Study Protocol

A PROTOCOL ON COMPARATIVE EVALUATION OF EPIDURAL AND SPINAL TECHNIQUE OF LABOUR ANALGESIA IN RURAL WOMEN OF CENTRAL INDIA AND THEIR PERCEPTIONS REGARDING PAIN RELIEF IN LABOUR

ABSTRACT

BACKGROUND

Labour pain while giving birth is one of the most excruciatingly painful and emotionally stressful experience for a woman that has piqued the interest of several academicians. Labour pain is induced due to the uterine ischemia, expansion of vagina and birth canal, muscle contractions, and pressure on the bladder. To relieve the severe pain during labour, analgesia is required, which offers pain relief without the loss of consciousness. Regional analgesia (Epidural and spinal) are most commonly used for offering pain relief to women.

Aim - To evaluate whether low dose spinal analgesia is a better alternative to lumbar epidural analgesia for pain relief in labour.

Objectives - Primary objective is to evaluate efficacy of lumbar epidural and spinal analgesia for pain relief in labour. Secondary objective is to evaluate the perceptions of women towards the use of labour analgesia, to evaluate the maternal and fetal outcome and to evaluate the barriers affecting the use of lumbar epidural and spinal analgesia for women during labour.

METHODS

In this randomized control trial study, where 60 patients are present in each group. In Patients in group E epidural analgesia will be given using 18-gauge Tuohy epidural needle by a loss of resistance to air technique, and after confirmation of space, an epidural catheter will be inserted cranially in L3 - L4 interspace, and a dose of 15ml of 0.125 % bupivacaine with 25µg of fentanyl would be given slowly. Group S patients will receive subarachnoid block using 25-gauge needle inserted and directed to reach the intrathecal space between L3 - L4 or L4 - L5 intervertebral space. After a successful Dural puncture with acceptable CSF flow, 0.1 % bupivacaine 2ml with 25µg fentanyl will be given via spinal needle. Throughout the duration of delivery, hemodynamic monitoring including SPO_2, ECG, heart rate and blood pressure of mother and fetal heart rate would be monitored under the guidance of obstetrician and anesthesiologists.

RESULTS

The groups are expected to be similar. However, Low dose spinal analgesia may be a better alternative to lumbar epidural analgesia in providing effective pain relief for women in labour in terms of cost effectiveness. There are no results found as it is just a protocol. Results are yet to come.

CONCLUSIONS

The study would offer new insights and knowledge into the use of epidural and spinal analgesia in India, particularly Wardha. The perceptions of women, towards labour analgesia, its consequences or side effects, and the myths associated with its use will be comprehended.

KEY WORDS

Labour Analgesia, Spinal Technique, Epidural Analgesia.

BACKGROUND

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One of the most memorable and important event in any woman's life is giving birth to a child.[1] Labour pain while giving birth is one of the most excruciatingly painful and emotionally stressful experience for a woman that has piqued the interest of several academicians.[2] Labour pain is induced due to the uterine ischemia, expansion of vagina and birth canal, muscle contractions, and pressure on the bladder.[3] To relieve the severe pain during labour, analgesia is required, which offers pain relief without the loss of consciousness.[4] Regional analgesia (Epidural and spinal) are most commonly used for offering pain relief to women. Combined spinal - epidural (CSE) analgesia and other neuraxial analgesia are found to be effective in most of the cases with minimum risk to the patient and the child.[5] But, there are several controversies and myths associated with taking analgesia during labour pain that women restrict themselves to opt for this option.[6] The literature has found confounding perspectives on lumbar epidural analgesia, where some say it increases the probability of caesarean surgeries in women, some found that there is no association with caesarean delivery and the intake of epidural analgesia.[7] It is however recognized that taking epidural increases the duration of delivering the child.[8] Women fear that taking any form of analgesia or anaesthesia during labour, will cause permanent back pain to them. While in developed nations, analgesia is used routinely for labour pain management, its use in developing countries is not a common practice.[9] In some cultures, labour pain is considered as a necessary punishment defined by the providence and seeking any pain relief is deemed as an action against him.[10] Women are also taught that pain during labour is natural and accepting that would bring more joy in their lives and is also an essential sign of womanhood. In earlier times, women were supported culturally by other women when giving birth, but in the 21st century with the popularity of institutional delivery, the support from other women has become a lost practice.[11] In a scenario with less support from other women, and myths associated with taking pain relief for labour, it has become difficult to provide the needed support and care to women during delivery. A study by Ezeonu et al. 2017 has acknowledged that labour pain is most critical and severe for a woman and must be offered with pain relieving methods under the careful supervision of a physician.[11] However, with the aforementioned controversies surrounding child delivery, offering labour pain management has become a challenge. It has become essential to educate pregnant women and health care providers on the different options available for labour pain management so as to ensure that the health of the women is not affected when providing care during delivery. Here, we will be comparing epidural technique with spinal technique of labour analgesia in rural women and their perception regarding pain relief.

The use of lumbar epidural and spinal analgesia during labour, though found as effective in several studies, its awareness among women is limited in our population. Considering the pain management in labour is one of the largest concerns for women, it is imperative to understand the myths or challenges associated with the adoption of epidural and spinal analgesia. Its current use in the hospitals, associated benefits and challenges, and maternal perceptions towards it would provide essential knowledge on how awareness can be increased so as to assist women better and also improve the healthcare services. With this study, the healthcare sector can also benefit and therefore, this is the rationale behind conducting the study.

Aim and Objectives

Our aim is to evaluate whether low dose spinal analgesia is a better alternative to lumbar epidural analgesia for pain relief in labour.

Primary objective is to to evaluate efficacy of lumbar epidural and spinal analgesia for pain relief in labour.

Secondary objective is to evaluate the perceptions of women towards the use of labour analgesia, to evaluate the maternal and fetal outcome and to evaluate the barriers affecting the use of lumbar epidural and spinal analgesia for women during labour.

METHODS

Study Area

AVBRH Hospital Sawangi (Meghe) Wardha.

Study Population

Full term booked parturients posted for normal delivery.

Study design

Randomised control trial.

Sample size

112. (56 in each group.)

Statistical Analysis

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Informations was written at the and of methods. I suggest should have some information fro example (please refer paragraph …)

Simple random sampling would be adopted for questionnaire distribution.

Chi- square test and unpaired student t-test by SPSS software.

Inclusion criteria will be ASA physical status 1 and 2, Nulliparous or multiparous parturient aged 18 - 42 years booked with the ANC clinic and women without any previous uterine surgery. All women will be excluded with, pregnant women with medical disorders, Patient refusal, women with a history of previous caesarean delivery. And Platelet count less than 100,000. The study will be conducted after approval of institutional ethical committee. Written informed consent will be taken. The aim of the study would be explained to each participant who will give consent for the study. Pre - procedure questions will be filled by the study population. The Patients will be enrolled and divided two groups (S group = Spinal group and E group = Epidural). Patients in active labour with cervical dilatation between 4 - 5 cm and normal fetal heart rate tracings will be considered. After proper counselling and patients who are willing for labour analgesia, each patient will be randomized, using a computer generated randomization table, weather to receive either spinal or epidural analgesia. Each patient will receive at least 1000ml Ringer lactate solution. Under all aseptic precautions the block will be performed with the patient in sitting position. In Patients in group E, epidural analgesia will be performed using 18 - gauge Tuohy epidural needle by loss of resistance to air technique, and after confirmation of space, an epidural catheter will be inserted cranially in L3-L4 interspace, and a dose of 15ml of 0.125 % bupivacaine with 25µg of fentanyl would be given slowly. Patients in group S will receive subarachnoid block using 25 gauge needle inserted and directed to reach the intrathecal space between L3 - L4 or L4 - L5 intervertebral space. After a successful Dural puncture with acceptable CSF flow, 0.1 % bupivacaine 2ml with 25µg fentanyl will be given via spinal needle. Throughout the duration of delivery, hemodynamic monitoring including SpO2, ECG, heart rate and blood pressure of mother and fetal heart rate would be monitored under the guidance of obstetrician and anesthesiologists. Bupivacaine is most commonly used for labour epidural analgesia because of its long duration of action and relative motor-sparing effect.[12] The duration of analgesia will be defined as the time from the injection of local anesthetic solution until the patient requested additional analgesic dose. Patient will be assessed every 5min for the first 15 min, and then every 15 minutes until additional analgesia was requested. The severity of labour pain would be assessed using visual analogue scale. (0 = no pain; 10 = severe pain). Within the first 24 - 48 hours postpartum patient will fill the self-administered questionnaires.

Assuming onset of sensory block of 4.4 minutes and standard deviation of 1.5 minutes (Tarek AbdELBarr et al), keeping power at 80 % and confidence interval at 95 % (alpha error at 0.05) a sample of 56 patient would be required to detect a minimum of 20 % difference for evaluating efficacy of lumbar epidural and spinal analgesia for pain relief in labour. We include 60 patients in each group to compensate for possible drop outs.

Technical feasibility - Instrumentation and available expertise-feasible and expertise available. Approximate cost (Budget) for Epidural analgesia will be approximately Rs.2500 and Spinal Analgesia will be Rs.500.

DISCUSSION

Pain in labour continues to be a prominent issue and universal concern for several women during labour. In labour pain management, providing effective solution and care increases women satisfaction while lowering the pain and enhancing the clinical outcomes.[13] Apart from providing pain relief, other factors such as the relation between the woman and the doctor, and the ability to make relevant decisions also affect the satisfaction level of the patient. Therefore, it is imperative for the healthcare professionals such as nurse and doctors to have complete knowledge and awareness towards analgesic options such they can discuss it with pregnant women and cater to their expectations throughout the child delivery experience.[8] However, not every woman, especially in Indian public hospitals, are provided with choices of pain relief methods. Women must have their own choice of opting the mechanisms of pain relief during delivery but at the current time, the healthcare professionals and not equipped with awareness towards labour pain management so as to offer relevant choices to women without endangering their health.[14] The nurse and doctors must provide relevant care and labour management practices; they must also be able to identify the problems in the patients plan of labour pain management.

When compared to the western countries and developed nations, the average use of labour analgesia is only 11 % which is eminently low.[15] While it is introduced in the hospitals of India, it is essential to note that being a very religious country, several women are not aware and due to myths would not indulge in labour pain relief practices. Regardless, it is essential to understand all the barriers affecting the intake of labour analgesia in India. The lack of physician's support and below par quality of care affects the overall experience of a women during labour, who may not be subjected to epidural analgesia or other options.[3] Painful labour is not only an issue for women but it also produces different changes in maternal physiology that may have significant impact on the fetus, thus making it crucial to understand all the facets associated with labour pain management.[16]

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Labour pain management while actively practice in developed nations and though introduced in India, is not commonly practiced in India, especially in the public hospitals. The current study will therefore focus on the use of lumbar epidural and spinal analgesia in the management of pain during labour in rural hospital, Wardha. The labour pain management including the identification and management of adverse complications would be studied. Also, the study will look into the effectiveness of lumbar epidural and spinal analgesia for pain relief among women in labour. The women who did not receive labour analgesia during their previous child delivery would also be considered for the study. The perceptions of women towards the risks, fallacies, and uncertainties will be studied.

The study would offer new insights and knowledge into the use of epidural and spinal analgesia in India, particularly Wardha. As there are no concrete research on this area, the study will offer valuable contribution in the current body of literature regarding the impact of labour analgesia on women with a history of normal delivery. The perceptions of women, towards labour analgesia, its consequences or side effects, and the myths associated with its use will be comprehended. The uncertainties associated with epidural analgesia during labour pain management will be comprehended. Such information and inputs on the awareness levels of women in Wardha will provide key knowledge on how labour pain management can be improved. The study would be useful for not only researchers in this domain but also practitioners and women who have no knowledge on the benefits and effectiveness of epidural and spinal analgesia and other options. Further research can be done by comparing the usefulness of regional with other analgesic options used in Indian hospitals.

RESULTS

The groups are expected to be similar in terms of age, sex, weight and American society of anaesthesiologists grading. It is expected that, Low dose spinal analgesia may be a better alternative to lumbar epidural analgesia in providing effective pain relief for women in labour as it is more cost effective as compare to epidural analgesia. There are no results found as it is just a protocol.

CONCLUSIONS

The study would offer new insights and knowledge into the use of epidural and spinal analgesia in India, particularly Wardha. The perceptions of women, towards labour analgesia, its consequences or side effects, and the myths associated with its use will be comprehended

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