidural analgesia group had a higher prevalence of LBP (11.3%) at their one- and three-months' follow-up appointments. Although the duration of labour in the epidural group was longer, according to Malevic, Jatuzis and Paliulyte (2019), there was no significant correlation between the duration and development of postpartum LBP. They found that the type of anaesthesia received, epidural, intravenous or nothing, had no significance in the development of LBP postpartum. Thirty percent of women develop LBP irrespective of the anaesthesia used.

Lower back pain in previous pregnancies, in the antenatal period, after delivery, and after receiving epidural, were some of the reasons women refused epidural anaesthesia for their next delivery (Wong and To, 2007; Abassi, et al., 2014; Malevic, et al., 2019). According to Mogren (2007) and other more recent studies as seen above, there is no association with receiving epidural or spinal anaesthesia and the development of lower back pelvic pain (LBPP). The administration of epidural techniques has changed over the years from point of insertion to different drugs used, and the association seems to have become less (Silva and Halpern, 2010). The percentage of women suffering from long-term LBP, however, has not decreased but rather increased.

The consensus is that factors such as pregnancy itself, mode of delivery, trauma during labour, delivery, and the effectiveness of pain control, irrespective of the analgesia used, all play a role in the development of persistent LBP postpartum. As the discussed studies were conducted in high-income countries, further research is therefore necessary to investigate interrelated factors that is contextualised, that can

contribute to the onset of LBP postpartum, internationally as well as in Africa and South Africa.

Once these factors have been established, an intervention and prevention plan can be put into place to ensure good health and wellbeing under the sustainable development goals (SDG) for both mother and child.

CHAPTER 3

3. METHODOLOGY

3.1 Introduction

This study was conducted to establish the association between the onset of LBP postpartum and all the variables such as the mode of delivery, the analgesia used and the neuromusculoskeletal profile. In this chapter the methodology will be discussed that was used to determine these associations.

3.2 Type of study

The study took the form of a prospective cohort study, following the participants over a period of six months, starting at three months prior to delivery, at 24 weeks gestation, and extending to three months postpartum (Figure 3.1). Re-evaluation was done at the six-week and 12-week postpartum intervals.

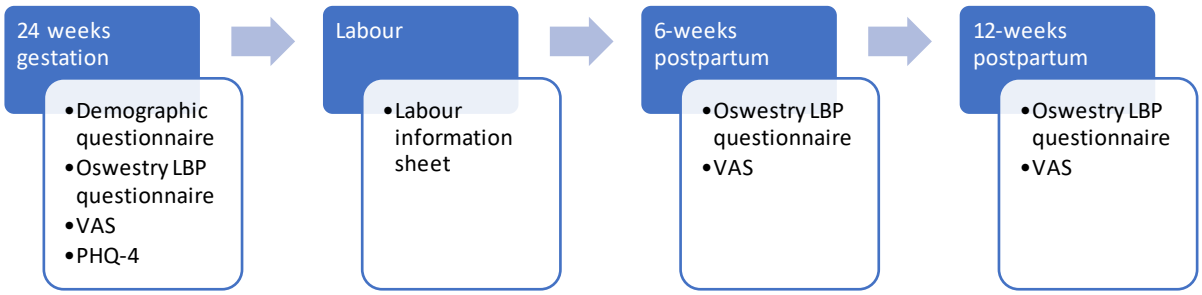

Figure 3.2.1 Outline of the study

3.3 Participants

3.3.1 Source of participants

All the pregnant women of East London and those attending the participating doctors' rooms, who were willing to take part in the study, were approached for inclusion in the study.

3.3.2 Sample selection

Initially the sample selection and size were based on the number of births in the private hospital in East London over a period of four months.

Due to Covid and the restrictions it has brought about, the sample selection and size had to be changed. Only one doctor was willing to participate in the study. The sample size was decreased to correlate with the number of deliveries she had in 2019, which was 75 that year, and over a period of four months it added up to be a sample estimation of 24. The whole population was therefore included. Using a sample size calculator from Calculator.net with a population size of 24 over a period of four months, a confidence level of 95% and a margin of error of 5%, a sample size of at least 23 participants were estimated. An estimated sample size would therefore be 28 participants to make provision for a 20% fall-out rate.

Eligibility criteria included the following:

Inclusion Criteria

Pregnant women from 24 weeks gestation.

Exclusion Criteria

- Lower back pain prior to pregnancy or back related problems i.e. surgery, fractures.
- Pregnancy-related LBP before 20 weeks gestation as research shows that current and previous LBP makes them more prone to developing long-term LBP (Östgaard and Gunnar, 1991; Katonis, et al., 2011).
- If they had a stillborn or lost the infant within the study period, or post-natal complications like Symphysiotomy, Osteitis pubis, pelvic dislocation, they were excluded.

3.4 Instrumentation and Outcome measures

3.4.1 Demographic questionnaire

Based on literature and general information needed to answer the objectives of the study, a self-developed demographic questionnaire was compiled to gather the information (Appendix A1). Information gathered included questions like age, education level, occupation, height, weight at the different interval levels i.e., before pregnancy, at 24 weeks, on admission to hospital before labour, after labour, and six- and 12-weeks postpartum. The number of pregnancies, expectations of LBP, sex of baby (if known), history of LBP in previous pregnancies, severity of LBP at that time,

treatment taken/received, medication in ante-natal period, and exercises in ante-natal period were established.

3.4.2 Oswestry Lower Back Pain Disability Questionnaire (OLBPDQ)

The Oswestry Lower Back Pain Disability Questionnaire (Appendix A2) was used to measure the percentage of perceived disability (Fairbank and Pynsent, 2000).

It has been proven valid and reliable, $r = 0.9$, with an Intraclass Correlation Coefficient (ICC) = 0.94 (Davidson and Keating, 2002). Minimal Clinically Important Difference (MCID) values range from 3.5 to 19.5 points (Copay and Cher, 2016).

It comprises of ten sections with six (6) statements under each section. Each statement is scored starting with a zero (0) for the first statement through to a five (5) for the last statement. If all sections are completed, the total score out of 50 is calculated and multiplied by 100 to get the percentage of perceived disability. If one section is incomplete or not applicable, then the total score (50) is deducted by five for each section missed and calculated accordingly.

- 0% - 20%: Minimal disability
- 21% - 40%: Moderate disability
- 41% - 60%: Severe disability
- 61% - 80%: Crippled
- 81% - 100%: Bed bound or exaggerated symptoms

3.4.3 Visual Analogue Scale (VAS)

To add a numeric value to the participants' pain, the Visual Analogue Scale was used (Appendix A3). The VAS has been validated and proven reliable and reproducible, with an ICC of 0.97 and a Minimum Detectable Change (MDC) of 0.08 (Joos, et al., 1991; Bijur, et al., 2001; Alghadir, Anwer, Iqbal and Iqbal, 2018).

The VAS was measured on a 100mm line, and a ruler was used to determine the numeric value of their pain experienced.

- 0 – 4 mm - No Pain

- 5 – 44 mm - Mild Pain
- 45 – 74 mm - Moderate Pain
- 75 – 100 mm - Severe Pain

3.4.4 Patient Health Questionnaire 4 (PHQ-4)

The Patient Health Questionnaire 4 (PHQ-4) was used to indicate the amount of anxiety and depression the participant was experiencing, (Appendix A4). The PHQ-4 has an ICC = 0.49 (Kroenke, et al., 2009).

The PHQ-4 consists of four questions with a score of zero (0) for "Not at all" and a score of three (3) for "Nearly every day". A total score of three and more for the first two questions suggest anxiety and for the last two questions, suggest depression (Löwe, et al., 2010). The total score is determined by adding all four scores together.

- 0 – 2 - Normal
- 3 – 5 - Mild
- 6 – 8 - Moderate
- 9 – 12 - Severe

3.4.5 Labour information

A labour information sheet, (Appendix A5), was given to the participants to gather information about the participants' labour, method of delivery, analgesia used, time spent in labour, the number of attempts/complications during insertion of the epidural. The position during labour, time spent in that position, effectiveness of the epidural or other analgesia used, concern of backache shown by the patient, the baby's weight, height and sex, mothers' mobility, complications during labour, last pain control received, and sensation was documented.

3.5 Procedure

3.5.1 Pilot study

The pilot study was conducted after ethical approval from the human research committee (medical) was obtained, clearance certificate number M200727 (Appendix D), and permission from the participating gynaecologist was granted (Appendix C3).

The pilot study aimed to identify the time consumption, problems, or bias of the assessment. Two participants from the participating gynaecologist were assessed following the same method as the main study. Their data was included in the main study as no major changes were made to the study.

3.5.2 Main study

The information sheet (Appendix B1) explaining the study, the consent forms (Appendix B2) and questionnaires (Appendix A1, A2, A3, A4) were dropped off at the participating gynaecologist's office in East London by the investigator. Recruitment of participants commenced in March 2021 with participants who were 24-weeks pregnant at the time and willing to participate in the study. Participants were recruited up until June 2021 by the gynaecologist's nurse. All pregnant women at their 24-week gestation follow-up visit with the gynaecologist were asked by the gynaecologist's nurse for voluntary participation. Those who were interested were given an information sheet (Appendix B1). If they were happy to participate, they signed the consent form (Appendix B2).

An assistant (nurse) was informed regarding the study procedures should the patients have any questions. Participants were asked by the nurse to complete the demographic questionnaire (Appendix A1), Visual Analogue Scale (VAS) (Appendix A2), Oswestry Low Back Pain Disability Questionnaire (OLBPDQ) (Appendix A3) and a Patient Health Questionnaire-4 (PHQ-4) (Appendix A4). The questionnaires were collected, by the investigator, from the doctors' offices once completed. The demographic questionnaire was assessed to determine the extent of previous LBP experienced to provide information whether the participants will be included or excluded from the study.

Due to the restrictions imposed on by Covid by the hospitals namely, their "No visitor policy", the labour information questionnaire was emailed to the participants after delivery, for completion.

At six weeks and 12 weeks postpartum, the investigator emailed each participant the Oswestry Low Back Pain Disability Questionnaire and the VAS which they completed. An email reminder was sent to complete the forms and those who failed to reply to the email received a reminder WhatsApp message. The participants who were experiencing pain at those intervals were contacted to arrange a face-to-face session to do a subjective and objective evaluation of the neuromusculoskeletal structures namely: lumbar spine, sacrioiliac joint (SIJ) and palpation of relevant structures. As advised by Gutke, Östgaard and Öberg (2008), a neurological assessment was included to make sure no serious pathology existed. The mechanosensitivity of the neural structures were measured by means of the SLR neural tension test. All the tests were conducted by the primary investigator in the same sequence.

3.6 Ethical considerations

Approval from all participating entities were needed to conduct the study. These included the Human Research Ethics Committee of the University of Witwatersrand, the participating doctor, and the volunteers. All subjects were informed about the study and were requested to sign an informed consent form giving permission for participation. Participation was voluntary and they could withdraw at any stage without penalty to themselves or any detriment to their health.

To keep participants' information confidential during the distribution and collection of questionnaires and data, each participant was allocated a number and the identity of that number was kept safe in a locked drawer. Only the researcher had access to the participants' personal information. Contact details of professional health care providers were provided to the excluded participants who were already suffering from LBP and to the ladies who scored more than six on the PHQ-4.

The declaration of Helsinki's principles (World Medical Association, 2013) was followed, ensuring the protection and wellbeing of the subjects throughout the study. The study was open to anyone that was willing to participate. All necessary information were given to ensure they could make an informed decision about partaking in the study, and they were free to discontinue at any stage.

All precautions as per the stated guidelines from the World Health Organisation (WHO) and National Department of Health (NDOH) were followed with regard to the COVID-19 regulations. The only contact session with the participant would be the objective evaluation, if they were experiencing any pain. Participants who were experiencing pain were advised to contact their physiotherapist to assist with methods of pain control if they needed hands-on therapy or verbal advice was given. Both the participant as well as the therapist wore a mask, while the therapist wore a face shield and an apron. The contact area was disinfected between every contact session. Hand washing facilities as well as disinfectant was readily available.

3.7 Data analysis

Data was double entered on an Excel spreadsheet and exported to the statistical software by the researcher and biostatistician. Data analysis was done by means of the Statistical Software Package and Excel (Version 2016). Descriptive statistics, namely frequencies and percentages were used to describe categorical data; while means and standard deviations/medians and interquartile ranges described continuous data. The distribution of the data was checked for selection of appropriate statistical analysis. A regression analysis was done to determine associations and repeated measures ANOVA to determine change over time. The Kruskal-Wallis H test and the Chi Squared test was used to determine the respective nominal and ordinal differences within each group. The Wilcoxon test was initially included to compare the differences between the groups with and without LBP with a 5% significance level however, due to the small sample size, this analysis could not be done.

3.8 Conclusion of the methodology

A full description of the study design, the layout of the timeline and the selection of participants with the inclusion and exclusion criteria have been covered in this chapter. The instrumentation and outcome measures used with the procedure followed as well as the method of the study were outlined and discussed. The collection and the recording of the data has also been mentioned, which will be presented in the next chapter and discussed in chapter 5.

CHAPTER 4

4. RESULTS

4.1 Introduction

Data collected was analysed to determine the association between the mode of delivery, the type of analgesia used, the neuromusculoskeletal profile and the onset of LBP postpartum. These characteristics were also used to compare between the groups who developed LBP and those who did not. This chapter will highlight the different findings.

4.2 Participants

There were 116 births during 2021 of which 43 was during the months our data collection took place. Sixteen of these subjects were willing to participate in the study. Two participants who completed only half of their baseline questionnaires had to be excluded. Six participants filled in the baseline questionnaires but never returned or replied to the reminder messages for the follow up questionnaires at six weeks and only one of these six replied for the 12 week follow up. One participant had a miscarriage and was excluded from the study. Another participant was excluded as she had a history of LBP and scoliosis. Seven participants were therefore included in the study for which longitudinal data collection over the six-month period was possible, while the data of 12 participants were analysed at baseline. Refer to Figure 4.2.1 for an illustration of the participants included and excluded in the study.

4.3 Descriptive statistics

The descriptive data describes the distribution in the mean age, height, number of previous pregnancies and LBP during their previous pregnancies, and are illustrated in Table 4.3.1, Figure 4.3.1, and Figure 4.3.2, respectively. The Shapiro-Wilk test was used to determine normality.

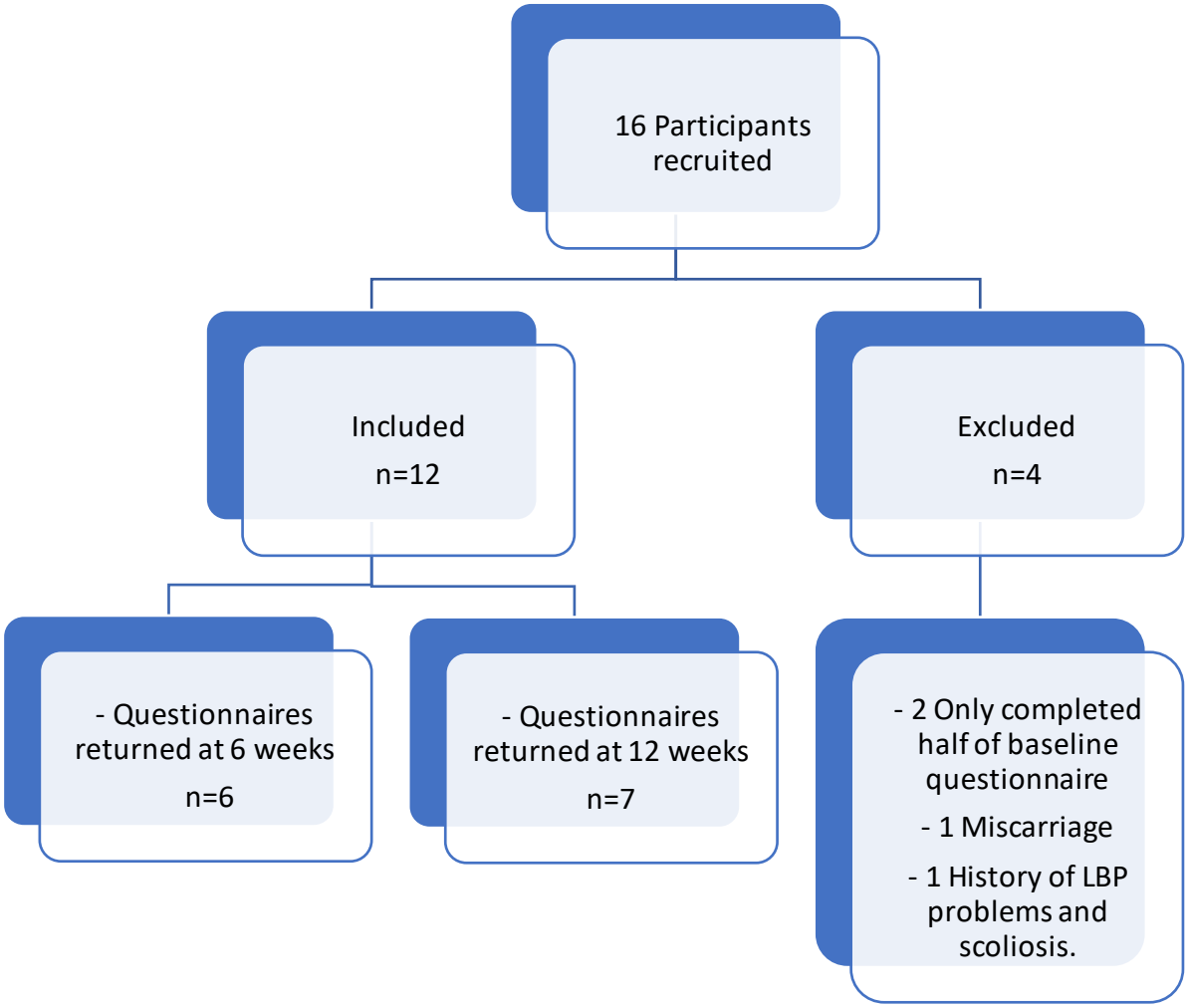

Figure 4.2.1 Flow diagram of participants

Table 4.3.1 Descriptive statistics of height and age (n=12)

	Age (years)	**Height(m)**
Mean	31.83	1.62 (median)
Standard Deviation	2.7247	
Min.	27	1.52
Max.	37	1.74
Normality (Shapiro-Wilk Test)	Yes	No

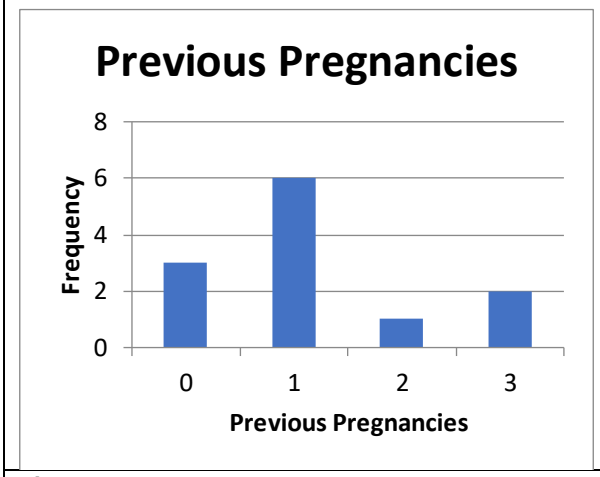

Figure 4.3.1

Number of previous pregnancies in participants (n=12)

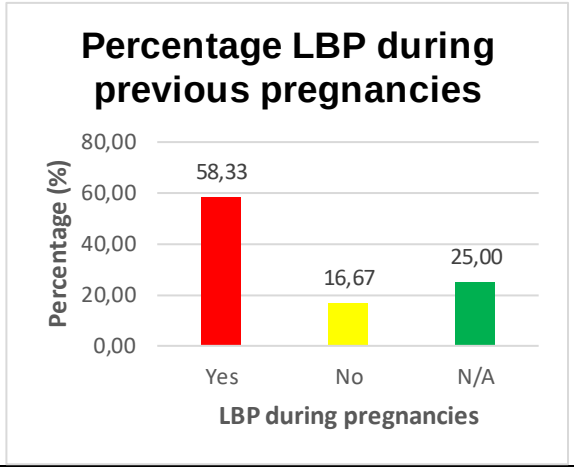

Figure 4.3.2

Percentage LBP during previous pregnancies (n=12)

Nine of the 12 participants had previous pregnancies and 58% of them experienced pain, ranging from mild to severe, during those pregnancies. Seven of the twelve participants expected pain for their current pregnancy. At 24 weeks gestation, 92% of the twelve participants experienced LBP, with the perceived intensity of pain felt, measured on the VAS, as a median of 24 mm. The disabling effect of the LBP measuring at a median of 18% (minimal disability) on the Oswestry LBP disability questionnaire.

4.4 Categorical statistics

4.4.1 Mode of delivery

In this data set, 16.66% (2/6) probability of births were natural births and 50% of the babies were born via caesarean section. Thirty three percent of the participants that presented for the 24-week antenatal examination did not return their follow-up questionnaires. Of the five babies born via caesarean section, two thirds were planned caesarean sections (66.66%) and one third were emergency caesarean sections (33.33%). The frequency distribution of onset of LBP in the various mode of delivery groups at various stages of their pregnancy and postpartum is illustrated in Figure 4.4.1 below.

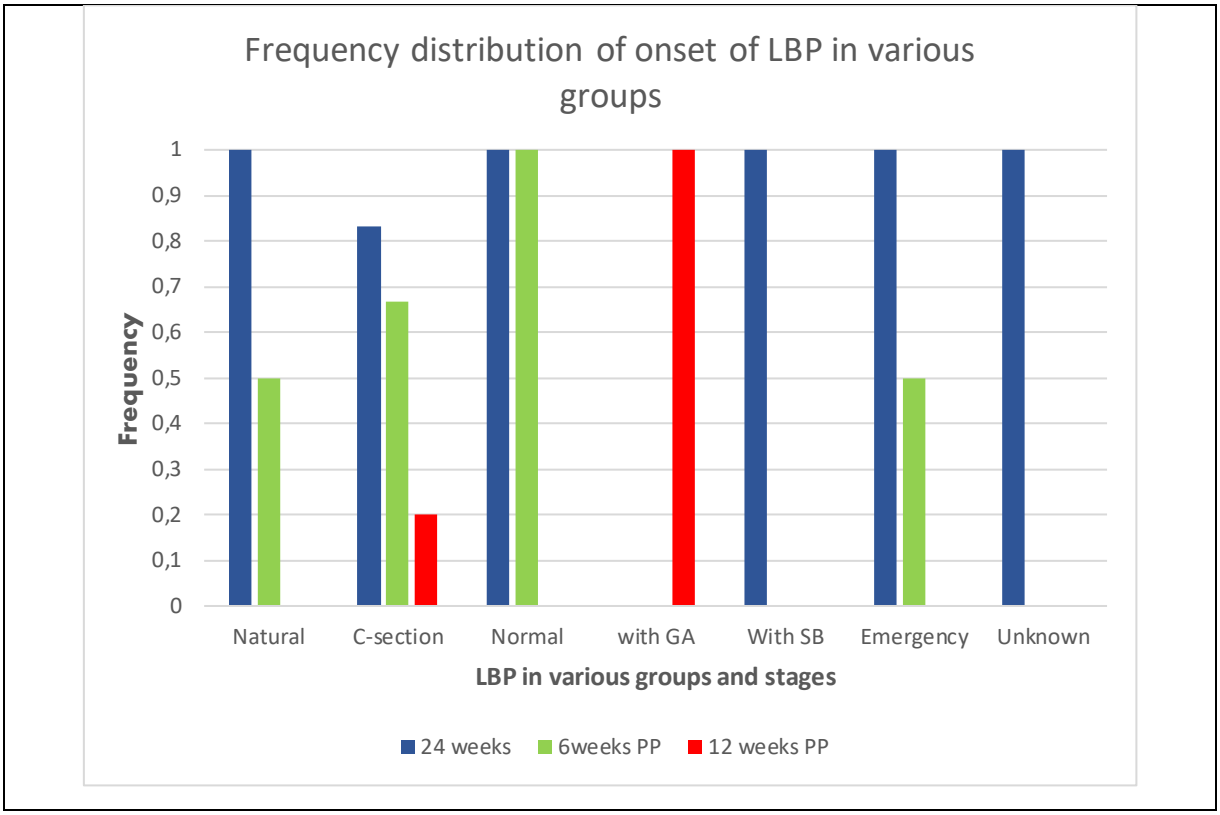

Figure 4.4.1 Frequency distribution of onset of LBP in various groups at various stages. 24 weeks (n=12), 6 weeks PP (n=6), 12 weeks PP (n=7) (Caesarean-section (CS), General anaesthesia (GA), Spinal block (SB), Postpartum (PP))

Fisher's exact tests' *p*-value is greater than 0.05, meaning that the study fails to reject the null hypothesis. There is thus not enough evidence to prove an association between the mode of delivery, be it natural or caesarean section, and the onset of LBP at six- and 12-weeks postpartum. Please refer to Table 4.4.1 for a summary of the *p*-values.

There is also not enough evidence to prove that there is an association between various methods of caesarean delivery and LBP at six- and 12-weeks postpartum (*p-value* = 0.3 and 0.6 respectively).

The natural delivery scored only 2% on the Oswestry LBP disability questionnaire and 0mm on the VAS. The caesarean deliveries scored an average of 18% and 60mm on the Oswestry LBP disability questionnaire and VAS respectively.

4.4.2 Analgesia/anaesthetic used.

Of the 12 participants examined only six returned their questionnaires for the six week follow up. That equalled 50% of the participants. Only seven returned their questionnaires for the 12-week follow up (58.3%).

Table 4.4.1: Summary of Fischer's exact test and independence (n=7)

		Onset of LBP			
		6 weeks postpartum		12 weeks postpartum	
		p-value	Significance	*p-value*	Significance
Method of delivery	**Natural vs Caesarean section**	1	No	1	No
Method of pain control	**Epidural vs Other**	1	No	1	No

At the six-week examination, 50% (n=6) of participants had LBP with a third having had an epidural (n=1), a third had a combined spinal and epidural (n=1), and a third had various analgesic techniques (n=1).

At the 12-week follow up, only one participant of the seven presented with LBP (14.28%) and the baby was delivered under general anaesthesia.

The Chi-Square test was used to determine the *p*-value of the collected data at six- and 12-weeks (p=0.5 and p=0.07, respectively). The *p*-value is more than 0.05, thus the null hypothesis cannot be rejected due to the lack of significant evidence to prove dependence of method of analgesia and LBP at six- and 12-weeks postpartum.

4.4.3 Neuromusculoskeletal profile

Unfortunately, due to Covid, none of the participants gave consent for an objective evaluation by the investigator to determine the neuromusculoskeletal profile of those who experienced LBP at various intervals.

4.5 Summary of the results

According to this data set used, 92% (n=12) of the participants had LBP at 24-week gestation. At the six-week postpartum follow up, of the 50% (n=12) that returned their questionnaires, 50% (n=6), 3/6, had pain and 50% (n=6), 3/6, had no pain, irrespective of the mode of delivery and the method of analgesia/anesthesia used. Only one participant had LBP at the 12-week follow up (14.28%) (n=7) and it must be noted that she is the only one who did not have pain at the 24-week gestation period and her delivery was done under general anesthesia. Chapter 5 will elaborate on the discussion by delving deeper into the presentation of the patients to identify possible trends and link it to current literature. This will be followed by the recommendations, and limitations identified in this study.

CHAPTER 5

5. DISCUSSION

5.1 Introduction

The data collected and illustrated in the previous chapter to determine the association between the mode of delivery and the type of analgesia/anesthetic used, as well as the role it might play in the development of LBP postpartum, will be discussed in this chapter.

No specific analysis could be done for the third and fourth objective due to the small sample size and covid restrictions (Chapter 6). The results will therefore be discussed qualitatively on a case-by-case basis, to identify possible trends in the reported results.

5.2. Categorical statistics

5.2.1 Mode of delivery

Out of the 12 participants enrolled in the study, 92% (n=12) had LBP in the 24th week of gestation. Of the six participants examined six weeks postpartum, and the seven participants examined 12-weeks postpartum, 50% (n=6) and 14% (n=7) respectively had LBP. The 50% (3/6) that had LBP at six weeks, one had natural birth and two had caesarean section deliveries. One of the caesarean sections were an elective surgery, while the other was an emergency delivery. It must be noted that the one participant that presented with LBP on week 12 postpartum was not available for examination at week six postpartum which could increase the percentage participants showing signs of LBP at week six postpartum to two thirds, if the assumption is not made that the back pain started at week 12 postpartum.

According to Chai, et. al., (2016) caesarean deliveries are more likely to cause LBP postpartum than vaginal deliveries. We were unable to obtain permission to use the Pain Index Inventory which would have given us an exact indication of the location of the participants' pain. Due to the natural tissue healing process that takes six weeks, we cannot assume that the pain is caused by anything else but the tissue injury during delivery and the natural physiological process of the body. This was the reason for doing a follow up at 12-weeks postpartum – as tissue healing and trauma from the

pregnancy and delivery process itself should have healed and the assumption made that the source of the pain might be due to other factors (Eisenach, et al., 2013; Bijl, et al., 2016; Komatshu, Ando and Flood, 2020).

At 12-weeks, none of the above mentioned 50% of participants, who had pain at six weeks postpartum, had pain. The only participant that had pain at 12 weeks had a scheduled, elective caesarean delivery done and did not go into labour. She scored 48% on the Oswestry LBP disability questionnaire which classified her under the severe disability category. She also classified her pain intensity on the VAS on a 70mm, as moderate pain. This is in accordance with the findings of Eisenhach, et al., (2013), Mogren (2007) and Mukkunavar, et al., (2013) who stated that women who had elective caesarean deliveries had an increased risk of developing LBP postpartum.

5.2.2 Analgesia/anaesthetics used during labour.

There were three participants who reported LBP at the six-week follow up, two having received an epidural and combined spinal epidural, and one natural birth with various methods of pain control.

The participant that received the epidural, went into labour, and had an emergency caesarean section. There were no complications with the insertion of the epidural, and she reported effective pain control. Her mobility was restricted, and she only got out of bed two days after delivery. She scored an 18% on the Oswestry LBP disability questionnaire and 60mm on the VAS at her six week follow up. She had no pain at 12 weeks. Although her pain control from the epidural was very effective, one could argue that due to the anaesthetic effect from the epidural, the extent of tissue damage during labour and the caesarean section could have been extensive. This is possibly why her perceived pain at six weeks was a 60mm on the VAS, classified as moderate pain. Since she went into labour prior to having the emergency caesarean section done, the physiological protective process that takes place within the body during labour according to Eisenach, et al., (2013) was activated and therefore her pain subsided as tissue healing took place and was gone by 12 weeks postpartum.

The second participant that experienced pain at her six week follow up had a scheduled caesarean section with a combined spinal block and epidural. There were three attempts made before an effective block was managed. The patient reported the pain control to be effective. Her mobility was restricted for 24 hours. She scored an 18% on the Oswestry LBP disability questionnaire and a 0mm on the VAS. In this case, one could argue, according to the research by Gao, Weng, and Wang, (2013) and Russel, et al., (1993), that the three attempts at inserting the spinal block and epidural could have led to irritation of the neural tissue which is why the participant perhaps felt pain during daily activities, as the neural tissue needs to glide within the spinal canal during activities of daily living. We presume that it is intermittent and a mechanical pain and linked to activities, as opposed to a constant pain as she scored a zero on the VAS. At 12 weeks she had no pain and scored both the Oswestry LBP disability questionnaire and the VAS as a zero.

The third participant that had 2% pain, at her six week follow up, on the Oswestry LBP disability questionnaire and 0mm on the VAS, had a natural birth. She was in labour for 19 hours and used various methods of pain control during her labour, ranging from breathing techniques, TENS, and meditation amongst others. She had no pain at 12 weeks and scored on both the outcome measures a zero.

It is interesting to note that all three participants expressed effective pain control during birth. Although no assumptions can be made on this data, it raises the question if the post-partum pain at six weeks was perhaps not related to pain management after or during birth, but rather the physiological changes or type of delivery as previously unpacked (Chapter 2, 2.4.2). This contradicts the findings of Eisenach, et al. (2013) who found that pain during delivery was associated with the development of post-partum LBP. It might be noted for future research to investigate the effects of pain during delivery, on the development of post-partum LBP. This might be of particular value in a low/mid-income country where there are limited resources and management during birth, leading to ineffective pain control and suspected consequences of developing LBP.

The participant that did have pain at 12 weeks and scored her pain a 48% on the Oswestry LBP disability questionnaire and 70mm on the VAS, had a scheduled

caesarean section under general anaesthesia. Unfortunately, there was no data available on her six week follow up and we presume that her pain did not start at 12 weeks but that she had it since delivery as she had no pain at her 24-week gestation measurement. According to Eisenach, et al., (2013) women that have scheduled caesarean sections are more prone to develop persistent pain due to the physiological processes of the body preparing for labour and delivery, not taking place.

5.2.3 Neuromusculoskeletal profile

Unfortunately, due to Covid and reluctancy from the participants, for fear of exposure, the participants were unavailable for an objective evaluation by the investigator to identify the neuromusculoskeletal profile. These and other limitations will be discussed in more detail in chapter 6.

5.3 Summary

As seen above, 92% (n=12) of our participants experienced LBP at their 24-week gestation period during pregnancy. This is to be expected according to Bergstrom, Persson and Mogren's (2014) study where they mention that LBP peaks at 24 weeks. At the six weeks postpartum follow up, 50% (n=6) had LBP, irrespective of the mode of delivery and analgesia used, while only 14% (n=7) had LBP at 12 weeks. There seems to have been a tendency for LBP to subside over the three-month period postpartum.

Even though it is not scientifically significant, it is noteworthy that one in every category, be it caesarean section, emergency caesarean section or natural birth with an epidural, a combined spinal and epidural or various alternative pain control, had pain at six weeks. Under the assumption that tissue healing takes six weeks, we are presuming that that could be the cause of their pain, as their pain had settled by the 12 week follow up.

The profile of the participant that had pain at 12 weeks was slightly different. She had a scheduled caesarean section under general anaesthesia. This might be supported by the interpretation of Eisenach, et al., (2013) who stated: that an elective caesarean

delivery increases the probability of LBP postpartum since the natural processes the body goes through during labour, which assists in preventing postpartum pain, does not occur and cannot protect them or prevent them from developing LBP postpartum. This might actually have positive or preventative implications for the development of LBP postpartum, if investigated further in a low/mid income country such as South Africa, where majority of the population give natural birth.

The results from this small sample indicated that 30% of women will develop LBP irrespective of the mode of delivery and the analgesia used (Mukkunavar, et al., 2013; Malevic, Jatuzis and Paliulyte 2019). Establishing the risk profile to develop postpartum LBP can assist in developing and implementing preventative measures to prevent and reduce the number of women suffering from chronic LBP. Early intervention strategies can also enhance patients' health-related quality of life and reduce the financial burden on patients, their families and the healthcare system. Furthermore, healthcare professionals can advocate for all pregnant women who prefers a natural birth rather than a caesarean section, as this might have a protective effect for the development of LBP.

In the next chapter we will conclude the report by touching on the limitations of the study and future recommendations for further studies.

CHAPTER 6

6. CONCLUSION

6.1 Introduction

In this study we aimed to determine the profile of women developing LBP postpartum. We determined the mode of delivery and analgesics used for those who developed LBP but were unable to determine the neuromusculoskeletal characteristics due to Covid.

6.2 Conclusion

This was a cohort study following pregnant women over a period of six months from 24 weeks gestation to 12 weeks postpartum. The aim was to establish the association between the development of LBP postpartum with mode of delivery and analgesia used. It was found that irrespective of the mode of delivery or analgesia used, 50% (n=6) developed pain at six weeks postpartum and 14% (n=7) at 12 weeks. The neuromusculoskeletal profile could not be established due to Covid.

6.3 Limitation of the study

Only one gynaecologist was willing to take part in the study which decreased the population size. This was also affected by Covid, as a lot of restrictions were placed on the hospital sector, and we were unable to include the population of all the private sector deliveries. This number further decreased with the hospital placing restrictions on visitors and the fathers were not allowed into hospital for the birth of the child. This forced a lot of participants to rather use a midwife and have a home birth and made them not attend all their gynaecological visits. Another restriction on the numbers were the fact that a lot of people had to cancel their medical aid and was no longer able to attend a private gynaecologist. Due to the limited sample size, one cannot assume that it is a typical sample of the population in East London or any other city in South Africa. Socio-economically one presumes that the participants are middle class, employed people that can afford private health care.

The small sample lead to a couple of additional restrictions, such as restricted analysis regarding possible confounding factors, such as comorbidities, that should be

considered in future research. Loss of follow-up also seem high due to the small sample size (50%), but this was mainly due to the effects of the COVID pandemic at the time of data collection.

We could not obtain permission to use the Pain Index Inventory to determine pain characteristics. Due to the restriction covid placed on the attendance for the objective evaluation we were also limited in determining the area of pain and source of pain. This assessment could have provided more information on possible interactions or confounding regarding acute pain management on the development of chronic LBP and the profile of the patients.

6.4 Recommendations for future studies

In future studies, to get a statistically significant result, a larger population size and a longer period of data collection, is recommended. As pregnancy is a long process, and the delivery is unpredictable and can either be shorter or longer than expected, it is recommended that data collection takes place over two to three years rather than just a couple of months. It is also recommended to use a broader population by including midwifes, doulas and the public sector clinics and hospitals. Investigating the current assumptions made from high-income countries, such as the association of caesarean section and pain during delivery, in a low/mid-income country, might be of value in a population where vaginal delivery and poor management during delivery might be prominent. Due to the limitations of this study, no valid clinical recommendations or conclusions can be made at this stage.

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APPENDICES

Appendix A1 - Demographic Questionnaire

Name:……Log Number:……

Age:……

Expected date of birth:……

Phone number: Work:……

Home:……

Cell:……

Next of kin: Name:……

Number:……

Email address:……

Home address:……

City/Town:……

Postal address:……

Education:……

Occupation:……

Height:……

Weight: Before pregnancy:……Currently:……

History of previous lower back pain, injuries or fractures:……

Number of previous pregnancies:……

History of back pain in previous pregnancy: No:…… Yes:……

Severity of back pain at that time: Mild:….. Moderate:….. Severe:….. Very Severe:…..

Treatment taken/received:……

Medication in ante-natal period:……

Exercises in ante-natal period:……

Are you expecting any back pain during this period:……

What is your preferred method of pain control during labour:……

POSTPARTUM INFO:

Weight on discharge from hospital:……

At 6 weeks:……At 12 Weeks:……

Appendix A2 - Oswestry Low Back Pain Disability Questionnaire

Oswestry Low Back Pain Disability Questionnaire

Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

Section 1 – Pain intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- ☐ The pain is very severe at the moment
- ☐ The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc)

- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it causes extra pain
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but manage most of my personal care
- ☐ I need help every day in most aspects of self-care
- ☐ I do not get dressed, I wash with difficulty and stay in bed

Section 3 – Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift very light weights
- ☐ I cannot lift or carry anything at all

Section 4 – Walking*

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me from walking more than 1 mile
- ☐ Pain prevents me from walking more than 1.6km
- ☐ Pain prevents me from walking more than 800m
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time

Section 5 – Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favourite chair as long as I like
- ☐ Pain prevents me sitting more than one hour
- ☐ Pain prevents me from sitting more than 30 minutes
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6 – Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than 1 hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7 – Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

Section 8 – Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9 – Social life

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

Section 10 – Travelling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from travelling except to receive treatment

References

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Appendix A3 - Visual Analogue Scale

What is your current pain level on?

I_____I

No Pain Worst pain imaginable

Appendix A4 - PHQ-4

PHQ-4

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Little interest or pleasure in doing things	0	1	2	3
4. Feeling down, depressed, or hopeless	0	1	2	3

The PHQ scales were developed by Drs. Robert L. Spitzer, Janet B.W. Williams, and Kurt Kroenke and colleagues. The PHQ scales are free to use. For research information, contact Dr. Kroenke at kkroenke@regenstrief.org

Kroenke K, Spitzer RL, Williams JBW, Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4 Psychosomatics 2009;50:613-621.

Appendix A5 - Labour information questionnaire

Name:……Log number:……

Date of delivery: ……

Labour:	Yes	____	No	____
Caesarean section:	Yes	____	No	____
Emergency caesarean section:	Yes	____	No	____
Natural birth:	Yes	____	No	____
Labour epidural received:	Yes	____	No	____
	Epi	____	CSE	____

Other modulation of pain: Intravenous:_____Intramuscular:_____

Number of attempts/complications of epidural:……

Effectiveness of epidural analgesia: Fair:____ Good:____ Excellent:____

Duration of labour: _____h_____min

Position during labour:……

Time spent in that position:……

Concern of backache shown by participant:……

Weight on admission:……

Babies weight:……

Babies sex:……

Mobility: How soon did you move or get up after delivery:……

Any loss of sensation or tingling:……

Appendix B1 – Information sheet

STUDY INFORMATION DOCUMENT

STUDY TITLE:

Mode of delivery, analgesic and neuromusculoskeletal profile of women developing new onset lower back pain postpartum.

Dear Madam,

I, Joretha Steyn, a physiotherapist of profession, am conducting a research study on pregnant women like yourself, for my Master's degree. In this study I aim to determine the profile of women who experience low back pain post-delivery. All the different factors will be taken into account i.e. Back pain prior to pregnancy, back pain during pregnancy, the type of delivery, the method of pain control chosen and the neuromusculoskeletal structures involved in the pain experienced.
I would hereby like to invite you to take part in the study. Allow me the opportunity to explain the study in more detail. Your participation in the study will help us increase our understanding and knowledge of women who suffer from lower back pain after delivery.

What is involved in the study?

This study will in no way alter any care or treatment that you would normally receive for your pregnancy, nor will it interfere with the course of your pregnancy or delivery. It is a mere add on in the form of questionnaires to be filled in at certain stages of your pregnancy and an objective evaluation with the primary investigator, me, to determine the neuromusculoskeletal structures (nerves, muscles, joints and bones) involved, if you experience any lower back pain.

All participants will be given and requested to sign an informed consent form prior to the commencement of the study. All participants will be asked to fill in three questionnaires and a demographic information sheet at the 24-week gestation period. A labour information sheet will be filled in after delivery. At six and twelve weeks post-delivery another two questionnaires will be filled in and an objective evaluation will be

scheduled with me if pain is present at any of those times in order to evaluate the neuromusculoskeletal structures involved.

The questionnaires will be emailed to you or alternatively you can fill it in while you wait in your gynaecologist's office and I will fetch it, ensuring that your identity and details stay concealed and confidential at all times. No one else will have access to the details except the primary investigator, which will be me. The questionnaires should not take more than 10 minutes to fill in. Most of these questions will be related to the presence of back pain and the effect it has on your life. If an objective evaluation is needed, you will be asked to come to my offices in order for me to conduct an objective evaluation. This will entail functional movements of the back to determine which structures are contributing to the pain. This should not take more than 30 minutes.

As stated before, this study will in no way interfere with any of the participants' care plan during and after their pregnancy, it is a mere add on and there are no risks involved.

Benefits of being in the study:

Due to the nature of the study, being questionnaire based rather than treatment based, there are no direct benefits in taking part in the study other than the advancement in knowledge about factors playing a role in lower back pain experienced in women post-partum. Contact details of health care professionals for those who suffer from back pain will be distributed and a treatment plan will be set in place if they wish to seek treatment for their pain.

The results of the study can be distributed and made available to all participants who are interested to have them after completion of the study.

Voluntary participation:

Participation in this study is completely voluntary and by choice of each participant. You are allowed to discontinue or withdraw participation from the study at any stage with no penalty or loss of any benefit to you. You will not be required to provide a reason for discontinuation of the study and any data collected on such person will be destroyed, unless the participant specifically consents to its retention. Certain

postpartum complications may lead to termination of participation by me without regard to the participants consent.

Reimbursement:

You will incur no cost or financial expenses for this study nor will you receive financial compensation for participation.

Confidentiality:

The participants' personal information will only be disclosed if required by law; if the Human Research Ethics Committees of the University may exceptionally require personal data to respond to a formal complaint or conduct a compliance audit.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg. A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research. Their contact details will be provided below for any reporting of complaints or problems. Every participant will receive a copy of the participation information document.

Contact details:

Joretha Steyn, primary investigator, telephone no. 072 333 5575, or by e-mail at jo.steyn@hotmail.com,

Dr Corlia Brandt, Supervisor, on telephone no. 011 717 2014, or by e-mail at corlia.brandt@wits.ac.za.

If you have any concern with regard to the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretaries are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

Yours in health.

Joretha Steyn

Appendix B2 – Informed consent form

Informed consent of participants

Clinical Research Study

Mode of delivery, analgesic and neuromusculoskeletal profile of women developing new onset lower back pain postpartum.

I, ..., hereby agree to take part in Joretha Steyn's research study.

- I have been given a Study Information Sheet, which is attached hereto, which explains the nature and processes involved in this study;
- I was given time to read it, or had it read to me, in the language I best understand;
- I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;
- I believe I fully understand why the study is being conducted and what the intended outcomes will be;
- I understand that there will be no immediate benefit to me, should I agree to participate, nor will I receive any payment; conversely, participation will not cost me anything but my time;
- I understand that, even if I initially consent to take part in the study, I may subsequently withdraw at any time and would not be required to give any reasons; if that happened, any data collected about me for the purpose of the study would immediately be destroyed, unless I give consent for it to be retained;
- I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study, I am free to speak to any of these contacts.
- The study will be conducted for a six-month period from 24-week pregnancy till three months post-natal. I might be contacted after this period if any other information with regard to the study is required.
- There are minimal risks involved as I will follow the normal course of my labour process as explained by my Doctor and this will just be extra information given during the process.
- This study and Joretha's visits will not in any way replace my normal physiotherapy sessions if the Doctor deems it necessary to refer me for in-hospital physiotherapy treatment. If I do get referred and Joretha treats me, I will be billed according to the treatment received and it will not be part of the study but fall under Joretha Steyn Physiotherapists practice.
- Joretha will have access to my health and medical records during this process in order to make the correct decisions with regard to my health and she will be using my information within her research study for statistical purposes. However, my personal details will remain confidential at all times and will not be disclosed.

Signed at _____ on this _____ day of _____ 20__.

Signature: _____

Printed name and surname: _____

Email address: _____

Telephone number: _____

Witnessed by:

Name of Witness: _____

Signature: _____

Date: _____

Contact details:

Joretha Steyn, Principal Investigator, telephone no. 072 333 5575, or by e-mail at jo.steyn@hotmail.com,

Dr Corlia Brandt, Supervisor, on telephone no. 011 717 2014, or by e-mail at corlia.brandt@wits.ac.za.

Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretaries are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Appendix C1 – Doctors request letter for approval

Doctors request letter for approval

Dear Doctor,

I would hereby like to inform and invite you and your patients to take part in a study I want to conduct for my Master's degree in 2020/21. Your participation and contribution will play a big role in conducting the study and it will be highly appreciated.

As a physiotherapist, I treat both hospital and out patients. I have been seeing more and more young women between the ages of 28 - 39 complaining of back pain which started after they had their baby, majority of them being convinced that their back pain started when they had their epidurals.

We both know the literature is inconclusive about the role epidural analgesia plays in the cause of back pain. The aim of my study is to determine the profile of women developing new onset lower back pain postpartum by comparing the mode of delivery, method of analgesia received and neuromusculoskeletal profile of these patients.

All your pregnant patients will receive the Oswestry Low Back Pain Disability Questionnaire as well as the Visual Analog Scale (VAS) to fill in at their 24-week gestation period in order to get a base line of their current pain. These questionnaires will be repeated at their six weeks postpartum follow up appointment with you and again 12 weeks post-delivery. I will do an objective evaluation on those that do complain of back pain in order to determine which structures are involved.

Included is a consent form that you will have to sign in order to confirm your willingness to participate in my study.

I would've liked a personal introduction with a short discussion and explanation but with the Corona virus and lockdown, I hope you don't mind if we communicate telephonically or via email. Feel free to contact me if you have any questions with regard to the study.

Yours in health



Joretha Steyn

BPhysT (Pta)

072 333 5575

jo.steyn@hotmaill.com

Appendix C2 – Doctors informed consent letter

Doctors informed consent letter

I understand/agree:

- To allow Joretha Steyn to have access to my patients and their clinical details of those willing to participate in her research study.
- That the study will in no way influence my treatment plan with my patients and that this is merely an add on.
- That this study will have no adverse effects on my patients and is safe to conduct.
- That my patients' confidential information will not be compromised.
- That this study and what Joretha will be doing with my patients postpartum will in no way replace my normal course of treatment or referral if I deem it necessary for the patient to receive in-hospital physiotherapy treatment. I will continue to refer to the physiotherapist of my choice as per normal.

Signed at _____ on this _____ day of _____ 20__.

_____ _____

Signature Printed name and surname

Email address: _____

Telephone number:_____

Appendix C3 – Signed consent letter from participating gynaecologist

Honouring Gerda Bence

JORETHA STEYN
PHYSIOTHERAPISTS

46 St James Road, Southernwood,
East London, 5201
The Village Centre, Schafli Road
Crossways, 5201

T: 043 722 1001 | **T/F:** 043 722 5550
E: steynphysio@gmail.com
Pr. No. 0825409

Doctors informed consent letter

I understand/agree:

- To allow Joretha Steyn to have access to my patients and their clinical details of those willing to participate in her research study.
- That the study will in no way influence my treatment plan with my patients and that this is merely an add on.
- That this study will have no adverse effects on my patients and is safe to conduct.
- That my patients' confidential information will not be compromised.
- That this study and what Joretha will be doing with my patients postpartum will in no way replace my normal course of treatment or referral if I deem it necessary for the patient to receive in-hospital physiotherapy treatment. I will continue to refer to the physiotherapist of my choice as per normal.

Signed at East London on this 31 day of August 2020.

Signature

Robyn Spring

Printed name and surname

Email address: elgyn@mweb.co.za.

Telephone number: 083 6798660.

Appendix D – Ethics clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Ms J Steyn

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M200727

NAME: (Principal Investigator)	Ms J Steyn
DEPARTMENT:	School of Therapeutic Sciences Department of Physiotherapy Medical School University
PROJECT TITLE:	*Mode of delivery, analgesic and neuromusculosketal profile of women developing new onset lower back pain postpartum*
DATE CONSIDERED:	2020/07/31
DECISION:	Approved unconditionally
CONDITIONS:	Re-issued on 2021/07/05 - no longer any hospital involvement
SUPERVISOR:	Dr C Brandt
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2020/11/30

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

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 submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **July** and therefore reports and re-certification will be due in the month of **July** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature ...pal Investigator

2 February 2021
Date

Appendix E – Turn-it-in plagiarism report

Research report - final draft 19 March

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