A RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFICACY OF INTRAVENOUS PARACETAMO AND INTRAMUSCLAR TRAMADOL AS LABOR ANALGESIC

By

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ABBREVIATIONS

BP	-	Blood Pressure
CVS	-	Cardiovascular System
E.D.D.	-	Expected Date of delivery
E.F.W.	-	Estimated Fetal Weight
IP NO.	-	Inpatient Number
L.M.P.	-	Last Menstrual Period
R.S.	-	Respiratory System
U.S.G.	-	Ultrasound Sonography
SD	-	Standard Deviation
VAS	-	Visual Analogue Scale
NICU	-	Neonatal Intensive Care Unit
FTVD	-	Full-Term Vaginal Delivery
LSCS	-	Lower Segment Caesarean Section
I.V	-	Intravenous
I.M	-	Intramuscular
APGAR	-	Appearance, Pulse, Grimace, Activity and Respiration.

VAS	-	Visual Analogue Scale
N. R. S	-	Numeric Rating Scale
V. R. S	-	Verbal Rating Scale
F. P. S	-	Face Pain rating Scale

ABSTRACT

Some women breeze through giving birth, and some unfortunate women must go through the most painful moments for human beings. Epidural analgesia is the most effective analgesia for women in labor and is relatively safe. But epidural services are not routinely available in most obstetric units in developing countries because of the medical equipment, services and personnel cost. The basis of this study was to see whether paracetamol, a regularly used analgesic offers better and safer labor analgesia compared to tramadol.

OBJECTIVES OF STUDY*:* To know the efficacy and safety of intravenous paracetamol as a labor analgesic compared to intramuscular tramadol.

METHODS: All low risk primigravida's in active labour > 37 weeks period of gestation with singleton pregnancy were included in the study and all high risk cases were excluded and a total of 220 patients were randomised into two groups by computerised block randomisation. They were divided into two groups ;one group was given I.V Paracetamol 1000mg given over 15 minutes and the other group was given I.M Tramadol 100mg.The primary objective was to measure the individual pain intensity and scoring using the visual analogue scale (VAS) and progression of labour and the secondary objective was to measure the incidence of maternal and fetal outcomes in both the groups .

RESULT: In our study 220 primigravida's were taken into the study but 22 cases who went for emergency LSCS were excluded from the fetal outcomes but included for pain score analysis. It was noted that majority of the patients given paracetamol had individual VAS score of 4 (42.70%) and tramadol had a score of 7 (55.5%), with a significant p value of 0.0001. Patients given paracetamol had on an average moderate type of pain (90.90%) with a

significant p value of 0.0001 compared to tramadol where patients experienced severe pain (82.7%).It was also observed that the duration of active labor was reduced in the paracetamol group with a significant p value of <0.0001 and the duration of second stage of labor was reduced in the paracetamol group with a significant p value of 0.003.Only around 6.4% neonates born to patients given paracetamol went to NICU compared to tramadol with a significant p value of 0.0001.

CONCLUSION: According to the study conducted, it can be concluded that Paracetamol is better and economically friendly, with better maternal and fetal outcomes in developing countries as compared to tramadol along with additional advantage of shortening the duration of labor.

KEY WORDS: Pain, Labor analgesia, relief, paracetamol, tramadol, VAS score.

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1. INTRODUCTION

Some women breeze through giving birth and the unfortunate women must go through the most painful moments for a human being. Labor pain causes anxiety, pressure, strain, pressure on your back, perineum and uneasiness. It influences the progress of labor as well as the fetal fate. The associated sympathetic stimulation causes maternal hyperventilation, which causes respiratory alkalosis. Respiratory alkalosis, in turn, causes excessive catecholamine and cortisol release, which causes uterine vasoconstriction, which reduces placental blood flow and, as a result, reduces oxygen transfer to the fetus, resulting in fetal metabolic acidosis. Therefore, reducing pain during labor will help to enhance perinatal and mother outcomes. [1, 2].

Labor is one of the happiest as well as one of the most painful moments in a women's life. The most painful pain any woman has ever felt is during labor. The nature of labor is multifaceted, subjective, and individualized. It responds very differently to various stimuli that are each individually perceived and understood. Conditions that are emotional, motivating, cognitive, social, and cultural can change these stimuli.[2].

"Labor can be described as the contractions that happen in sequence in uterine which results in the dilation of cervix and voluntary movement of bearing down until expulsion" [3,4].

Pain is usually a very unpleasant, highly complex, unique process which has the complete emotional component and that is why the pain management is a very important part of good prenatal and postnatal care. It's very common for pregnant women to worry about labor pain. Labor being a very painful experience requires constant analgesia. The labor pain is which the pregnant women experience varies in intensity due to different physiological and psychosocial factors. In rare cases, women feel less pain while giving birth. But most commonly, they experience the most severe pain of their lifetime. The different factors that affect the labor pain can vary from previous experience, partner support, environment to position and mid-wife care [5-8].

During labor and delivery, pain always emanates from various locations. Contractions cause pain during the first phase of childbirth. It typically has a visceral or cramp-like quality, develops in the uterus and cervix, and is caused by uterine ischemia and cervix dilatation. Distension of the vagina, perineum, and pelvic floor is what causes the discomfort in the second stage of labor. The second stage of pain is characterized by a blend of somatic pain from the distension of

vaginal and perineal tissues and visceral discomfort from uterine contractions. The woman also feels rectal pressure and an impulse to bear down in addition to the aforementioned [9].

Physiologic repercussions, as well as sensory and emotional reactions, are the main outcomes of pain [9-11]. Labor pain, which is thought to increase minute ventilation and oxygen consumption during contractions, typically results in severe respiratory alkalosis and a shift to the left in the maternal oxyhaemoglobin dissociation curve, which reduces oxygen transfer to the fetus. We can infer that compensatory hypoventilation during the intervals between contractions results in momentary maternal and perhaps even fetal hypoxia. By using analgesic methods such systemic opioid analgesia, which cause some respiratory depression, these hypoventilation episodes can be made worse. Post-traumatic stress disorder development and labor pain have been linked [10].

Many different techniques have been described for reducing discomfort during labor. An ideal labor analgesic will typically have the following characteristics: administration simplicity; consistent, predictable, rapid start; mom's calm demeanor and high level of regulation during the first and second phases of labor; analgesia throughout every stages of labor; no motor blockade; enable ambulation and different birthing positions; preserve the stimuli for expulsive

efforts during the second stage of labor; and facilitate the opportunity for delivery. Sadly, none of the methods that are currently in use have all of these characteristics [12-18].

Commonly, both non-pharmacological and pharmaceutical therapies are used to relieve pain during childbirth. Hypnosis, biofeedback, intramuscular or subcutaneous sterile water injection, submersion in water, aromatherapy, relaxation techniques (yoga, music, audio), acupuncture or acupressure, manual techniques (massage, reflexology), and transcutaneous electrical nerve stimulation are among the non-pharmacological interventions that are typically used (TENS). Parental opioids, opioid antagonists, inhalational techniques, and localized analgesia, anaesthetics, or opioids are examples of pharmacological therapies [12–14]. The gold standard method for labor pain treatment is regional analgesia, however in developing nations like India, such facilities may not always be available. It also involves expensive equipment and continuous monitoring facilities, which may not be available everywhere. While pharmacological therapies focus primarily on pain relief during delivery, non-pharmacological approaches try to support women as they cope with labor pain [15–20].

It has long been established that epidural analgesia offers labor pain relief that is superior to that offered by other techniques. However, in our world, it is not always practical, inexpensive, or readily available. Opioids administered intravenously are frequently used to ease labor discomfort. If a general anaesthetic is used in an emergency, they may produce nausea, vomiting, and delayed gastric emptying, which raises the risk of aspiration. In general, opioids pass through the placenta. In the uterus, exposure to opioids causes the fetal heart rate to slow down and the variability between beats to decrease. Because of the substantial danger of infant respiratory depression, they cannot be used throughout the entire labor process. A non-opiate analgesic is paracetamol [16–18].

Typically, paracetamol works to relieve pain by preventing the manufacture of prostaglandins in the central nervous system of the patient and by decreasing the transmission of pain impulses to the peripheral nervous system [20].

Tramadol is a synthetic opioid that resembles pethidine and has a modest affinity for mu receptors. When administered intramuscularly, it takes effect within 10 minutes and lasts for 2-3 hours [26].

This study compares the effectiveness of injectable tramadol and intravenous paracetamol as labor analgesics to determine whether paracetamol, an easy-to-

use and often used analgesic, appears to deliver better and safer labor analgesia when compared to tramadol in primigravida's.

1.1 JUSTIFICATION OF THIS STUDY

Most of the patients in developing nations do not receive any analgesia during labor, even though labor is an extremely painful procedure. According to a Maiduguri study on the desire for pain treatment in labor, 81.6% of women would prefer it, but only 11% received analgesia, and 65.1% of them described the pain as being severe. In our context, epidural analgesia is not commonly offered [(22)].

The more popular opiate analgesics are linked to drowsiness, delayed stomach emptying, nausea, and vomiting in female patients. They cannot be used in advanced labor, which is when labor pain is typically at its worst because they cause respiratory depression in the newborn.

Thus, there is a need for an efficient alternative analgesic that can be utilized throughout the entire labor process without having the negative effects of opiates on the mother, fetus, or newborn. Previous studies have demonstrated that intravenous paracetamol is an excellent pain reliever throughout delivery (even

more so than pethidine), as well as following caesarean surgery and manual vacuum suction [20-22].

There is not enough information available currently about the effectiveness and safety of intravenous 1paracetamol in reducing labor pain. As a result, the goal of this study is to determine whether paracetamol, a simple and common analgesic, offers superior and safer labor analgesia when compared to tramadol.

1.2 HISTORICAL BACKGROUND

James Young Simpson, who gave ether to a patient with a malformed pelvis during labor in the year 1847, is credited with ushering in the era of obstetric anaesthesia. Criticism of his idea of "etherisation of labor" was fierce. [23] The religious argument over whether aesthetic should be used during childbirth persisted until 1853, when John Snow gave chloroform to Britain's Queen Victoria as she gave birth to her eighth child, Prince Leopold . [23-24] The era of "obstetric anaesthesia" started to take off in the years that followed. Stanislav Klikovitch wrote about the usage of nitrous oxide in Russian labor in 1881. [24] The first-time pethidine was administered during labor was in 1940, while morphine and hyoscine were first utilized in 1902. [23]

Cleland first discussed continuous lumbar epidural block during birth in 1949. Between 1900 and 1930, descriptions of paravertebral, spinal, and lumbar and caudal epidural, as well as pudendal nerve blocks for obstetrics, were published. [23] The first report of continuous caudal analgesia during childbirth was published by Hingson and Edwards in 1943, which marked the beginning of continuous neuraxial analgesia as it is used today. [25] Multiple developments over the past 20 years have resulted in the comprehensive and evidence-based management of labor pain.

Figure 1: The four stages of labor

1.3 THE STAGES OF LABOUR

Normal labor is typically a continuous procedure that is broken down into three stages. The latent phase and the active phase are further separated into the first stage. The time between the start of labor and full cervical dilation is typically regarded as the first stage of labor. In contrast, the second stage of labor lasts from when the cervical cervix has fully dilated until the baby is delivered. The time between the baby's delivery and the placenta's delivery is considered the third stage of labor.

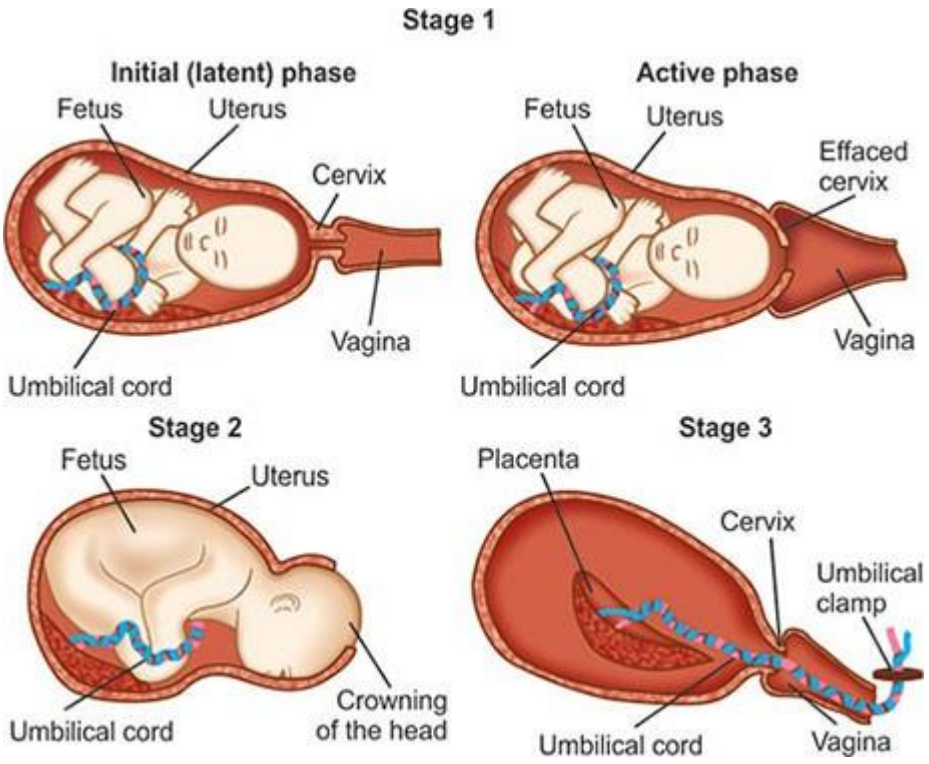


Figure 2: The three stages of labor; latent and active phase, delivery of the baby and delivery of the placenta

Friedman provided data describing the evolution of spontaneous labor in his well-known study of the labor market. “In most primiparous individuals, the initial stage of labor lasts 6–18 hours, and the lower limit for the rate of cervical dilatation in the active period is 1.5 cm, compared to 2–10 hours and 1.2 cm in multiparous patients. Contrarily, the second stage of labor lasts between five and thirty minutes for multiparas and between thirty and an hour for patients who are primiparous. The third stage lasts for any of them for 0–30 minutes “([26-27].

1.4 THE SOURCES OF LABOR PAIN AND PAIN PATHWAY

Pain is a term used to describe an unpleasant sensory experience that is characterized as an emotional reaction to real or probable tissue injury or as such tissue damage is explained. [(28)] Nociceptive sensations that arise in the uterus and cervix's mechanical and chemoreceptors during the early stage of labor are what cause pain perception. The tremendous pressure created by uterine contractions stimulates high threshold mechanoreceptors. In later phases of myocellular injury caused by repeated contractions, “bradykinin, histamine, serotonin, acetylcholine, and potassium ions are released, activating chemical nociceptors”. (29)

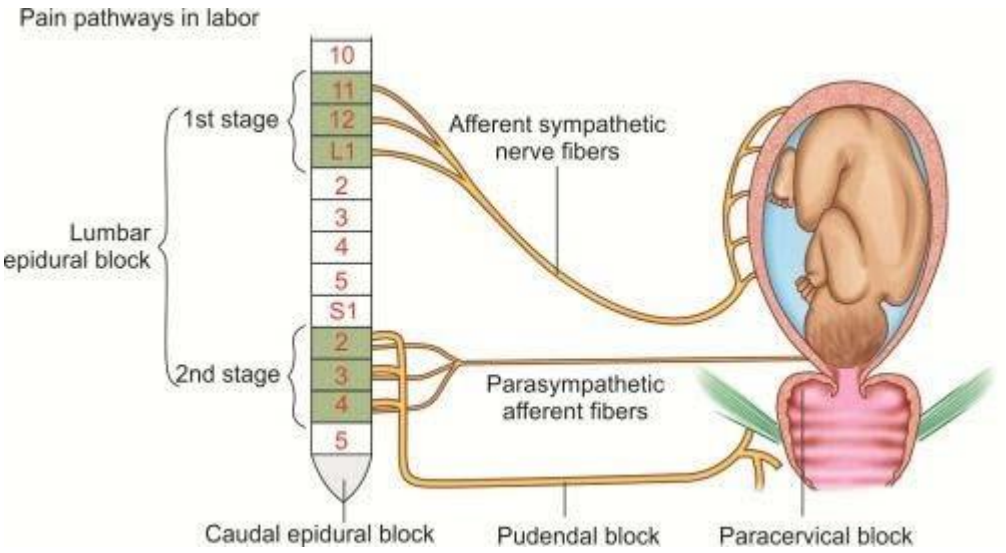


Figure 3: Pain pathways in labor

"Uterine contractions and the stretching of the cervix are the causes of the first stage of labor's pain. During contractions, constriction of the arteries feeding the myometrium causes uterine ischemia (reduced blood flow and subsequently a local oxygen deficit), which causes discomfort. As is common during the majority of the first stage of labor, the patient experiences pain or discomfort only during contractions and no pain in between. The discomfort is widespread and poorly localized, visceral, and cramping in nature. Referred pain is a type of discomfort that originates in the uterus and spreads to other parts of the body, including the lower back, iliac crests, gluteal region, thighs, and abdominal wall" (29-36).

"The C primary afferent fibers, which progressively pass through the inferior, middle, and superior hypogastric plexus, the lumbar, and lower thoracic sympathetic chains, and end in rami communicates connected with T10-L1 spinal neurons, are primarily responsible for carrying sensation. The neurotransmitter substance P is secreted at the type C nerve endings, and the C fibers transmit pain at a rate of 0.5-2m/sec. [30-36] Sensations from the cervix travel to the sacral segments S2-4 of the spinal cord through the pelvic plexus and pelvic parasympathetic nerves".

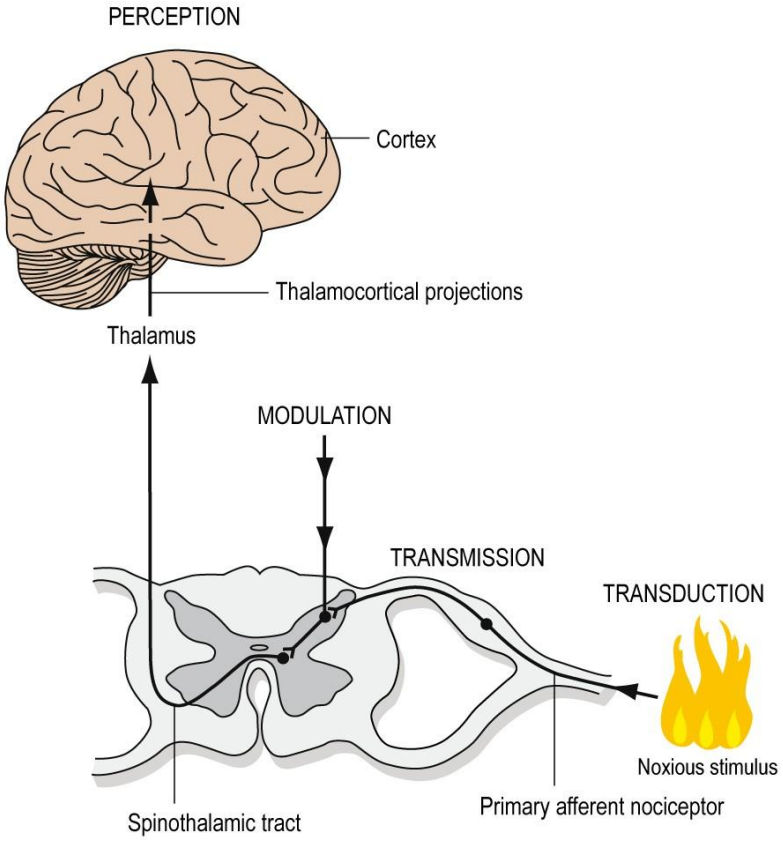


Figure 4: Perception of pain in labor

"Somatic pain predominates during the late first and second stages of labor due to traction and distension on the perineum, pelvic floor, and pelvic structures. This pain is transmitted through the genitofemoral nerve (L1-2), ilioinguinal nerve (L1), and posterior cutaneous nerve of the thigh as well as the pudendal nerve (through the anterior rami of S2 through S4) (S2-3). Contrary to first-stage visceral pain, it is acute and well-localized and is primarily caused by reduced arborization and faster conduction velocity in the sacral pathways. Pain is mostly transmitted at a speed of 6 to 30 m/sec by tiny type A fibers. Glutamate is the neurotransmitter released at the ends of type A pain nerve fibres". [30-31]

"Both ascending and descending pathways are used by the labor feeling after it enters the central nervous system. The dorsal grey matter of the spinal cord (Rexed's Laminae I to V) contains the first synapse in the ascending pathways. Most primary afferent neurons initially form synapses in the substantia gelatinosa's laminae I and II; locally projecting interneurons then form synapses on the deeper located wide dynamic range (W.D.R.: lamina V) neurons. Both the big myelinated Aâ and Aä mechanoreceptor afferents and the C polymodal nociceptive afferents send synaptic excitatory input to the W.D.R. neurons" [36-38].

"It's significant that all the lamina V cells that respond to high threshold cutaneous afferents from a skin area supplied by the same spinal cord segments also respond to low threshold cutaneous afferents from the same skin location. The neurological underpinning for the phenomena of referred pain, which happens during each uterine contraction, is thus provided by the lamina V cells. The spinothalamic tract leads from the dorsal grey matter cephalad to the thalamus, brain stem, and cerebellum, where spatial and temporal analysis take place, as well as to the limbic and hypothalamic systems, which are the source of emotional (affective) and autonomic responses". [30]

"The descending routes start in the primary sensory cortex and extend to the midbrain's peri aqueduct grey matter and rostral ventral nuclei of the thalamus. Dorsolateral funiculus is where thalamic projections enter the spinal cord and exit the spinal cord, ending in the dorsal grey matter". [29-31]

1.5 GATE CONTROL THEORY

Sometimes, even very strong pain cues could be disregarded. This is only possible because specific nerve cell clusters in the cerebral cortex, brainstem, and spinal cord have the capacity to block pain impulses and regulate them. The labor pain-relieving effects of hypnosis and the pain-relieving methods taught 1in childbirth education classes are explained by the gate-control theory of pain.

[32] This hypothesis states that while pain feelings often travel down sensory nerve routes to our brain, only a small number of sensations, or messages, may ever pass through these nerve channels at the same time. Utilizing distraction tactics like music, visualization, focal spots, and massage or stroking can lessen or even totally block the ability of neural pathways to convey pain. By shutting down a fictitious gate in the spinal cord, these diversions have been shown to work in stopping pain impulses from reaching the brain. Thus, the sensation of pain is lessened. [33]

Additionally, when the laboring lady engages in neuromuscular and motor activity , the spinal cord's activity further changes the pain's transmission. Most of the cognitive effort, which calls for focus on breathing and relaxation, necessitates selective and focused brain activity, which in turn opens and shuts the gating mechanism. More sophisticated cognitive strategies will be needed to sustain effectiveness as work gets harder. The gate-control theory thus emphasizes 1the necessity for a comforting delivery environment that enables the laboring mother to unwind and engage in a variety of higher mental activities. [30]

1.6 THE FACTORS INFLUENCING PAIN PERCEPTION

Pain perception is a complicated process made up of interrelated physical and psychological components. Women have a wide range of it. The endogenous opioids known as beta endorphins, which are released by the pituitary gland and work on the central and peripheral nerve systems to relieve pain Endorphin levels in humans often rise during pregnancy and childbirth. Endorphins are strongly linked to our experiences of euphoria and pain relief. As endorphin levels rise, the pain threshold typically rises as well, allowing laboring women to endure severe discomfort. (32)

The degree of discomfort that a laboring woman is often willing to put up with during childbirth is referred to as pain tolerance. She will look for ways to lessen the pain if this threshold is exceeded. (33)

Adolescent females, nulliparous parturient, patients with higher education, and those in advanced labor are some of the factors linked to enhanced pain perception. (34) Additionally, greater pain scores during birth have been linked to anxiety. Because of the increased catecholamine release brought on by excessive anxiety and dread, which is known to restrict blood flow and increase muscle tension, the impulses coming from the pelvis to the brain are also increased. The impression of pain is heightened by this action. Thus, as worry and anxiety grow,

muscular tension rises, uterine contractions become less effective, discomfort grows, and a cycle of growing dread and anxiety starts.

This cycle will eventually cause labor to move more slowly. The patient will lose faith in their capacity to deal with pain, which could have a negative impact on how effective the pain management techniques are. [35] It has been demonstrated that prior experience (multiparity), the presence of a laboring partner and ongoing support, a comfortable or familiar setting, midwife-led care, and an upright position during the second stage of labor are all associated with decreased pain perception. [32-35]

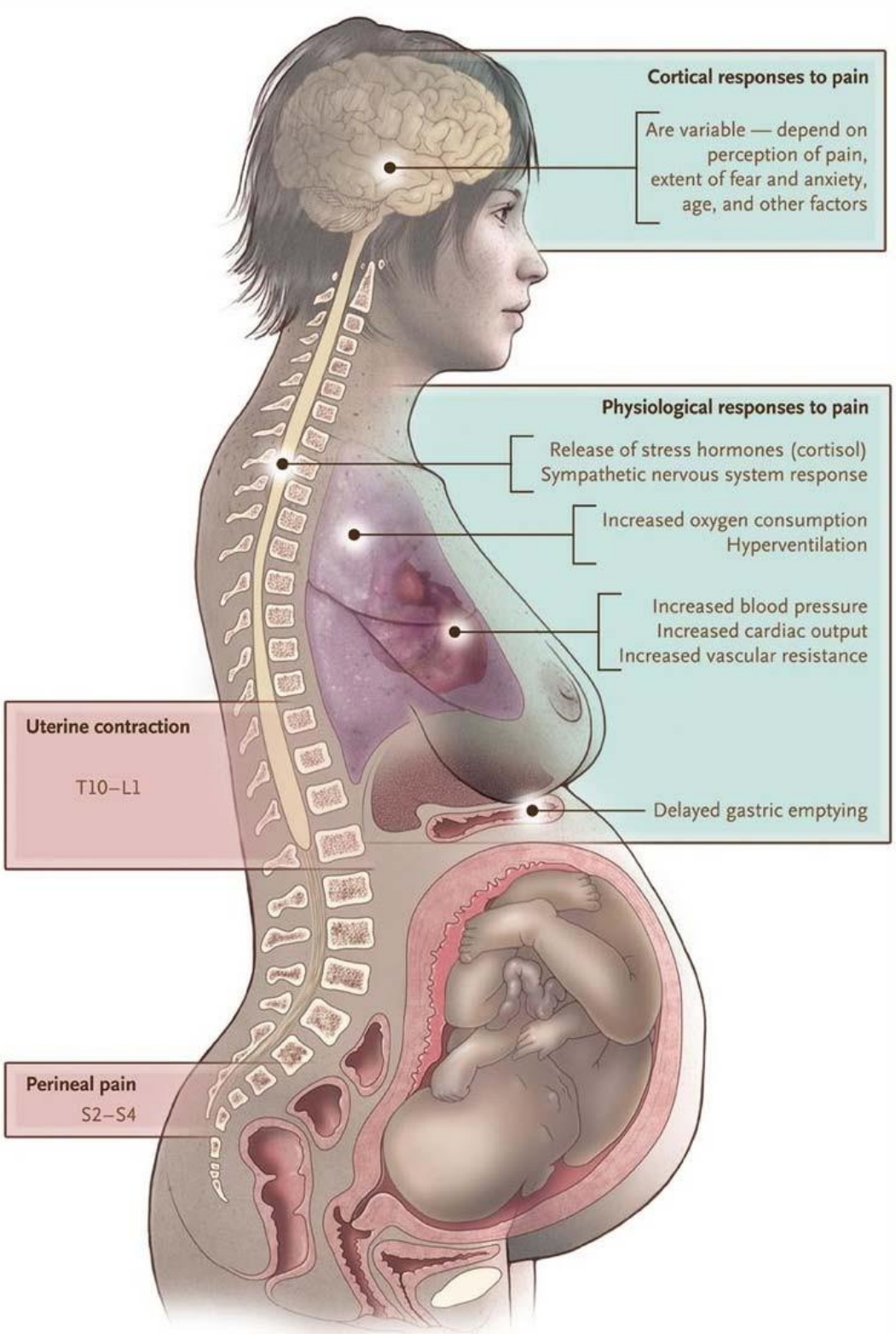


Figure 5: Factors influencing pain perception

1.7 THE EFFECTS OF LABOR PAIN

Pain typically has physiologic repercussions as well as sensory and affective (emotional) reactions. Thus, it is important to provide pain medication during labor for both medical and humanitarian reasons. Pain during labor intensifies observable physiological repercussions. As a result of the sympathetic nervous system being activated in response to increasing pain, blood pressure and heart rate are elevated due to higher catecholamine levels. The normal reaction of maternal respiratory patterns to an increase in oxygen demand is change. As the discomfort increases and faster, shallower breathing techniques are used during this period of contractions, hyperventilation, which can occasionally be accompanied by respiratory alkalosis, may also happen. There may be pallor and diaphoresis.

In the active phase of the first stage of labor , nausea and vomiting are more frequent as the gastric acidity rises. Uterine activity may also tend to decline, which could lengthen labor and have an impact on the health of the fetus. Psychiatric disorders like postpartum depression and post- traumatic stress disorder have also been linked to extremely painful labor. [7] Particular emotional (affective) manifestations of pain are frequently observed. These modifications typically involve an increase in anxiety accompanied by a

narrowing of the perceptual field, as well as writhing, sobbing, groaning, pointing (with hands clenched and wringing), and increased muscle excitability throughout the patient's body. [36]

1.8 DIFFERENT METHODS OF LABOR PAIN RELEIF

During labor, a variety of pain control techniques can be used. These frequently consist of both pharmaceutical and non-pharmacological therapies. Each woman's experience of labor pain is unique, and the way or methods selected to relieve it depends on the techniques that are available locally, the existence or absence of a treatment's contraindications, and the person's personal preferences.

1.8.1 N0N-PHARMAC0L0GICAL INTERVENTI0N

The main goal of these interventions is to aid women in managing the discomfort of labor. They consist of techniques like “hypnosis, biofeedback, sterile water injections intravenously or subcutaneously, submersion in water, aromatherapy, relaxation exercises like yoga or listening to music, acupuncture or acupressure, manual techniques like massage or reflexology, and transcutaneous electrical nerve stimulation (TENS)”. Non-pharmacologic interventions can be utilized throughout labor and are frequently straightforward and safe, with few to no

serious side effects. [32] However, there isn't much proof to back up the effectiveness of many of these tactics, and some of them might be expensive and time-consuming. [33-34]

1.8.2 PHARMAC0L0GICAL INTERVENTI0N

These can be categorized as localized methods and systemic methods. Inhalational drugs and systemic analgesics, which may be opioid or non-opioid , are examples of systemic approaches. [35-40] "Epidural analgesia, spinal analgesia, and local nerve blocks" are some of the regional techniques. Combinations are another option.

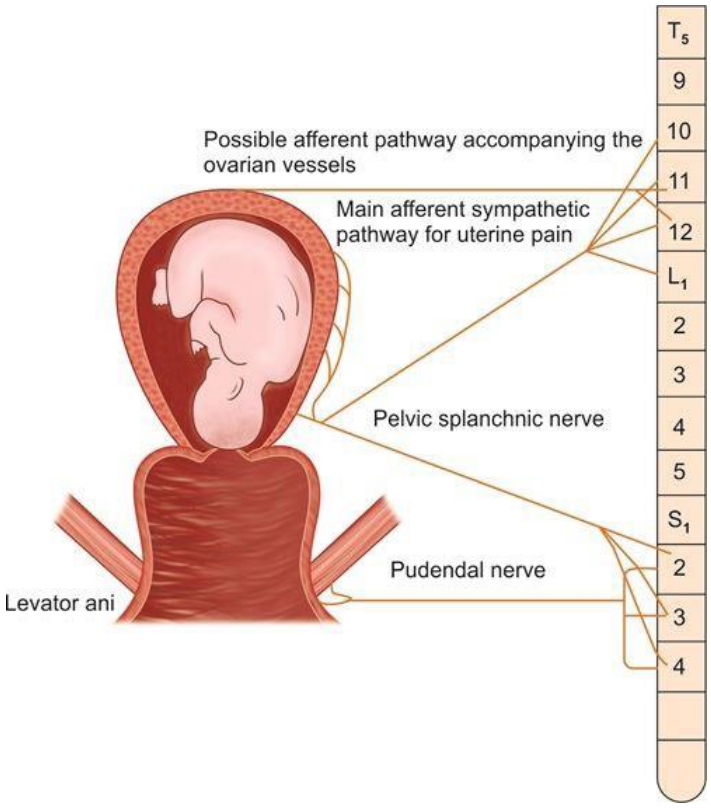


Figure 6: Different uterine pain pathways

1.8.3 INHALATIONAL AGENTS

During labor, a mother can remain awake and maintain the function of her protective laryngeal reflexes by breathing in sub-anesthetic doses of anesthetic drugs. “Nitrous oxide, also known as Entonox (N2O:O2 50:50), isoflurane, sevoflurane, desflurane, trichloroethylene in air, cyclopropane, nitrogen protoxide, nitralgin, anesoxyn, and eutonal are all options for inhaled analgesia for pain management during labor”.

Because uterine contractions are not appreciably reduced by sub anesthetic dosages of nitrous oxide or isoflurane, they are recommended. However, in contemporary obstetric practice, only nitrous oxide (in 50% oxygen) is frequently utilized for analgesia. [40] This is due to its simplicity in administration, comparatively low flammability, absence of offensive odor, lack of impact on uterine contractions, lack of reports of malignant hyperthermia , minimal toxicity, minimal cardio-vascular system depression, and rapid onset and elimination from pregnant women, fetuses, and newborns. After receiving basic education, the woman can apply herself while being watched.

Inhaled analgesia is given either continuously by inhaling both during and between contractions, or occasionally, with use ceasing when the discomfort

from the contractions lessens or vanishes (preferred). However, there is concern about the impact of prolonged exposure, focusing on staff rather than patients, due to observed probable connections with loss of fertility, miscarriage, premature birth, and decreased vitamin B12 concentrations. [37] The fundamental reason is assumed to be nitrous oxide's inhibition of methionine synthase. [38]

Nitrous oxide labor analgesia is utilized in modern hospitals with good ventilation, thereby eliminating the danger of reproductive failure associated with work exposure to nitrous oxide. [39] Other negative effects could include "maternal drowsiness, hallucinations, vomiting, hyperventilation and tetany, as well as maternal or fetal hypoxia". These effects are typically seen when nitrous oxide use is excessively prolonged or extensive, particularly if the rule of self-administration is broken. [40]

Although the specific mechanism of inhaled analgesia's action is yet unknown, anesthetic effects are connected to the inhibition of activity in the brainstem's reticuloendothelial network. In their hypothesis, Maze and Fuginaga proposed that "nitrous oxide triggers the release of endogenous opioids in the peri-aqueductual grey area of the midbrain, which might be used to control pain stimuli via the descending spinal cord nerve pathways". [40]

Inhaled analgesics appears to be beneficial in lowering pain intensity and providing pain relief in labor, according to a new Cochrane review. The level of pain, however, showed significant heterogeneity. In addition, nitrous oxide seemed to cause more negative effects than flurane derivatives. Compared to nitrous oxide, flurane derivatives caused increased sleepiness. Nitrous oxide appeared to cause significantly more side effects, such as nausea, vomiting, dizziness, and drowsiness, when it was compared to the placebo or no treatment. For any of the outcomes comparing one strength of inhaled analgesia to a different strength, comparing various administration methods, or comparing inhaled analgesia with TENS, there was no evidence of differences. [35-40]

1.8.4 OPIOID ANALGESICS

Most medications used for labor analgesia fall under this category. “Pethidine, fentanyl, remifentanyl, tramadol, diamorphine, nalbuphine, butorphanol, and pentazocine” are a few examples. They can be given intravenously, intramuscularly, or under the patient's control. They work by attaching to the “m, d, and k opioid receptors in the neuronal cell membrane, which prevents the release of neurotransmitters”. [31]

They can also cause nausea, vomiting, sleepiness, and respiratory depression in the mother. Opioids all pass through the placenta. Fetal bradycardia, a reduction

in beat-to-beat variability, and neonatal respiratory depression can all be effects of in utero opiate exposure. [10-12]

54 randomized controlled studies comparing an opioid with a placebo or another opioid, involving more than 7000 women, were included in a recent Cochrane review on parenteral opioid use in labor. Overall, the results showed that although more women still reported moderate or severe pain, these opioids definitely have a tendency to reduce discomfort during labor. Opioid medicines are linked to drowsiness, nausea, and vomiting, and various opioids have been linked to a variety of side effects. There isn't any conclusive proof that opioids have bad impacts on newborns (most likely due to active precautions taken during those studies to avoid said side effects). There was a moderate level of maternal satisfaction with opioid analgesia.

There was insufficient data to determine which opioid medicine satisfied women the most or which offered the best pain relief while having the fewest negative effects on expectant moms and their offspring. [16]

1.8.5 NON-OPIOID ANALGESICS

Non-opioid medicines primarily serve as analgesics, antipyretics, sedatives, and anti-inflammatory agents. “Acetaminophen (paracetamol), non-steroidal anti-inflammatory drugs (NSAIDs), such aspirin, and antispasmodic medications like hyoscine” are some of them. Since acetaminophen and NSAIDs are efficient in treating mild to moderate pain, they are frequently combined with additional medications to treat moderate to severe pain. [32] Non-opioids frequently alter some of the chemical alterations that typically occur when bodily tissues are harmed or damaged. Inflammation and enhanced pain sensitivity are frequently the results of these chemical alterations at the site of the injury.

19 trials were randomly assigned a total of 2863 women were included in a recent Cochrane review on the use of non-opioid analgesia in labor. Three main comparison groups were present. 15 studies compared non-opioid medications to placebo or no therapy (2133 women); 3 studies compared non-opioid medications to opioids (563 women); and 3 studies compared one non-opioid medication type with another type or dose of non-opioid medication (590 women). Some of these studies involved three or more groups , making them the subject of many comparisons.

For most of the comparisons, there was little difference between groups in the overall opinion. Non-opioid pain relievers (edatives) were discovered to provide better relief (mean difference (MD) -22.00 ; 95% confidence interval (CI) -35.86 to -8.14 , one trial , 50 women) ; were associated with higher rates of positive pain relief satisfaction (sedatives and antihistamines) (risk ratios (RR) 1.59 ; 1.15 to 2.21; 1.80; 1.16 to 2.79; one trial, 223 women) ; and were associated with. However, compared to women taking opioids, those taking non-opioid medications (NSAIDs or antihistamines) reported feeling less pain alleviation (RR 0.50; 95% 1CI 0.27 to 0.94; one study, 76 women; RR 0.73; 95% CI 0.54 to 0.98 ; one trial, 223 women) .

Compared to antihistamine promethazine, women who got the antihistamine hydroxyzine reported being more satisfied with their pain relief (RR 1.21; 95% CI 1.02 to 1.43, one trial, 289 women). Compared to antihistamines, women who got sedatives expressed greater satisfaction with pain reduction (RR 1.52; 95% CI 1.06 to 2.17, one trial, 157 women). None of these trials utilized paracetamol, and the bulk were carried out more than 30 years ago. While non-opioids seem to be superior to placebo for pain relief and contentment with the delivery process, opioids seem to be superior to non-opioids in terms of satisfaction with pain alleviation. For

any comparison of non-opioids for safety outcomes, there was scant information and no proof of a meaningful difference.

Based on the aforementioned findings, it was determined that there was insufficient evidence to support the use of non-opioid medications to treat labor pain on their own. [42]

1.8.6 REGIONAL ANALGESICS

"Epidural analgesia, subarachnoid block, and combined spinal-epidural blocks" are the most often used regional analgesic procedures, but "lumbar sympathetic block, paracervical block, and pudendal block" are less frequently used. The treatment that seems to be most successful at reducing pain during labor is regional analgesia. [43]

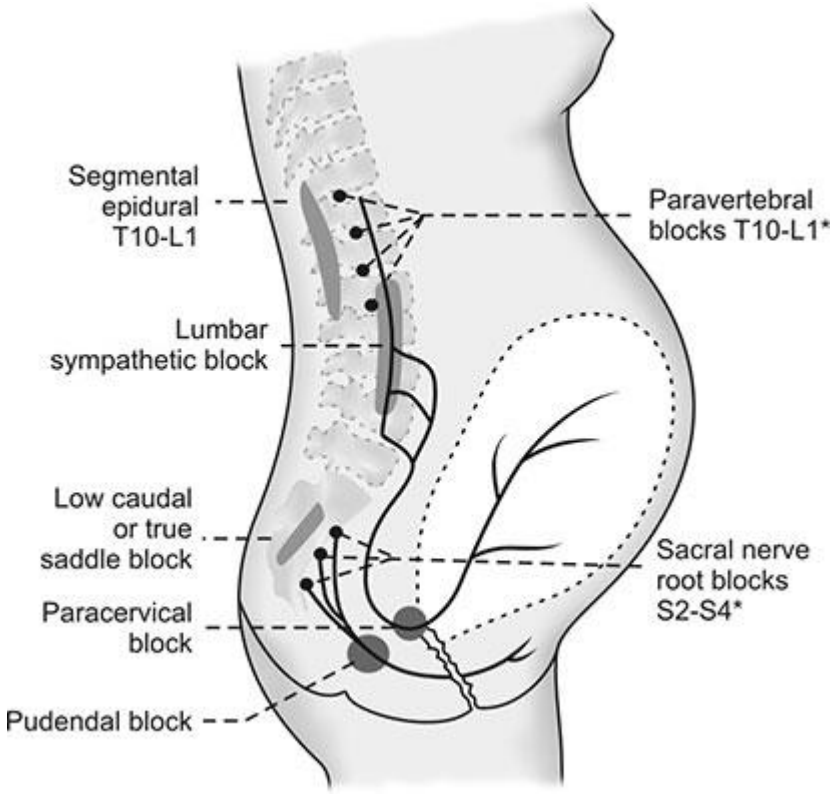


Figure 7a: Regional analgesia

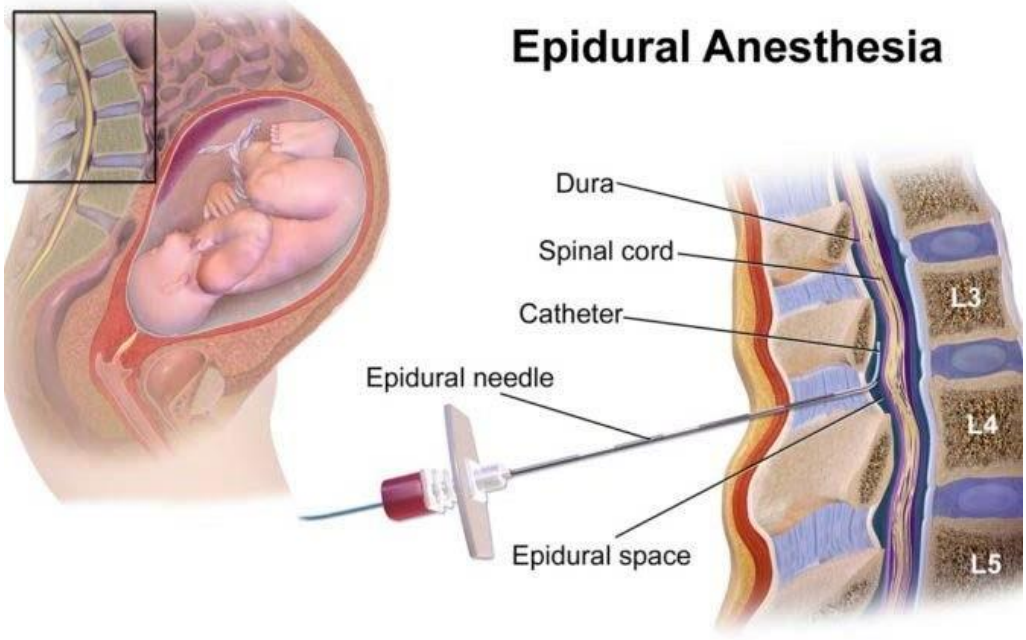


Figure 7b: Epidural and Spinal analgesia

“A local anesthetic, together with or without an opioid, is injected into the lower part of the spine close to the nerves that convey painful inputs from the contracting uterus and birth canal in the process of performing epidural analgesia, a central nerve blockage procedure”. Bupivacaine is the local anesthetic that is most frequently prescribed. Also utilized in epidural or intrathecal injections include ropivacaine, lignocaine, and levobupivacaine. Local anesthetics limit the propagation of nerve impulses along these fibers by obstructing sodium channels in the membranes of nerve cells.

Analgesia is induced by obstructing the passage of sensory nerve impulses across the epidural space, and it should begin to work 10 to 20 minutes after administration. Higher dosages of anesthetic cause total sensory and motor blockage, limiting mobility in labor, but smaller doses of anesthetic (such as 0.125% bupivacaine) only partially selectively block painful impulses while maintaining motor function. The anesthetic's concentration-specific action on the epidural space affects all modalities of inhibited nerve feeling to variable degrees. [42]

It's possible for the second stage of labor to drag out, and cesarean sections are more frequent. [35] Vasodilation and hypotension are signs of blocking

sympathetic nerves, which can happen at different concentrations. [34] "Retention of urine, shivering, fever, tinnitus, tremors, respiratory depression, and cardiovascular depression" are a few other issues that have been observed. [10-12]

"By bolus, continuous infusion, or patient-controlled pump", epidural solutions are given. Through a catheter positioned in the epidural area, local anesthesia is injected intermittently. Boluses with larger concentrations, which were more commonly employed in the past, have been linked to a dense motor block that impairs bearing down effort during the second stage of labor and reduces mobility and pelvic tone. [44]

Combining an epidural catheter with a local anesthetic or opiate, or both, into the cerebral spinal fluid is known as combined spinal-epidural (C.S.E.). The advantages of spinal analgesics (quicker onset of pain relief and more reliable analgesia) are combined with the benefits of epidural analgesia (ongoing pain relief that may be maintained for the course of labor). [46] "Itching, respiratory depression, and, in observational studies, lower breastfeeding rates" are still some of the drawbacks of opiate medication. [47]

1.9 PHARMACOLOGICAL ASPECTS OF PARACETAMOL AND TRAMADOL

1.9.1 ACETAMINOPHEN

A non-opioid analgesic, paracetamol is also referred to as acetaminophen or N-acetyl-p-aminophenol (APAP) . The paracetamol's exact mode of action is not entirely understood. It is believed to have a very potent central effect, which is further reinforced by the discovery of tiny but considerable amounts of APAP in the CSF following injections. Arachidonic acid is the primary substrate for the cyclooxygenase (Cox) enzymes, which are crucial for prostaglandin formation. Cyclooxygenase must unquestionably be in an oxidized state for this to occur.

This oxidized form appears to be reduced by paracetamol, which reduces the enzyme's efficiency. Analgesia may be explained by decreased prostaglandin production in this procedure. (45) It is also believed that paracetamol has an impact on the endogenous cannabinoid system.

N-arachidonoylphenolamine is produced during the metabolism of paracetamol. This substance prevents synaptic cleft reuptake of endogenous cannabinoids like anandamide. This notion is gaining support because blocking cannabinoid type 1 (CB1) receptors reduces paracetamol's effectiveness. [(46)] By attaching to the 5-

HT3 receptor, paracetamol may potentially have an impact. This idea is supported by the discovery that a 5-HT3 antagonist prevents intrathecal paracetamol's antinociceptive effects. [47] With IV paracetamol, the action takes place quickly because the maximal concentration is reached as early as the infusion is finished (about 15 minutes). The analgesic impact kicks in after five minutes, peaks after an hour, and lasts for four to six hours. Its antipyretic activity lasts for six hours, and its plasma half-life is 2.7 hours. [48]

The onset and time to peak impact will be delayed if the rate of infusion is lowered, whereas in liver failure , the metabolism may be compromised, extending the duration of paracetamol activity. [48] Paracetamol's metabolism may speed up in individuals who consume alcohol or substances that induce enzymes, which would cause paracetamol levels in plasma to fall more quickly. [48] Because paracetamol is eliminated through the kidneys, persons with renal impairment may require extra time to do so. Only 5% of administered paracetamol is excreted unchanged , and its metabolites , which are also eliminated by the kidneys , are inert. [48-50] Paracetamol plasma levels are typically elevated by probenecid. [49].

Intravenous paracetamol side effects are regarded as uncommon. They consist of infusion-induced hypotension, blood problems, and rashes. The absence of

adverse effects makes them unproblematic. [48] Given that the liver is where it is processed, administration would need to be cautious in the event of any liver damage. Additionally, persons who are taking medications that induce enzymes, such as phenytoin, alcohol, or rifampicin, may produce more hazardous metabolites by way of the cytochrome p 450 pathway. Chronic malnourished individuals and some alcoholics have insufficient glutathione stores to counteract the N-acetyl-p-benzoquinone- imine generated. [48]

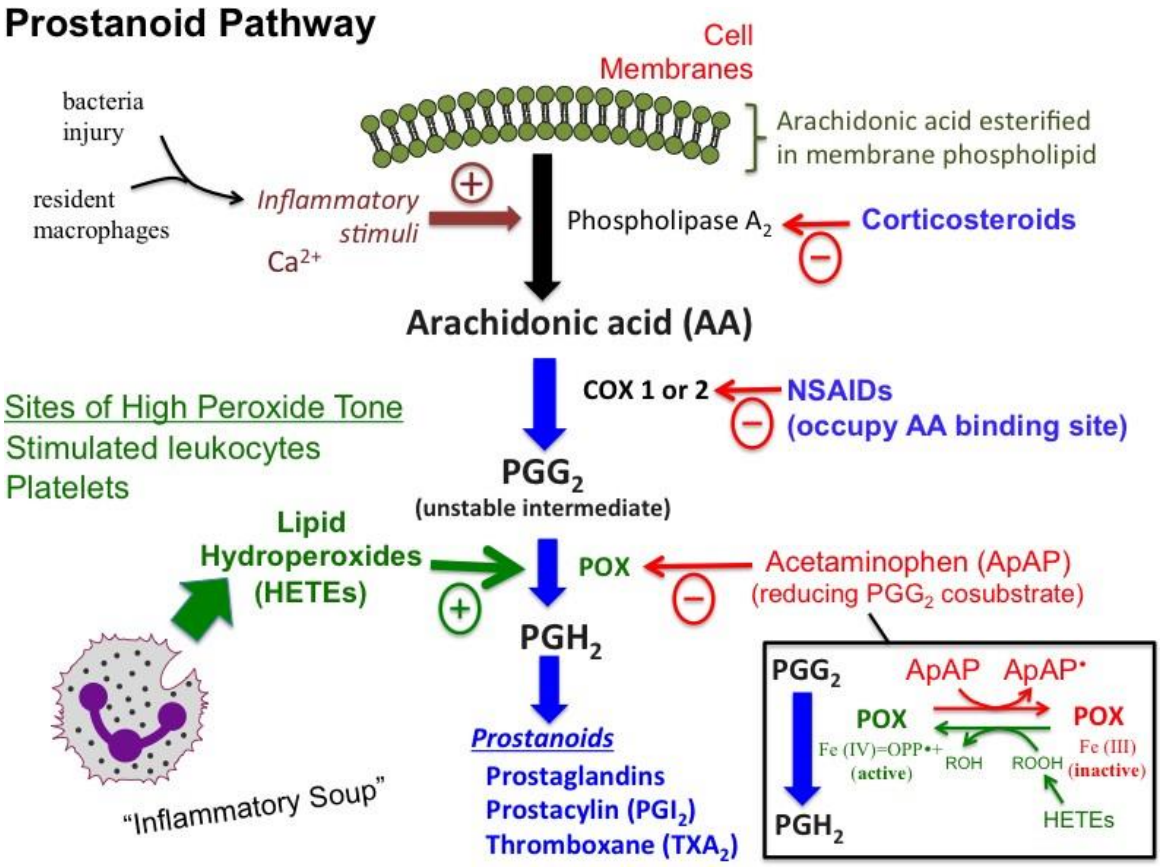


Figure 8: Paracetamol mechanism of action - Prostanoid Pathway

The use of intravenous paracetamol when nursing or pregnant is safe (category C). [50] When it is used in the recommended amount by healthy women at term, it has been demonstrated that the metabolism of acetaminophen is unaltered in pregnant women [51] and there are no reports of fetal injury. [52]

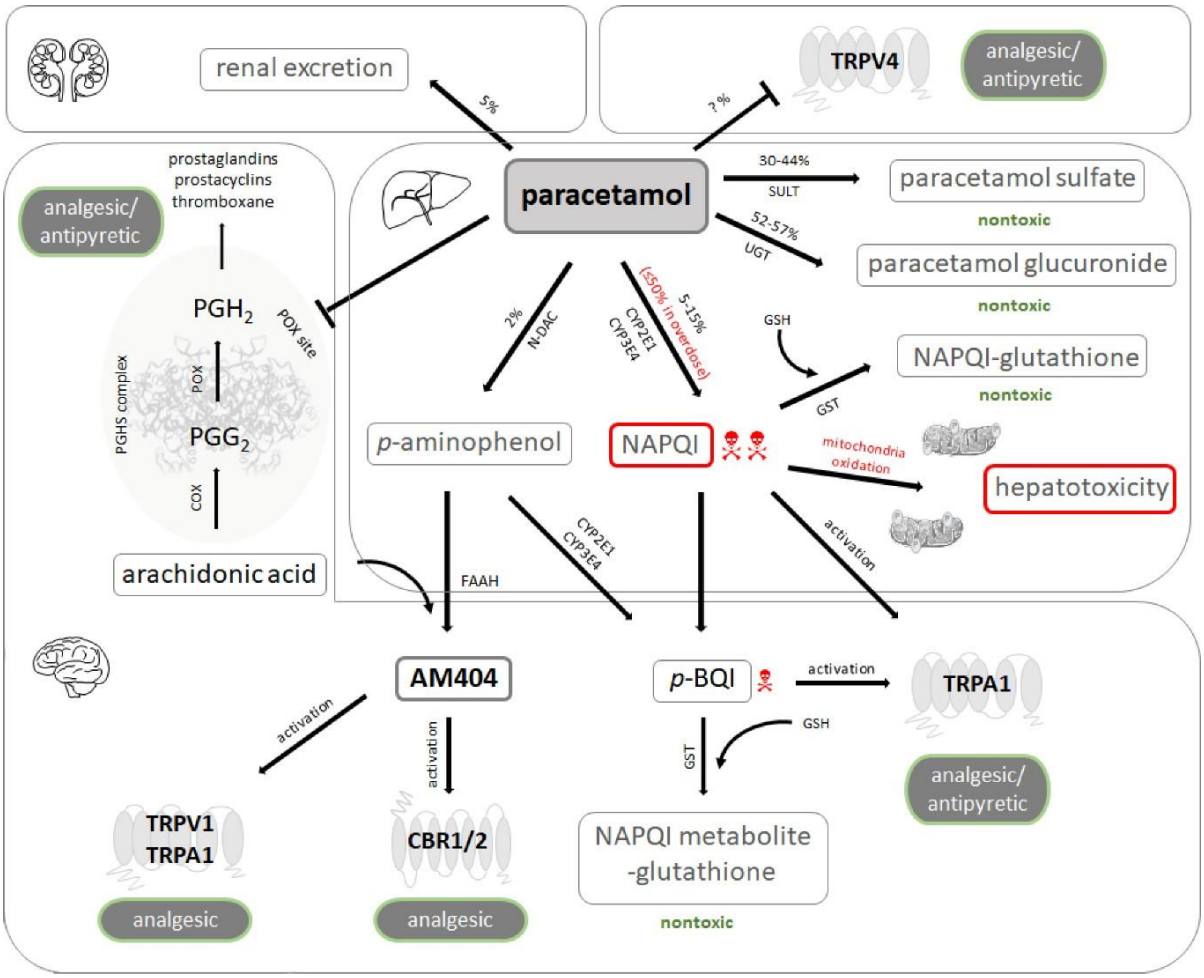
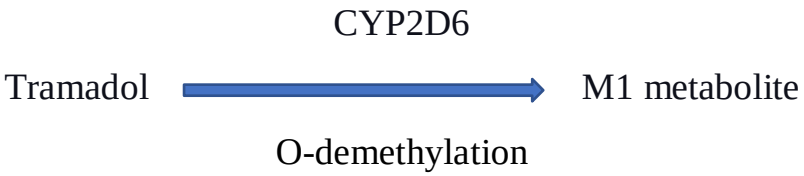


Figure 9: Paracetamol mechanism of action - Pharmacology

1.9.2 TRAMADOL

Atypical opioid with a central action, tramadol. It has a weak affinity for the mu opioid receptor and very weak affinities for the kappa and delta receptors. It is regarded as a stronger analgesic than NSAIDs. It works in two ways: it inhibits the absorption of norepinephrine and serotonin and binds weakly to the mu-opioid receptor sites. Its affinity for the mu-opioid receptor is 1/6000 that of morphine and 1/10 that of codeine. Supported by research showing that the alfa-2 adrenoceptor antagonist, ondansetron, and naloxone both partially suppress analgesia.

Tramadol, also known as cis-2-cyclohexanol hydrochloride, is a synthetic 4-phenyl-piperidine counterpart of codeine. Tramadol is predominantly removed through the kidneys, with 30% of it being excreted intact. It is extensively metabolized by the liver, with the main pathways being N- and O-demethylation and glucuronidation or sulfation. Tramadol's O-demethylated derivative, known as M1, has the potential to have a stronger analgesic impact than the (+) version. The cytochrome P450 isoenzyme CYP2D6 is in charge of turning the drug into the M1 metabolite. [53]



The M1 metabolite's analgesic effectiveness is 6 times greater than that of its parent medication. Because 7% of people lack this isoenzyme, tramadol metabolizes poorly and has a lower analgesic effect. Only 20% of the medication's bioavailability following oral delivery binds to plasma proteins. A healthy adult should take 50 to 100 mg every six hours on average. Peak plasma levels are reached following a single 100 mg dose in 1.6 hours for the parent medication and in 3 hours for the M1 metabolite. After a single 100mg dose, the parent medication's half-life is 6.3 hours, while the M1 metabolite's half-life is 7.4 hours.

The analgesic effect peaks at two hours after the initial dose and lasts for about six hours until reaching steady state after forty-eight hours. Due to the increased risk of side effects with greater doses, dosage modification is advised in the elderly and in patients with renal and liver disease. The amount recommended is 400 mg over the course of 24 hours.

The serotonin 5HT-3 receptor antagonist ondansetron prevents tramadol from having analgesic effects.

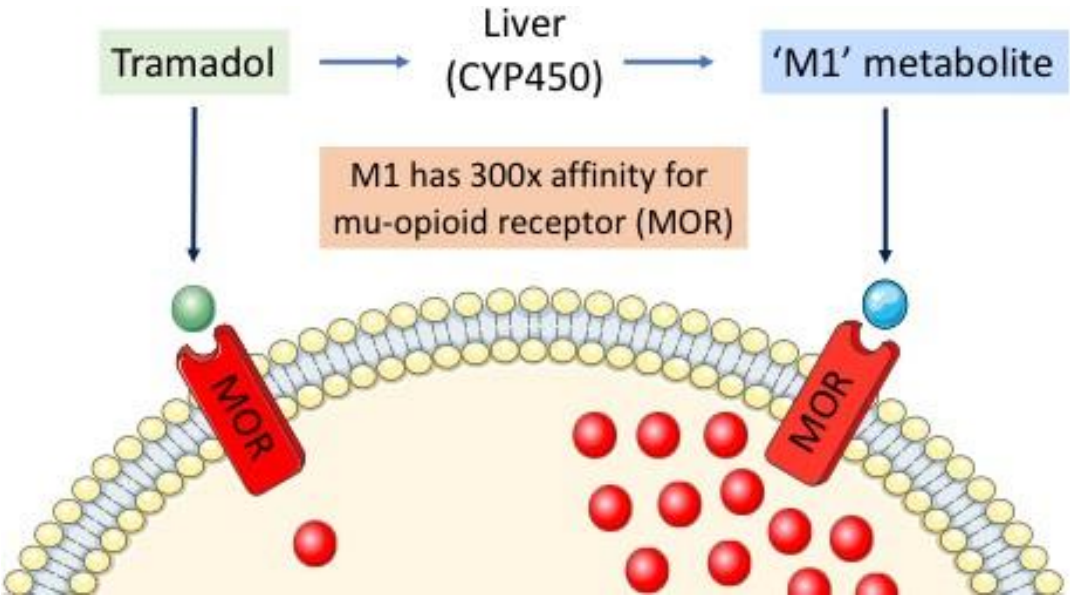


Figure 10: Tramadol mechanism of action - Pharmacology

Tramadol dosage should be changed for elderly people and individuals with liver or kidney disorders. The dosage shouldn't exceed 300mg/day due to the lengthened medication elimination period in the elderly. The half-life of the medication is extended by advanced liver illness, which necessitates a dosage reduction to 50 mg every 12 hours.

Patients with liver disease shouldn't take Ultracet.

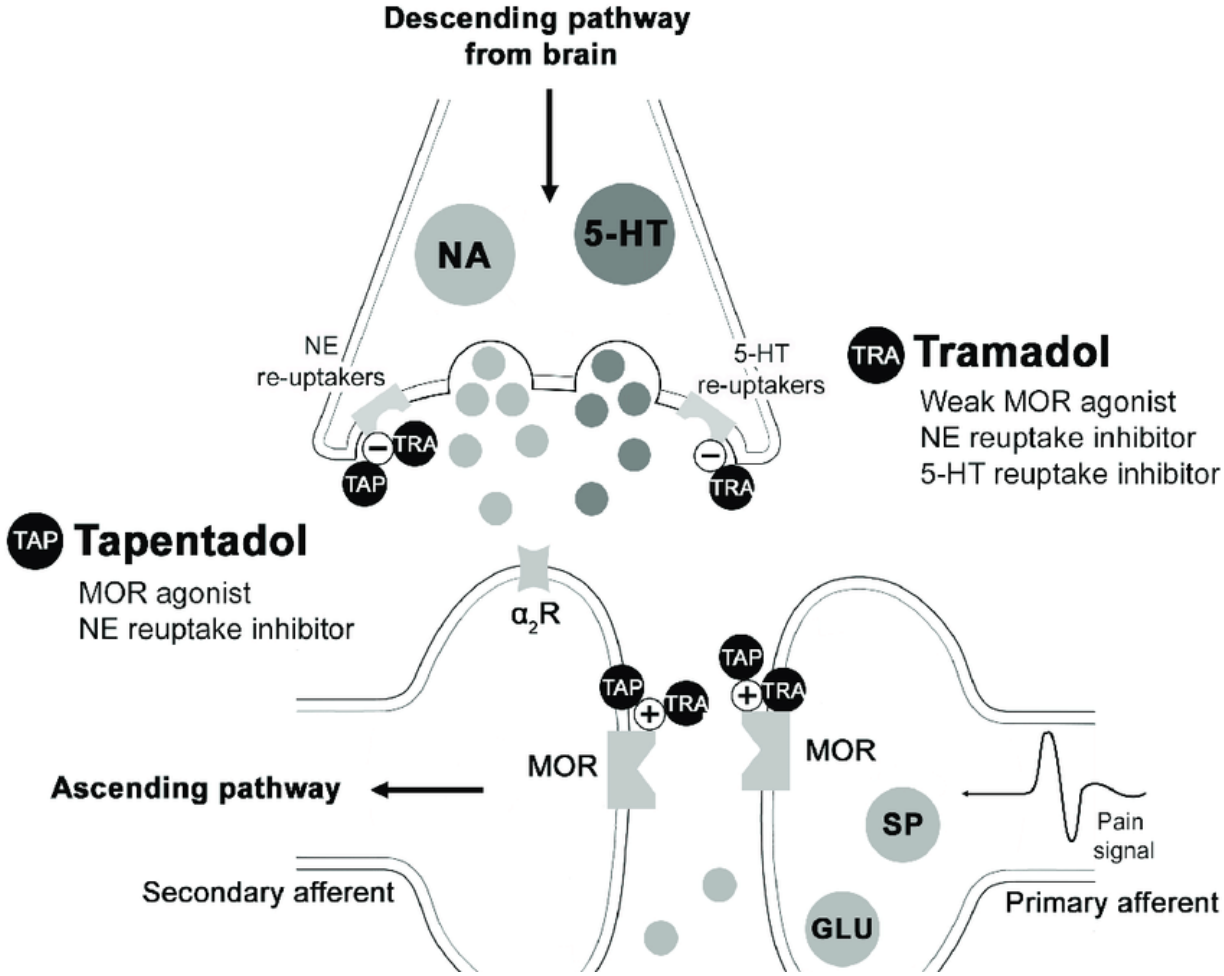


Figure 11: Mechanism of action of Tramadol and Tapentadol

Excretion occurs predominantly through the kidneys, and in patients with a creatinine clearance of less than 30 ml/min, the pace and amount of excretion will be greatly reduced [(54)].

Tramadol is categorized as pregnancy risk factor C; 0.1% of the dose is discovered in breast milk , and 1% of the dose is passed across the

placenta. It offers sufficient analgesia for the mother during labor without significantly depressing the baby's breathing.

Tramadol is recommended by the WHO as a step 2 analgesic for a number of painful conditions:

1. Malignant pain
2. Osteoarthritic pain
3. Low back pain
4. Diabetic neuropathy
5. Fibromyalgia
6. Restless leg syndrome
7. Postherpetic neuralgia
8. Pain from surgical and dental procedures
9. With NSAIDs to help control breakthrough pain

Tramadol's typical adverse effects include dizziness, drowsiness, nausea, vomiting, and constipation. Seizures and the serotonin syndrome are the two adverse effects that stand out the most.

At 500 mg of tramadol, respiratory depression can occur, and at 800 mg, coma can. Tramadol has fewer side effects than typical opioids such constipation, respiratory depression, and sedation, as well as a lower risk for abuse and physical dependence. Compared to conventional opioids, it has a reduced rate of dependence and physical abuse.

1.10 DIFFERENT METHODS OF PAIN ASSESSMENT

Most of the pain that we measure comes from self-report. The pain measurement needs to be precise, dependable, case-sensitive, valid, and applicable to both clinical and experimental conditions.

Pain is assessed using both unidimensional and multidimensional scales. Simple and evaluating only the patient's self-reported pain intensity, which is one dimension of pain, are unidimensional scales. They help us identify acute pain with a single recognized source as labor pain. These scales could be numerical or categorical (number rating or analog visual scales) (verbal or face rating scale). We evaluate the kind and severity of pain as well as its impacts on activity and mood using multidimensional instruments.

Using a range of 0 to 10 or 0 to 5, the numeric rating scale (N.R.S.) asks patients to rate their level of discomfort, with 0 signifying "no pain at all" and 5 or 10 signifying "the greatest suffering possible." The “visual analogue scale” is made up of a 100mm line with an anchor at each end (VAS). On one end , it says "no pain," and on the other, it says "pain as horrible as it may be" or "the worst suffering imaginable." After measuring the line with a ruler from the “left end to the patient's mark”, the doctor assigns a score,

either in millimeters or in centimeters, depending on where on the line the patient is experiencing the most discomfort. [1-10]

Studies have compared these pain rating measures' relative validity. Three commonly used pain rating scales —the "Visual Analogue Scale" (VAS), "Verbal Rating Scale" (V.R.S.), and "Numerical Rating Scale"— were investigated in one study (N.R.S.). The study found that all three pain-rating scales are valid, reliable, and adequate for use in clinical practice , despite the VAS having more practical difficulties than the "Verbal Rating Scale" or the "Numerical Rating Scale". The V.R.S. was also well-liked by patients due to its simplicity of use, despite its lack of sensitivity.
[55]

The relative validity of VAS, N.R.S., V.R.S., and F.P.S. for discriminating painful stimulation was compared in a distinct study. The following responses were given: N.R.S., VAS, V.R.S., and F.P.S. Only slight variations in the scales' responsiveness, though, were present. [56]

Although the VAS presents more real-world difficulties than the N.R.S, it is frequently used in clinical practice and research [55] This may be due to the fact

that only the numbers themselves are valued, hence there are only 11 possible N.R.S. responses on a scale of 0 to 10.

It only allows a less precise separation of pain levels than VAS, which theoretically has an endless number of possible responses. [57]

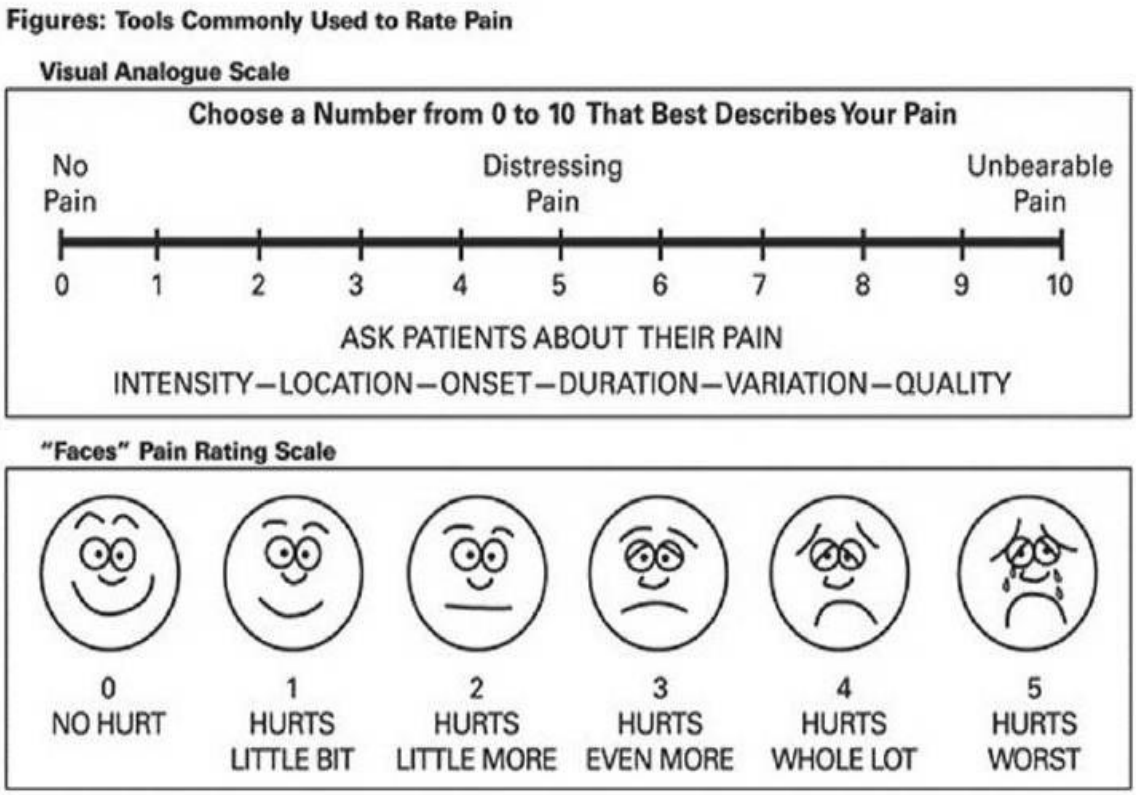


Figure 12: Visual Analogue Scale, Faces pain rating scale

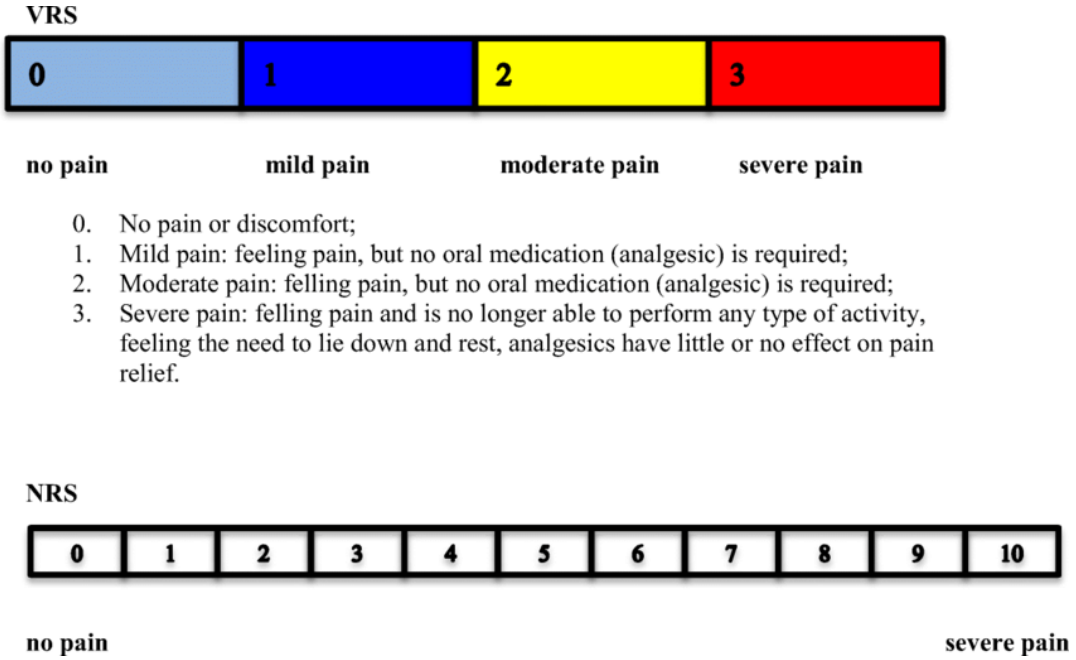


Figure 13: Verbal Rating Scale, Numerical Rating Scale

Figure 14: Wong-Baker FACES Pain Rating Scale

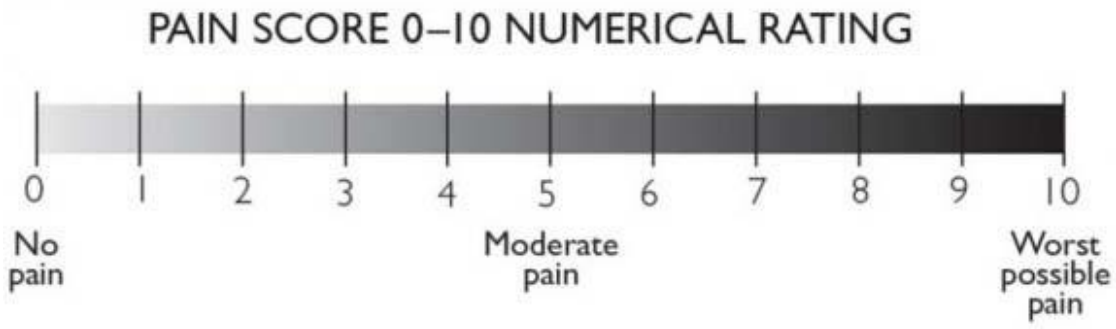


Figure 15: Pain Score 0-10 Numerical Rating

2. AIM AND OBJECTIVES

To know the efficacy and safety of intravenous paracetamol as a labor analgesic compared to intramuscular tramadol.

2.1 MATERIALS AND METHODS

2.1.1 SOURCE OF DATA

Patients delivered at B.L.D.E (Deemed to Be University) Shri B.M. Patil Medical College Hospital and Research Centre.

Health care setup - Tertiary care hospital

Sample size - 220 primigravida's (Group T110 and Group P110)

A computer-generated randomized table will be used with block size of 4.

Type of study - A randomized controlled trial

Study Period - January 2021 to April 2022

2.2 METHOD OF COLLECTION OF DATA

2.2.1 INCLUSION CRITERIA

Primigravida with a period of gestation ≥ 37 weeks in active phase of labor with singleton pregnancy with vertex presentation with cervical dilatation ≥ 4cm, cervical effacement ≥60% and with good uterine contractions of at least 3-4 contractions in 10 minutes , each lasting for 45 seconds .

2.2.2 EXCLUSION CRITERIA

1. Women with clinical evidence of cephalopelvic disproportion
2. Multiparous
3. Malpresentations
4. Multiple pregnancies
5. Previously scarred uterus (post myomectomy, post caesarean)
6. Preterm labour
7. Induced labour
8. Antepartum haemorrhage
9. Preeclampsia
10. History of drug allergy to paracetamol and tramadol.

11. History of medical disorders like cardiac, renal and liver diseases
12. Intrauterine foetal demise
13. Patients who refused to take part as per our protocol
14. h/o cervical incompetence [cervical encirclage]
15. Oligohydramnios, fetal growth restriction, congenital anomalies in the fetus.
16. Cervical dilatation >6cm.

2.2.3 SAMPLE SIZE

The anticipated Mean ± S.D. of VAS Score after one hour of drug administration in pregnant women with primigravida in group P 6.7±1.01 and in group T 7.2±1.42 respectively; ref (1).The required minimum sample size is 110 per group(i.e. a total sample size of 220, assuming equal group sizes) to achieve a power of 80% and a level of significance of 5% (two-sided),for detecting an actual difference in means between two groups.

$$n = 2\left[\frac{(\propto + \beta) * \sigma}{d}\right]^2$$

$\propto$- Level of significance=95%

β- the power of the study=80%

d=clinically significant difference between two parameters

SD= Common standard deviation

2.2.4 STATISTICAL ANALYSIS

The data was loaded into an Excel sheet for Microsoft, and statistical analysis was carried out using the social sciences statistical program (Version 20). Results were displayed using graphs, counts, and percentages in addition to the Mean SD. The "Independent t-test" was used to compare two groups' values for continuous variables with normally distributed distributions. "Mann Whitney U test" was employed for variables that were not normally distributed. Using the "Chi-square test," categorical variables between the two groups were compared. $P<0.05$ has been considered statistically significant. All statistical tests were performed two-tailed.

3. METHODOLOGY

It is a Randomized controlled study.

All the patients who fulfilled inclusion criteria were studied. Consents of the patient were taken once they were admitted. Drugs were given when the patient was in 4-6 cm cervical dilatation. Patients were classified into two groups. GROUP P: IV Paracetamol 1000mg (acetaminophen in 100ml solution); GROUP T Injection Tramadol IM (100mg) according to the randomized table. After giving the drugs the pain was measured by visual analogue scale (VAS) before the administration of the drugs ,1 hour after administration and 3 hours after administrations of the drug and at 2nd stage and 1hr after delivery. The pain is taken by using "visual analogue scale" (VAS) in which we use a ruler; the score is determined by; none (0), mild pain (1-3), medium pain (4-6), and extreme pain (7-10).

Outcomes: The main outcome measures which recorded were:

Primary outcome: a] Relief in labor pain by VAS, b] Progression of labor

Secondary outcome: c] Incidence of instrumental delivery, d] Maternal side effects , e] The neonatal outcomes.

If patients had to undergo L.S.C.S. for any other reason after randomization, they were included in the study for pain management and analysis but fetal outcomes and follow up of neonates were excluded from the study.

4. REVIEW OF LITERATURE :

1. “According to research by Meenakishi Lallar(5) et al., in contrast to intramuscular tramadol, intravenous paracetamol lessens the period of labor and is a more potent labor analgesic. It has fewer negative effects on the mother. 200 primigravida in active labor who were split into two groups of 100 each were participants in this prospective, randomized research. 100 women were divided into two groups, one receiving 1,000 mg of paracetamol intravenously and the other receiving 100 mg of tramadol intramuscularly”. “The McGill scale measures the level of pain before, one, and three hours after the medicine has been administered. Using McGill's scale, prior to the administration of the drugs, there was no statistically significant1 difference in1 the levels of pain between the two groups (p=0.010). However, after receiving an intravenous paracetamol infusion for an hour, as well as after receiving paracetamol and tramadol for three hours, the difference between the two groups was statistically significant (p=0.000)”.

2. “In Guwahati's Gauhati Medical College and Hospital during the years of 2015 and 2016, Bishnu Prasad Das (2) et al. conducted a single-blinded prospective randomized trial on 200 primigravidae women. Using a visual

analogue scale, pain was quantified. With a substantial statistical difference between the two groups and a p value of 0.001, the mean VAS score significantly fell in both groups, but more so in the paracetamol group than the tramadol group. With a significant p value of 0.0001, paracetamol was statistically found to shorten labor time compared to tramadol, and patients receiving tramadol experienced higher maternal side effects and NICU admissions. They concluded that in underdeveloped nations with limited access to healthcare, intravenous paracetamol is a more convenient, secure, affordable, and practical choice for labor analgesia. Additionally, it reduces the duration of labor".

3. "In the study by Jeetinder Kaur Makkar [(7)] et al, 60 primiparous women with singleton uncomplicated pregnancies in labor with cervical dilation between 3 and 5 cm participated. Patients were divided into two groups and randomly assigned to receive either 1 mg of paracetamol intravenously or 1 mg of tramadol intramuscularly. At all periods of observation, the VAS scores for the two groups were comparable. A higher incidence of maternal side effects, such as nausea, vomiting, and sedation, was associated with the use of tramadol. The duration of the 1st stage of labor was shorter in the group paracetamol with a p value of 0.003, the duration

of the 2nd stage of labor was comparable between the 2 groups. They found that paracetamol delivered intravenously offers equivalent analgesia".

4. "With p values of 0.36, 0.06, and 0.10 at 120 minutes, 180 minutes after rescue, and 60 minutes after delivery, respectively, Aimakhu, Saanu OO [(3)] et al. concluded that 600 mg of paracetamol offers similar and modest pain relief in labor compared to 100 mg of intramuscular tramadol. However, the difference was not statistically significant. Additionally, the mean time from taking the medicine till delivery was shorter in the paracetamol group than in the tramadol group, albeit this difference was not statistically significant because the p value was only 0.73. The neonatal result was favourable, and paracetamol had fewer adverse effects on the mother. Therefore, injectable paracetamol is a straightforward, affordable, and easily accessible labor analgesic in low resource situations".

5. "In 2016, Nana -Ama E et al [(4)] , in their study conducted to compare the effectiveness of intravenous acetaminophen with that of morphine in reducing pain in the first stage of labor in 40 primigravida's > 34 weeks period of gestation the primary outcome of labor analgesia was similar in both the groups with a p value of 0.53 and most patients who received

paracetamol required rescue dose compared to morphine but the fetal and maternal outcomes in both the groups were similar".

6. "In 2017, Srinivas Rapolu [6] et al. conducted a study on 150 primigravida patients between the ages of 20 and 30 years old with spontaneous onset of labor. They found that intra-venous administration of paracetamol is straightforward, practical, and affordable, and is a more effective labor analgesia than intra-muscular tramadol with a significant p value of 0.003. Better in reducing pain, paracetamol also speeds up labor and has a lot less negative side effect".

7. "In 2019, Neha Garg [1] et al. conducted a study on 273 primigravidas with cervical dilatation >4 cm and spontaneous onset of labor who met the inclusion and exclusion criteria. They randomly assigned the participants to one of two groups, and the pain score was measured using the VAS score. They concluded that the mean VAS score decreased significantly to a greater extent in the paracetamol group, with a significant statistical difference with a p value of 0.001, Thus, compared to tramadol as a labor analgesic, intravenous paracetamol is a better analgesic, shortens the length of labor, and has less adverse effects on the mother".

8. “P Viswanandh [9] et al, studies from 2021 involved 60 cases of active labor who met the inclusion and exclusion criteria. They were divided into groups of 30 each for paracetamol and tramadol, and the results showed that paracetamol significantly reduced pain compared to tramadol at the fourth and fifth hours after administration, but there was no statistically significant difference in the analgesic effects of the two drugs overall. Paracetamol reduced maternal side effects and newborn discomfort. Therefore, compared to tramadol, paracetamol had a comparable, if not superior, analgesic efficacy. It also had a better side effect profile for both the mother and the newborn”.

9. “In 2021, Kanchan Samir et al. (10), in their single blinded randomized study in primigravida's of 120 patients divided into two groups of each 60 patients, demonstrated that paracetamol was generally well tolerated in comparison to tramadol. Pain was assessed using the McGill's pain intensity scale score. Patients who got paracetamol reported less nausea and vomiting as a side effect. The difference had a Chi-square value of 0.091 and a p value of 0.018, both of which were statistically significant. As a result, paracetamol is a safer labor analgesic than intra-muscular

tramadol, although additional research involving a larger sample size is required to confirm the study's findings".

10. "In 2021, Amal N. M. Nada et al. [11], in their prospective randomised study for labor analgesia on 90 patients divided into three groups A, B, and C in the ratio of 1:1:1, where group A is nalbuphine group, group B meperidine group, and group C paracetamol group, concluded that the use of paracetamol as an analgesic in the first stage of labor showed a significant decrease between paracetamol However, compared to pethidine and nalbuphine, paracetamol significantly reduced the length of labor, with a significant p value of 0.001. Opioids (pethidine and nalbuphine) had greater adverse effects on the mother, the newborn, and the fetus than paracetamol did".

11. "In 2021, Mohamed Elsibai Anter [12] et al concluded that intravenous paracetamol is superior to pethidine as a labor analgesic because it is more effective, safe, affordable, and readily available. It also has no adverse effects on the mother or the fetus. After taking paracetamol for 30 minutes, 1 hour, 2 hours, and 3 hours, the VAS score dramatically improved (3.92+/-

1.42, and 5.69+/-1.07). Particularly in our communities, paracetamol needs to have more of a chance than other types of analgesics for labor pain".

12. "In 2022, N. Monisha et al. [13] concluded that compared to IM tramadol, IV paracetamol has a longer duration of action and fewer maternal side effects, making it suitable for parenteral analgesia in labor. They conducted a study on comparison between paracetamol and tramadol as labor analgesia on 110 primigravida's randomized into two groups and pain score was analysed using the VAS score Until 180 minutes after medication administration in the paracetamol group and 120 minutes in the tramadol group, there was a statistically significant decline in pain score; at 60 minutes after delivery, the paracetamol group had significantly lower pain score levels, with a p value of 0.004. There is no requirement for rigorous maternal and fetal monitoring with IV paracetamol due to a higher safety profile".

13. "In 2022, Oluwatunmobi Opadiran et al[14] in their study done on comparison between pentazocine, tramadol and paracetamol on 218 patients concluded that intravenous pentazocine provides better pain relief in labor but the tramadol-paracetamol combination has fewer side effects.

The average pain score in the tramadol-paracetamol group was significantly higher compared to the pentazocine group with p value of 0.02. Nausea and drowsiness occurred more frequently in the pentazocine group at p values of 0.047 and 0.0015, there was no statistically significant difference in the duration of labor between the tramadol- paracetamol and pentazocine group".

14. "Pooja Namdeo et al. [(15)] found that intravenous acetaminophen infusion during delivery helps to relieve labor pain without having any negative effects on the mother or the fetus in their study on paracetamol and placebo conducted on 50 patients randomized to 25 each in 2022. The mean VAS scores for subjects in groups A and B, who received paracetamol and a placebo, were 6.25 and 7.13 after 30 minutes, respectively, and 6.12 and 7.96 after 60 minutes, respectively, with a significant p value of 0.000, demonstrating that intravenous paracetamol is effective in reducing labor pain".

15. "In 2013, Wesam Farid Mousa et al [(16)] in their study conducted for epidural analgesia during labor in primigravida's studied that epidural is the best labor analgesic during labor but there was no statistical difference in the

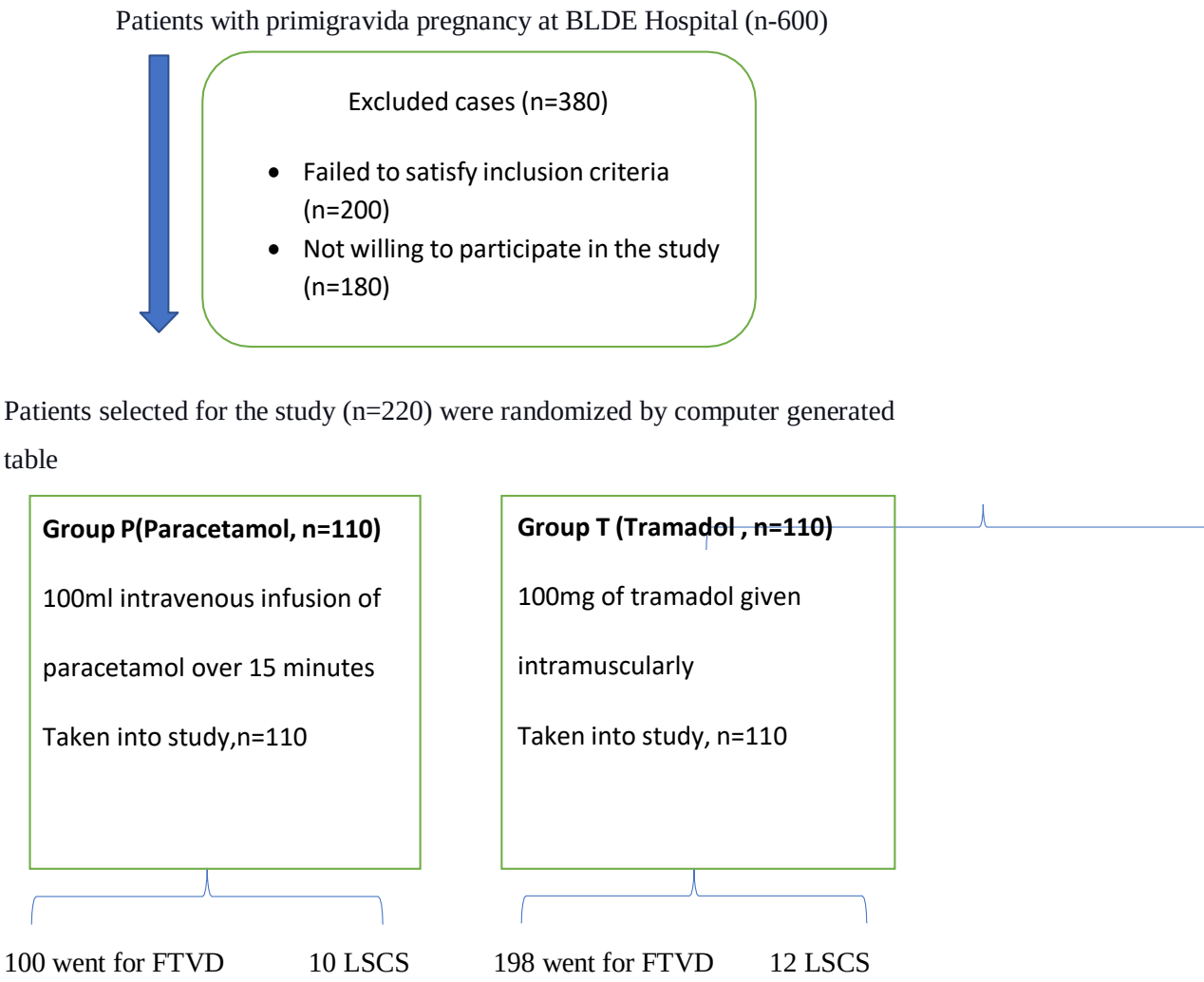
duration of active first and second stage of labor , instrumental delivery , vacuum assisted delivery or cesarean delivery rates , the number of newborns with 1 minute and 5 minute Apgar scores less than 7 . Hence epidural analgesia does not prolong labor compared with patients without analgesia but significant augmentation with oxytocin is required to keep up the average labor duration in these patients".

16. "In 2016 , K.Gupta et al [17] in their study conducted for intravenous paracetamol as an adjunct to patient -controlled epidural analgesia with levobupivacaine and fentanyl in labor there was no significant difference in the VAS scores in both the groups during the course of labor with a p value of 0.89 , there was no difference in the incidence of operative delivery and neonatal outcome as measured by the Apgar score , also there was no difference in the mean duration of labor between both the groups with a p value 0.35. Hence in their study they concluded that intravenous paracetamol is safe and effective adjunct to PCEA – Patient controlled epidural analgesia in labor analgesics".

5. RESULTS

In our study conducted, 220 parturient' s were taken and randomized into two groups each paracetamol and tramadol respectively and their effects on labor analgesia , feto-maternal outcomes and progression of labor .

There was no difficulty or failed follow up cases in this study. Patients who went for Emergency LSCS 21 cases were included in the study for pain analysis but excluded for fetal outcomes. The results of the study are described below:



Age(Years)	No. of Patients	Percentage
18-22	80	36.4
22-26	94	42.7
26-30	40	18.2
30-34	6	2.7
Total	220	100.0

Table 1: Age distribution in the study

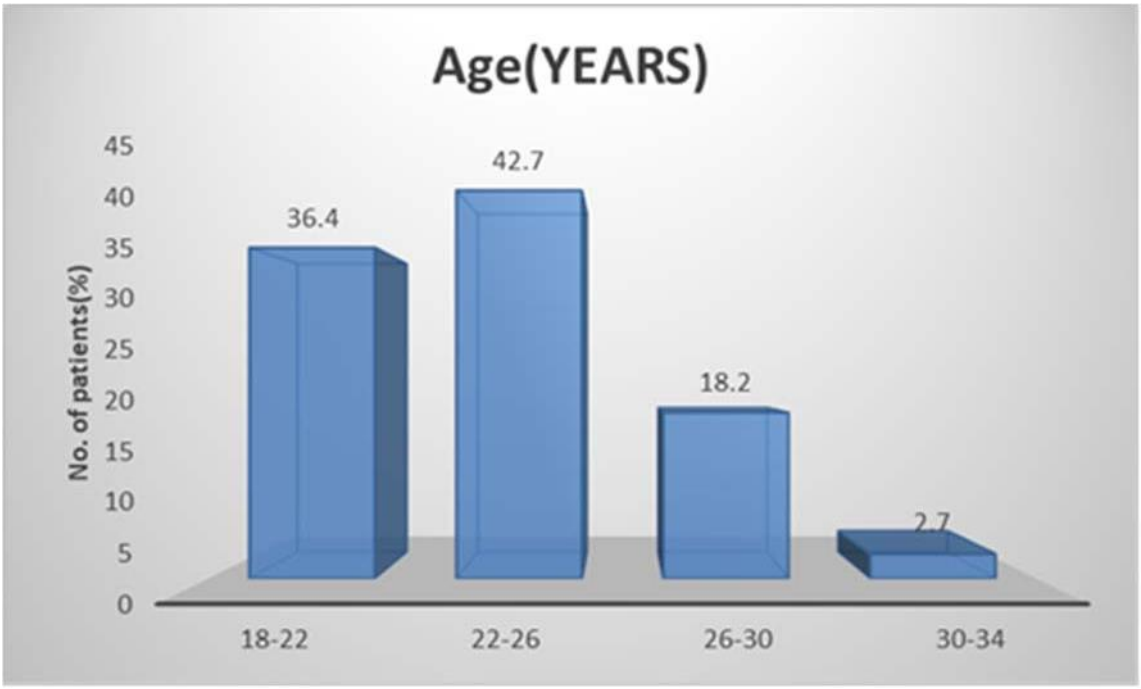


Figure 16: Bar diagram for Age distribution

Labor analgesia	Age					Chi-square value	p-value
	18-22	22-26	26-30	30-34	Total		
Paracetamol	43	47	17	3	110		
%	39.10%	42.70%	15.50%	2.70%	100.00%		
Tramadol	37	47	23	3	110	1.350	0.717
%	33.60%	42.70%	20.90%	2.70%	100.00%		
Statistically Insignificant							

Table 2: Comparison of age between tramadol and paracetamol

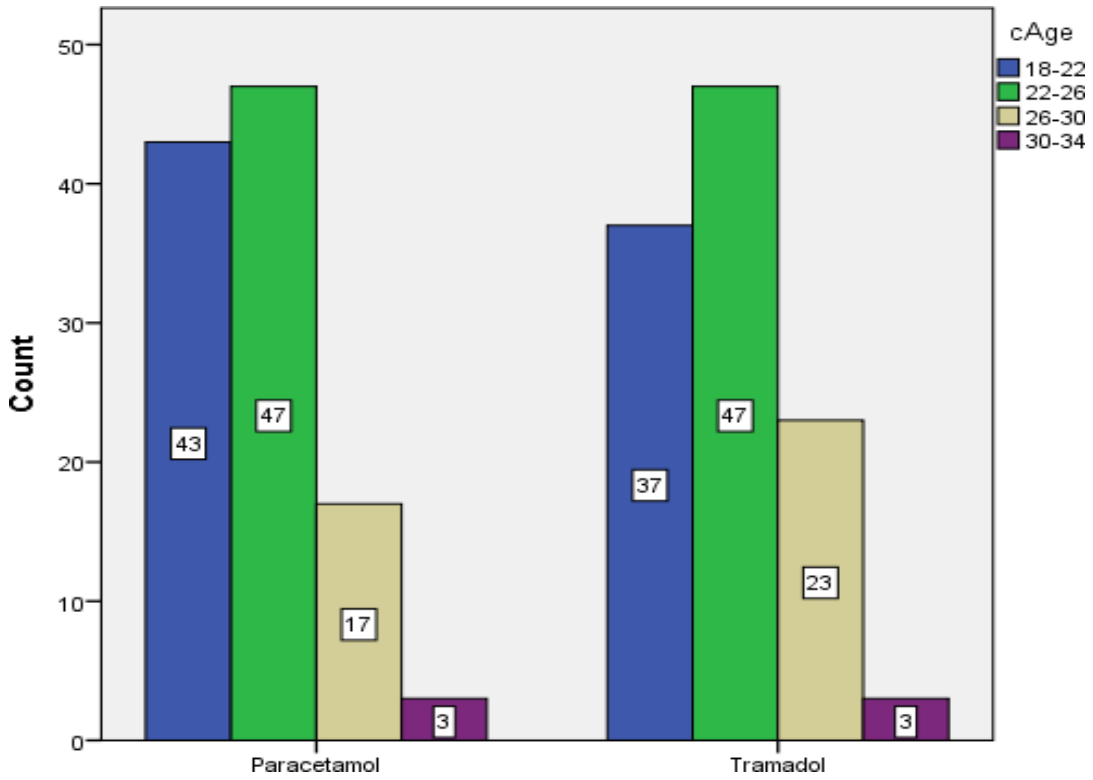


Figure 17: Bar diagram for comparison of age distribution between paracetamol and tramadol

As depicted in both the tables and bar diagrams , most of the patients belonged to the age group of 22-26 years constituting 42.70% in both the groups respectively with a p value of 0.717 , but on comparison between both the groups in age distribution it was not statistically significant .

Episiotomy	No. of Patients	Percentage
NO	22	10
YES	198	90
Total	220	100.0

Table 3: Episiotomy

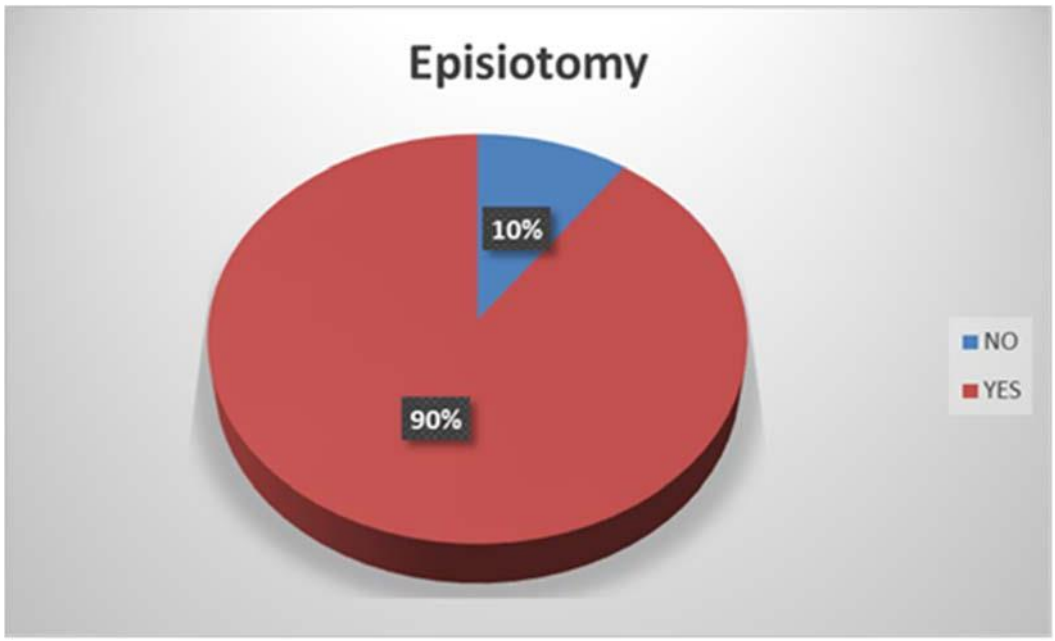


Figure 18 : Pie chart for episiotomy

Labor analgesia	Episiotomy			Chi-square value	p-value
	YES	NO	Total		
Paracetamol	100	10	110	.638	.888
%	90.9%	9.1%	100.00%		
Tramadol	98	12	110		
%	89.1%	10.9%	100.00%		
Statistically Insignificant					

Table 4: Comparison between both groups for episiotomy

According to this table both paracetamol and tramadol patients were given episiotomy irrespectively for delivery and hence the p value is statistically insignificant being 0.888.

S.No	Mode Of Delivery	No. Of Patients	Percentage
1	FTND	196	89.2
2	Forceps delivery	1	.5
3	Vacuum assisted delivery	1	.5
4	LSCS	22	10.5
	Total	220	100.0

Table 5: Mode of delivery

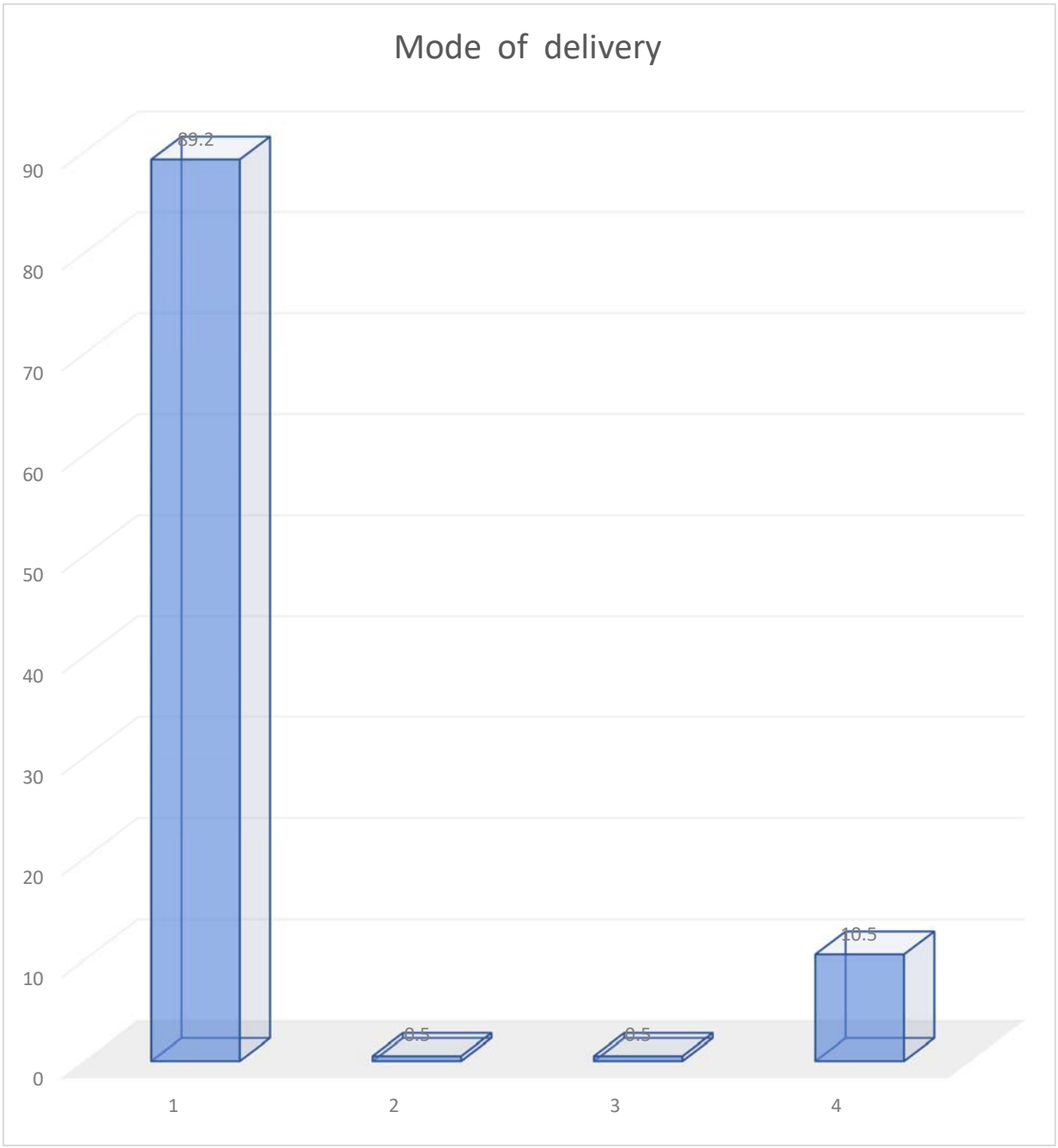


Figure 19: Mode of delivery

Labor analgesia	Mode of delivery					Chi-square value	p-value
	FTND	Vaccum	Forceps	lscs	Total		
Paracetamol (No of patients)	98	1	1	10	110	13.187	0.213
%	89.10%	0.90%	0.90%	9.00%	100.00%		
Tramadol (No of patients)	98	0	0	12	110		
%	89.10%	0	0	10.80%	100.00%		

Table 6: Comparison between both the groups for Mode of Delivery

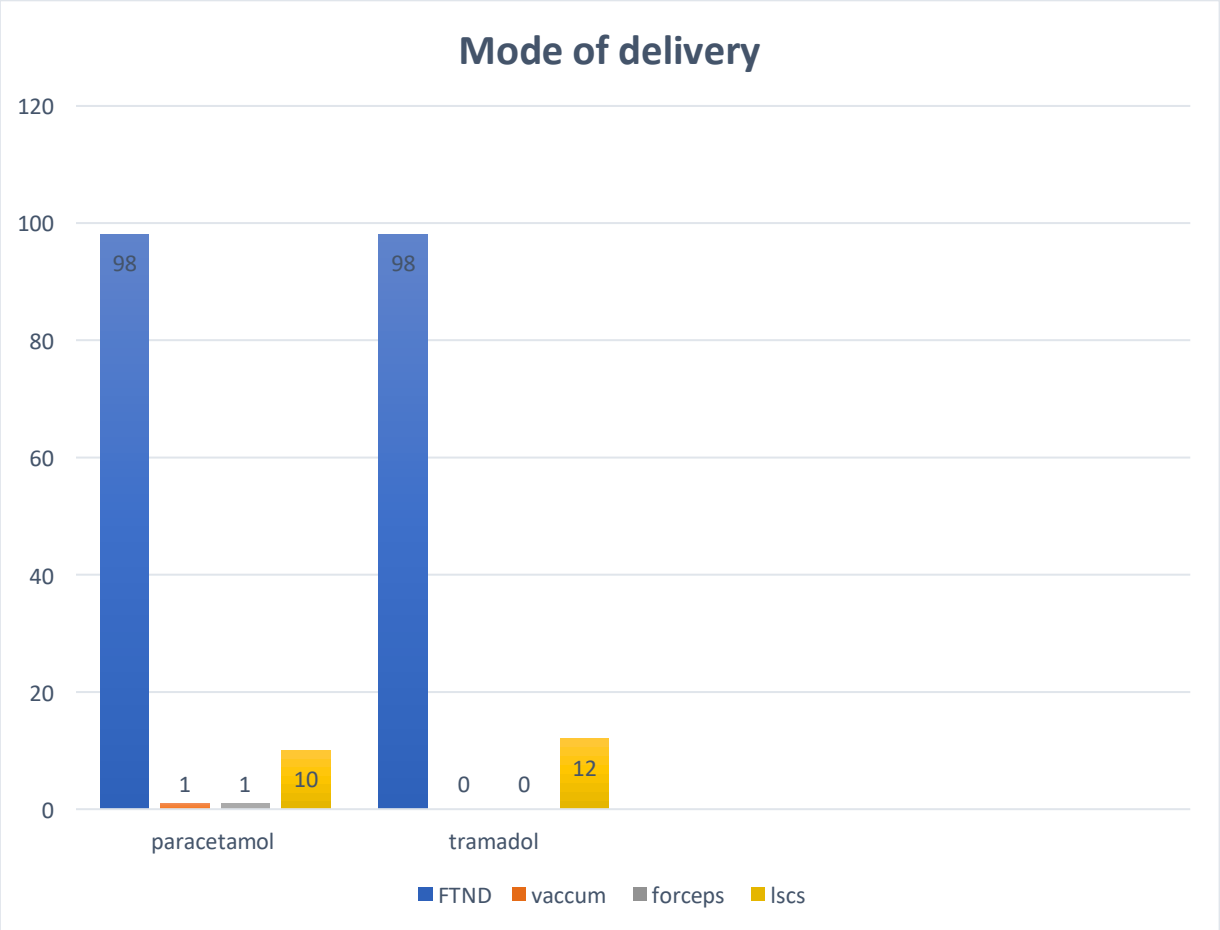


Figure 20: Comparison between mode of delivery between paracetamol and tramadol

According to the above tables and diagram , it is noted that most of the patients went for normal delivery equally between paracetamol and tramadol , with one each of vacuum assisted vaginal delivery (0.9%) and one forceps delivery for patients with paracetamol (0.9%) and more patients around 10.8% of cases among tramadol went for LSCS due to various reasons with p value of 0.213 making it statistically insignificant. But its been observed that instrumental delivery was seen only in patients given paracetamol and not significant enough hence studies with more sample size is needed to comment more on that aspect.

Meconium stained liquor	No. of Patients	Percentage
NO	213	96.8
YES	5	3.2
Total	220	100.0

Table 7: Meconium-Stained Liquor

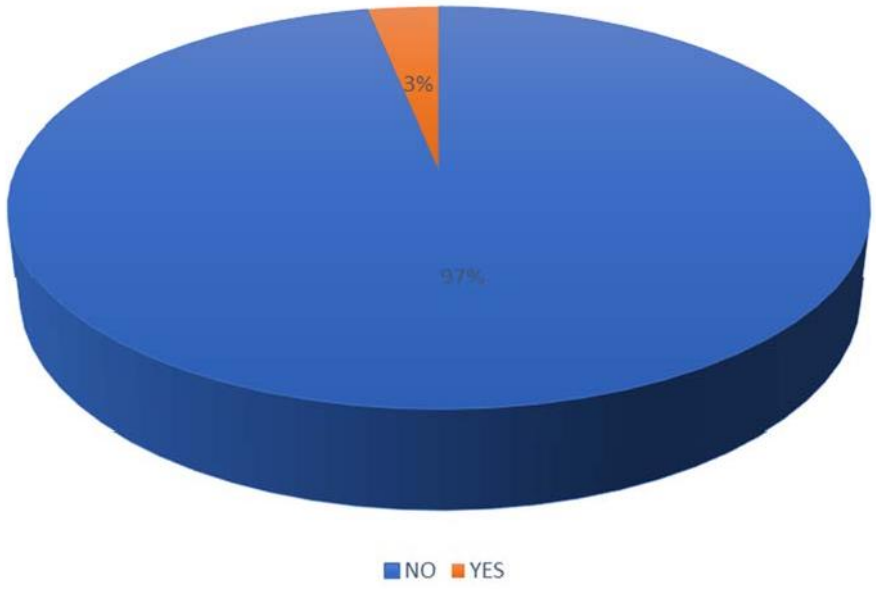


Figure 21: Pie chart for meconium-stained liquor

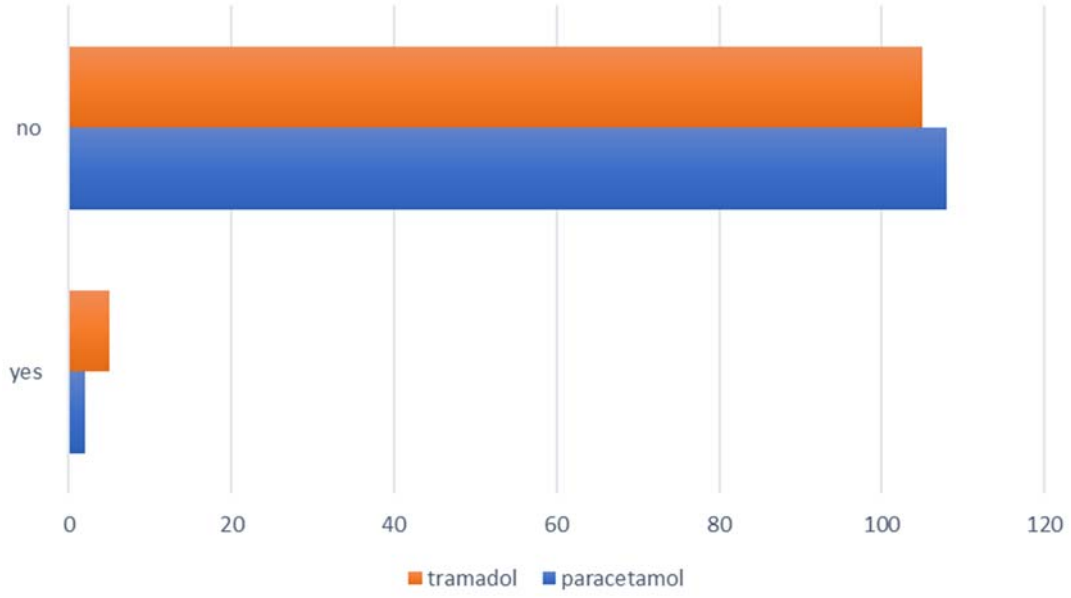


Figure 22: Bar diagram for comparison of meconium-stained liquor between both groups

Labor Analgesia	Meconium Stained Liquor			Chi-square	p-value
	YES	NO	Total		
Paracetamol(No of patients)	2	108	110	7.042	0.134
%	1.80%	98.2	100.00%		
Tramadol(No of patients)	5	105	110		
%	4.50%	95.50%	100.00%		
Statistically Insignificant					

Table 8: Comparison between both the groups for Meconium-Stained Liquor

According to the above tables and diagrams , it is noted that most of the patient's dint have meconium stained liquor and on comparing between paracetamol and tramadol , patients given tramadol had more cases of meconium stained liquor of 4.5% of cases , but the p value being statistically insignificant 0.134.

VAS scoring (1to10)	No. of Patients	Percentage
3	6	2.7
4	50	22.7
5	42	19.1
6	27	12.3
7	65	29.5
8	30	13.6
Total	220	100

Table 9: Detailed VAS score from 1-10

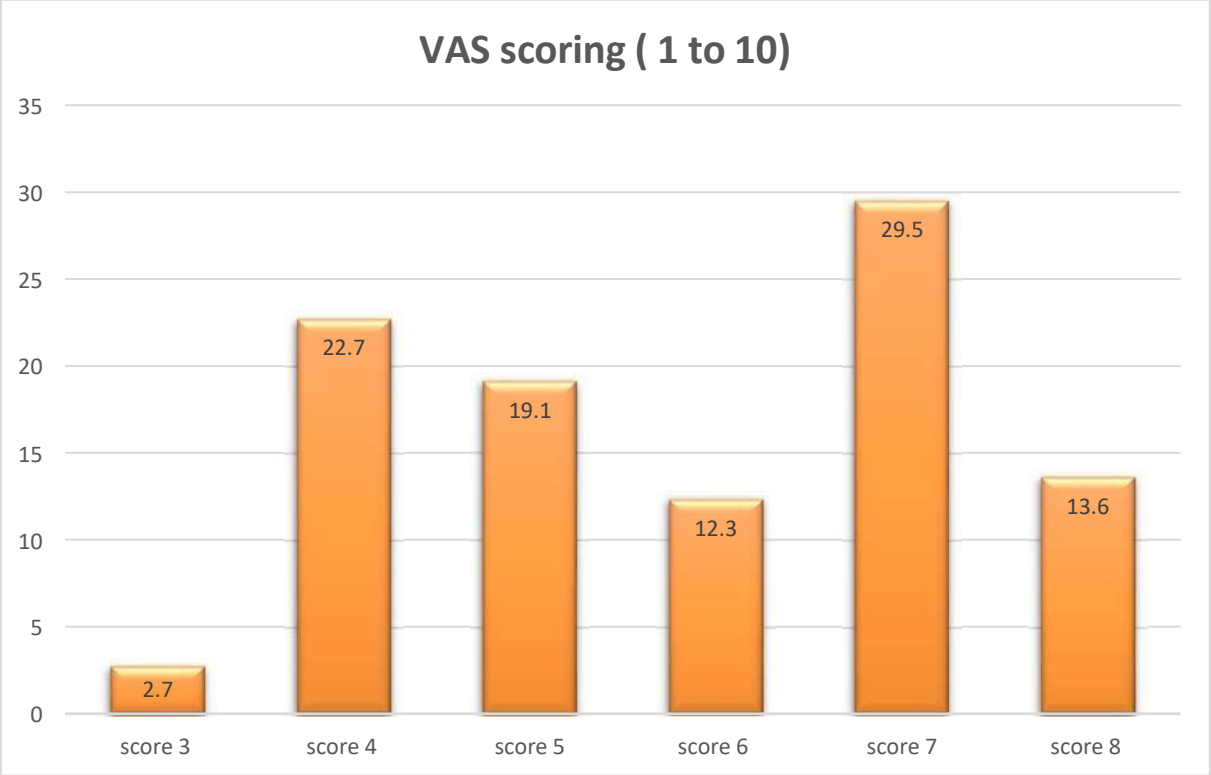


Figure 23: Bar diagram for detailed VAS scoring Grades

Labor analgesia		VAS score						Total	Chi-square	p-value
		3	4	5	6	7	8			
Paracetamol	No of patients	6	47	39	14	4	0	110	155.599	0.0001
	% within Labor analgesia	5.50%	42.70%	35.50%	12.70%	3.60%	0.00%	100.00%		
Tramadol	No of patients	0	3	3	13	61	30	110		
	% within Labor analgesia	0.00%	2.70%	2.70%	11.80%	55.50%	27.30%	100.00%		

Table 10: Comparison table between both the groups for detailed VAS SCORE grades

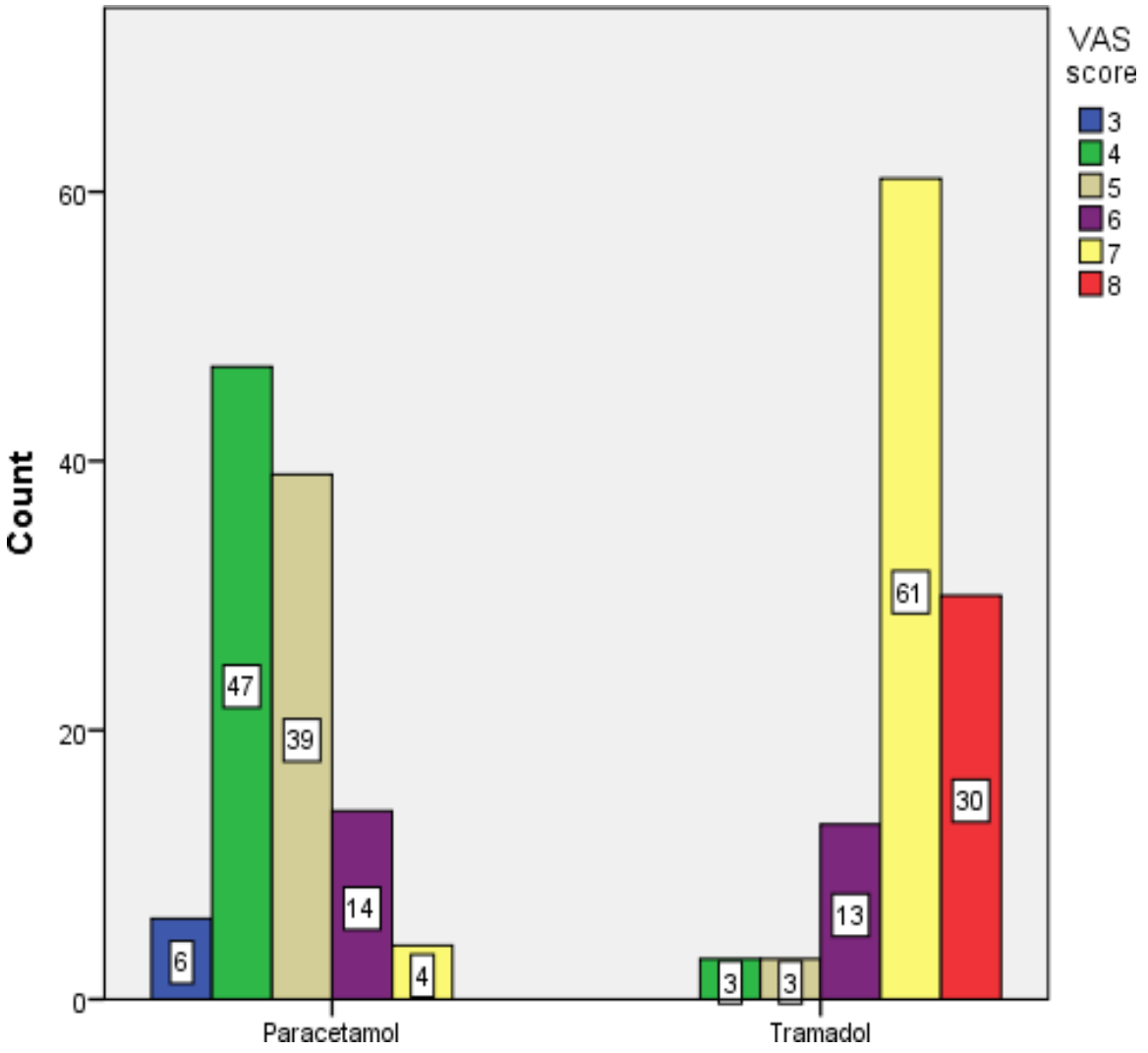


Figure 24: Bar diagram for comparison of detailed VAS Scoring between both the groups

According to the VAS scoring system , majority of the patients given paracetamol had better pain relief of a VAS score of 4 constituting 42.70% of the cases , while compared to tramadol most patients had a VAS score of 7 constituting 55.5% of the cases making paracetamol a better labor analgesic with a significant p value of 0.0001.

VAS score	No. of Patients	Percentage
Mild	6	2.7
Moderate	119	54.1
Severe	95	43.2
Total	220	100.0

Table 11: Average VAS scoring

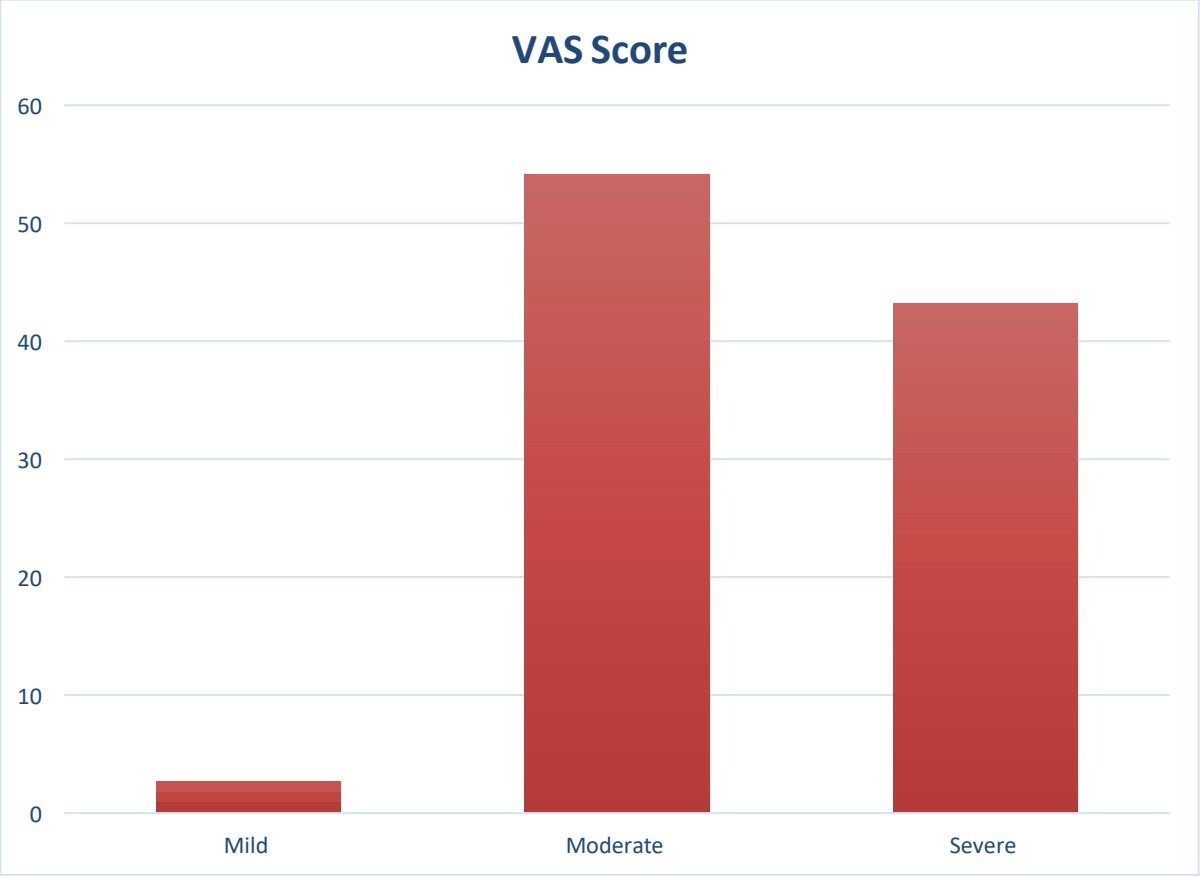


Figure 25: Bar diagram for VAS score in all primigravida's taken into study

Labor analgesia		Category			Total	Chi square	P value
		Mild	Moderate	Severe			
Paracetamol	Count	6	100	4	110	140.808	0
	% within Labor analgesia	5.50%	90.90%	3.60%	100.00%		
Tramadol	Count	0	19	91	110	167.306	0
	% within Labor analgesia	0.00%	17.30%	82.70%	100.00%		

Table 12: Comparison for average VAS score between paracetamol and tramadol

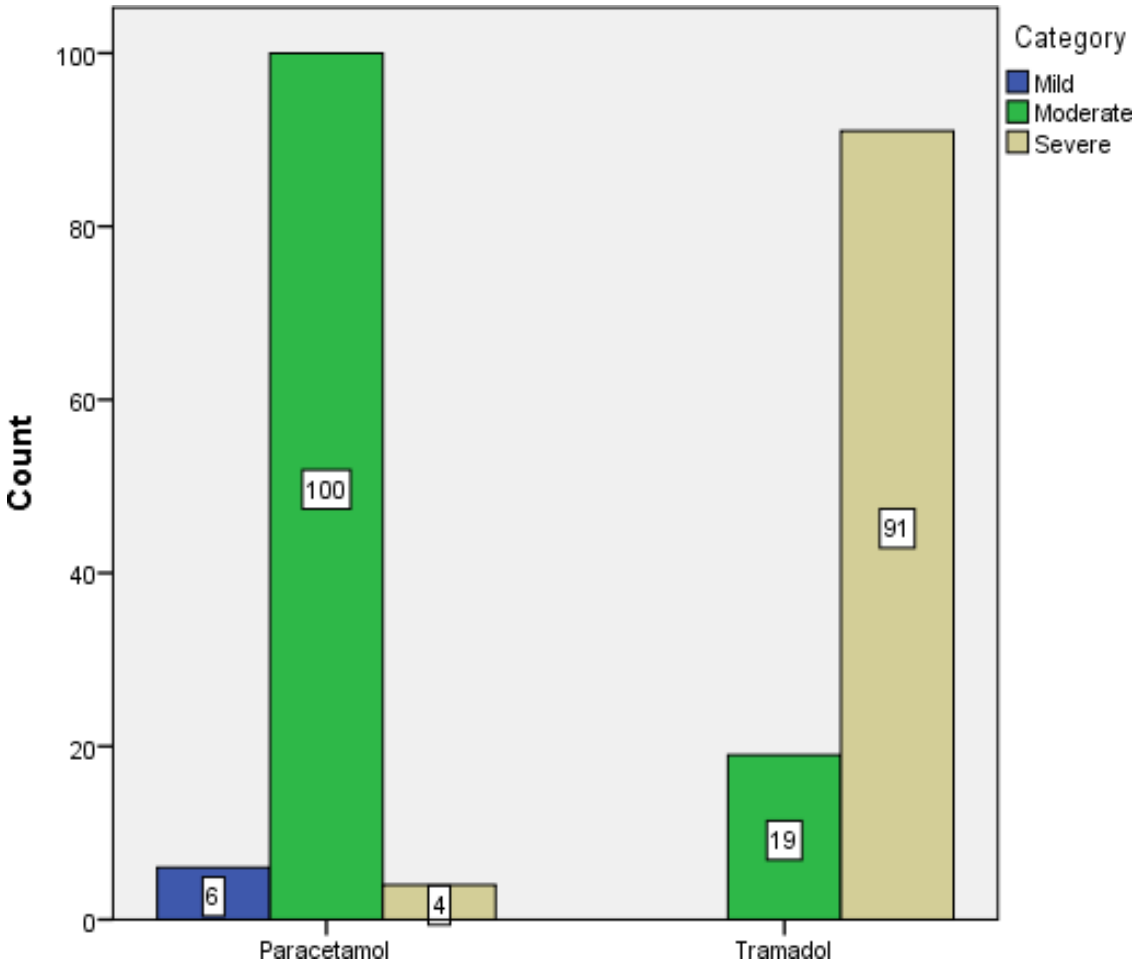


Figure 26: Bar diagram for comparison between average VAS score between both groups

From the above tables and diagram , we can come to the conclusion that paracetamol is a better analgesic compared to tramadol as majority of the patients given paracetamol had moderate pain relief (90.90%) and was able to give better maternal effort compared to tramadol where majority of the patients had severe pain (82.70%) , with a significant p value of 0.0001.

S.no	NICU ADMISSION	No. of Patients	Percentage
1	No	169	85.35
2	Yes – LBW	2	0.9
3	Yes – on HFNC	2	1.01
4	Yes – on nasal prongs	1	0.5
5	Yes – on oxygen hood	34	17.17
	Total	198	100

Table 13: Fetal Outcome

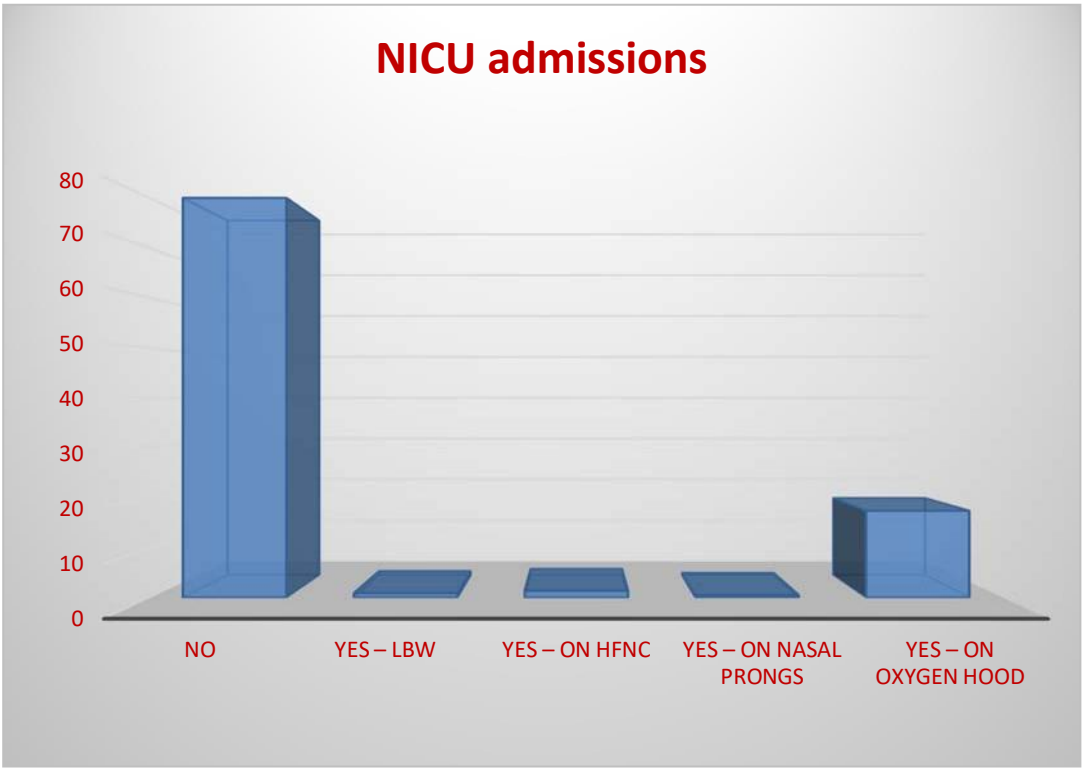


Figure 27: Bar diagram for NICU admission

Labor Analgesia	NICU admissions					Chi-square value	p-value
	NO	Yes	Yes	Yes	Yes		
		Nasal Prongs	Oxygen Hood	HFNC	LBW		
Paracetamol	100	0	5	1	0	26.236	0
%	93.00%	0%	5.50%	0.90%	0%		
Tramadol	69	1	30	2	2		
%	66.00%	0.90%	29.10%	1.80%	1.80%		
22 neonates born by Emergency LSCS were excluded from the fetal outcomes							

Table 14: Comparison for NICU admission between both the groups

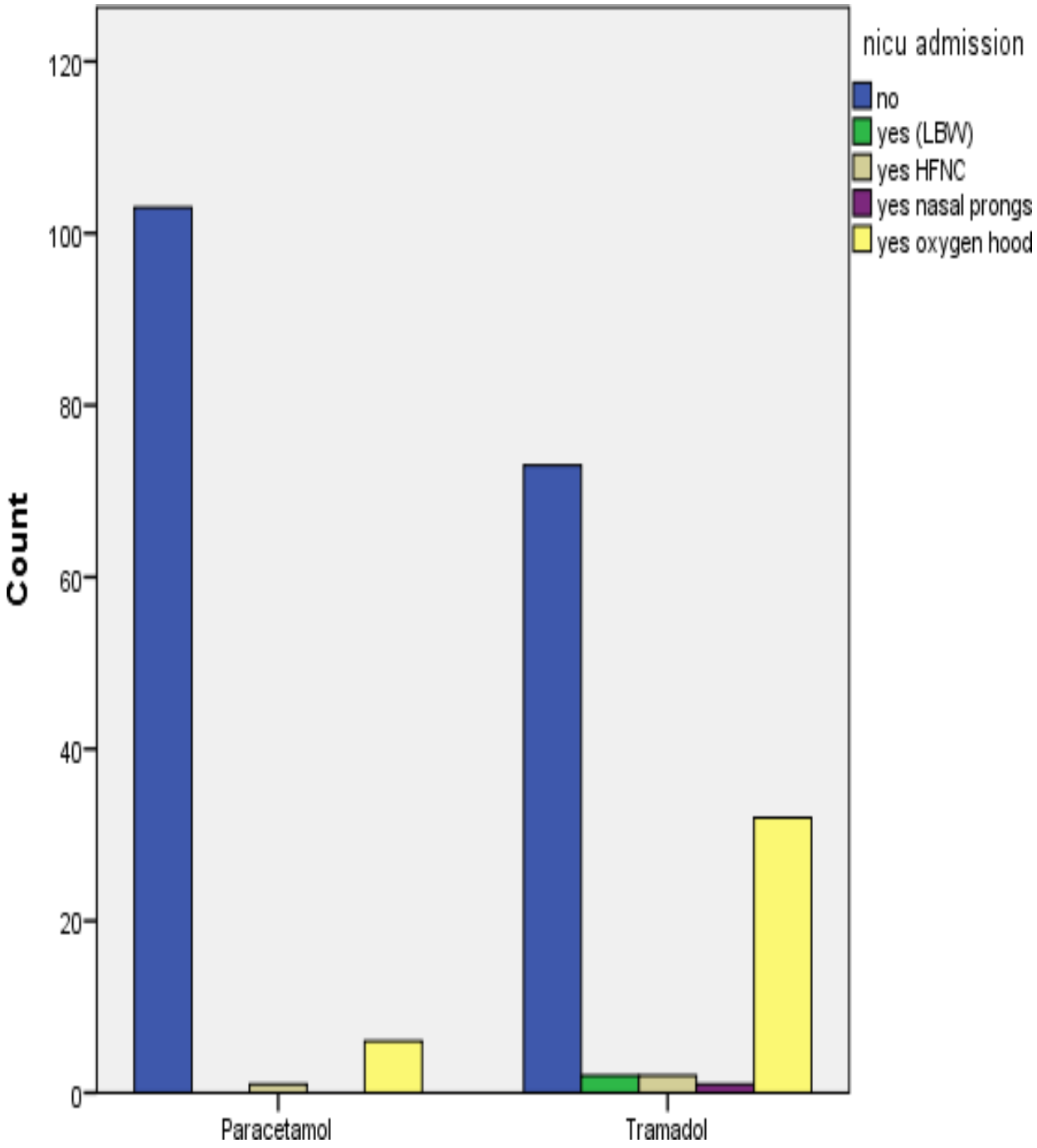


Figure 28: Bar diagram for comparison between both groups for NICU admissions

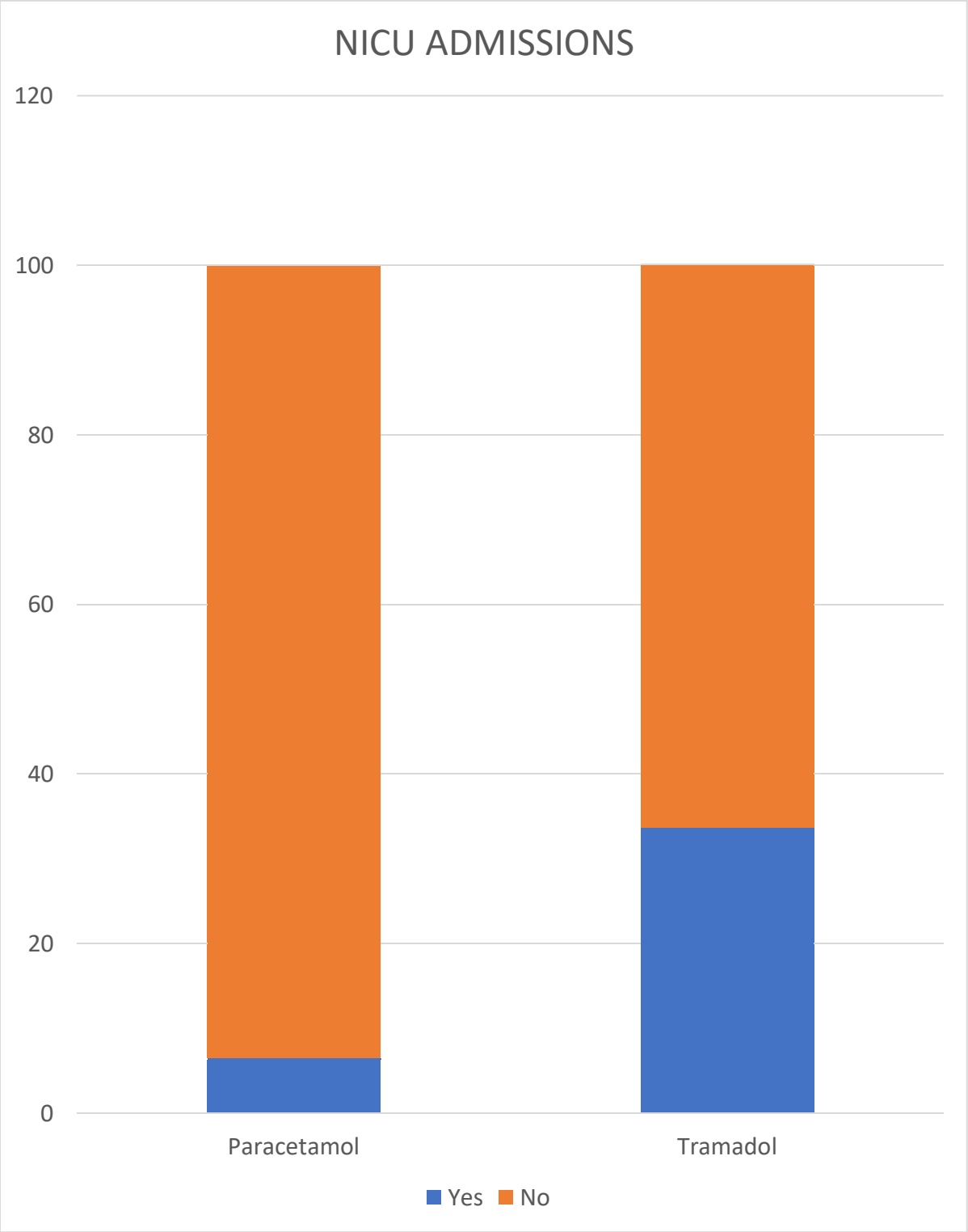


Figure 29: Bar diagram for comparison between both the groups for NICU admissions

According to the above tables and diagram its observed that most of the neonates born to patient's given tramadol had more NICU admission (33.6%) compared to paracetamol making paracetamol better for fetal compliance and outcomes with a significant p value of 0.0001 . But those neonates born by emergency LSCS (10%) were excluded from the study for fetal outcomes.

Variables	Group	N	Mean	SD	Mann-Whitney U test value	p-value
Pulse (bpm)	Paracetamol	110	91.309	4.727	6210	0.73
	Tramadol	110	91.018	4.408		
Gestational age (weeks	Paracetamol	110	38.764	1.165	6603.5	0.228
	Tramadol	110	38.518	1.269		
B.P systolic	Paracetamol	110	118.818	7.867	5991.5	0.895
	Tramadol	110	118.909	8.278		
Diastolic	Paracetamol	110	76.091	5.762	5935.5	0.785
	Tramadol	110	76.364	6.016		
duration of active	Paracetamol	110	3.999	1.179	2786	<0.001
	Tramadol	110	5.355	1.347		
duration of 2nd stage	Paracetamol	110	14.356	3.719	3936	0.003
	Tramadol	110	16	3.483		
Apgar1 min 0/10	Paracetamol	100	7.018	0.302	6782	0.006
	Tramadol	98	6.891	0.367		
Apgar 0/10	Paracetamol	100	8.827	0.38	7757	<0.001
	Tramadol	98	7	0.602		

Table 15: Independent samples Mann -Whitney U test

According to the Mann – Whitney U test for independent variables in our study , it is seen that the mean age for paracetamol is 22 and that of tramadol is 23 with a p value of 0.378 , the mean pulse rate for both the groups was 91 with a p value of 0.730 , coming to the mean gestational week for both groups was 38 weeks with a p value of 0.228 and the mean systolic and diastolic blood pressure in mm Hg was 118 and 76 with a p value of 0.895 and 0.785 respectively , all these variables were statistically insignificant. But the mean duration of active stage of labor was noted to be significantly shortened for patients given paracetamol with a mean duration of 3.9 hours with a significant p value of <0.001 .

Similarly, the duration of second stage of labor was also significantly shortened with an average time for patients given paracetamol being 14.3 minutes with a significant p value 0. 003. The mean Apgar score at 1 minute of birth for neonates to patient's given paracetamol and tramadol was 7 and 6 respectively with a p value of 0.006 and Apgar at 5 minutes of birth for neonates for paracetamol and tramadol was respectively 9 and 8 with a significant p value of <0.001.

	PARACETAMOL	TRAMADOL	P value
Duration of active stage of labor (in hours)	3.9	5.3	<0.001
Statistical y significant			

Table 16: Comparison between both the groups for duration of active stage of labor in hours

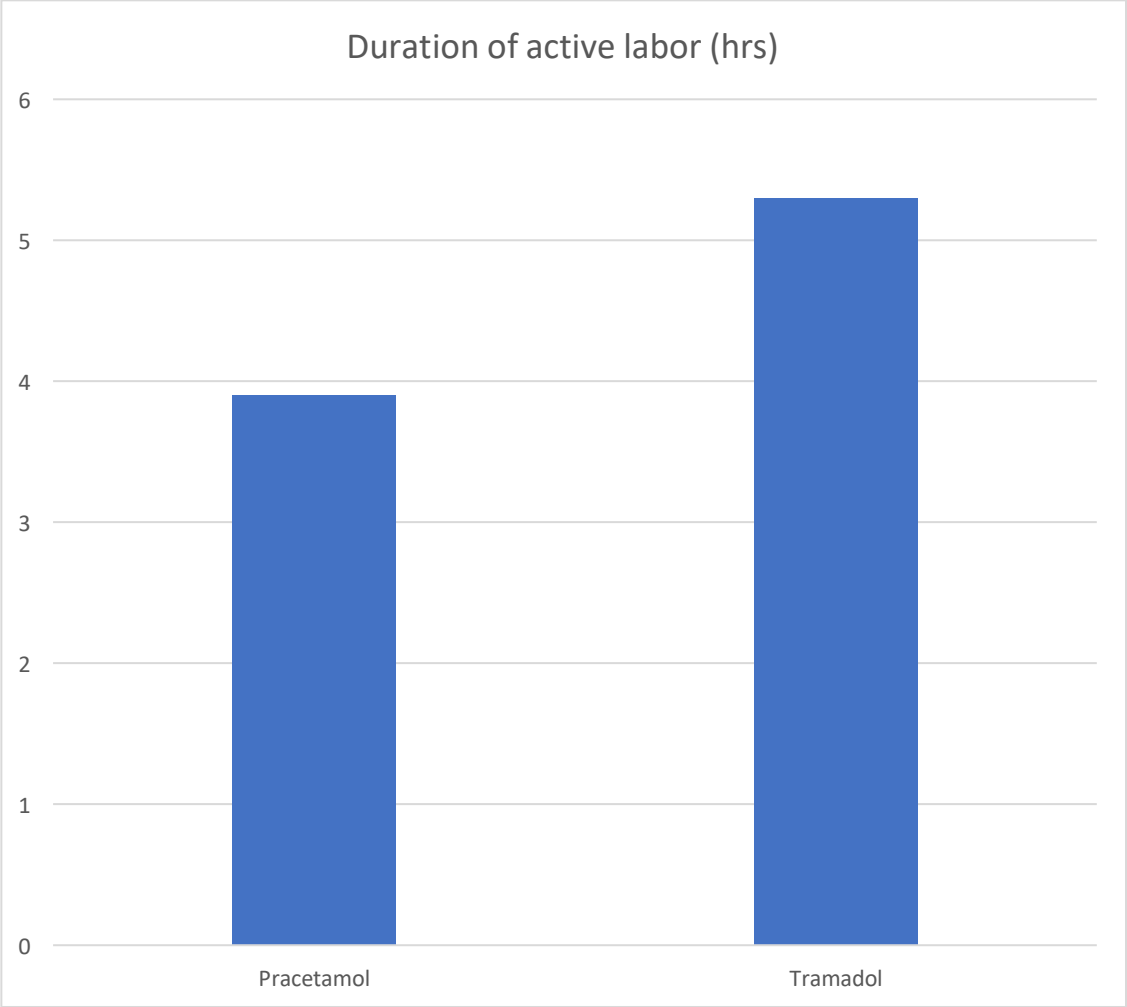


Figure 30: Bar diagram for comparison between both the groups for duration of active labor (in hours)

Hence according to the above-mentioned table and bar diagram it's been observed in our study that there is a significant shortening in the duration of active stage of labor in patients given paracetamol with a mean time of 3.9 hours and with a significant p value of <0.001 hence making paracetamol along with acting as a labor analgesic also helping in shortening the duration of the active stage of labor and helping in progressing the labor faster.

	PARACETAMOL	TRAMADOL	P value
Duration of 2nd stage of labor (in mins)	14.3	16	0.003

Statistically significant

Table 17: Comparison between both the groups for the duration of second stage of labor in minutes

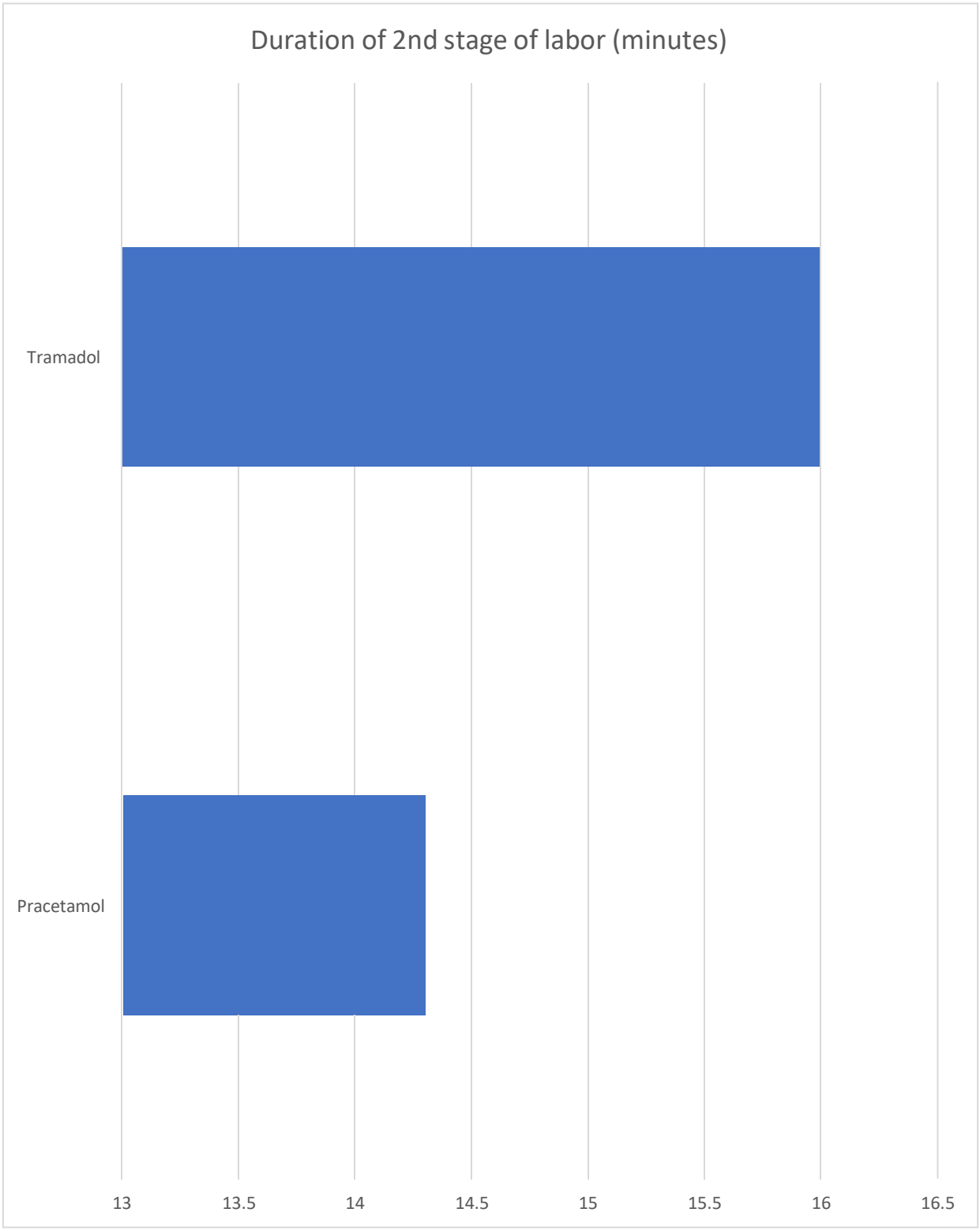


Figure 31: Comparison between both the groups for duration of second stage of labor in minutes.

According to the above table and diagram for comparison between paracetamol and tramadol for duration of second stage of labor in minutes its been observed that patients given paracetamol had a shorter second stage with a mean average time of 14.3 minutes with a significant p value of 0.003.

	PARACETAMOL	TRAMADOL	P value
Apgar at 1 minute	7	6	0.006
Apgar at 5 minute	8.8	7	<0.001

Table 18: Comparison between both the groups for fetal APGAR score

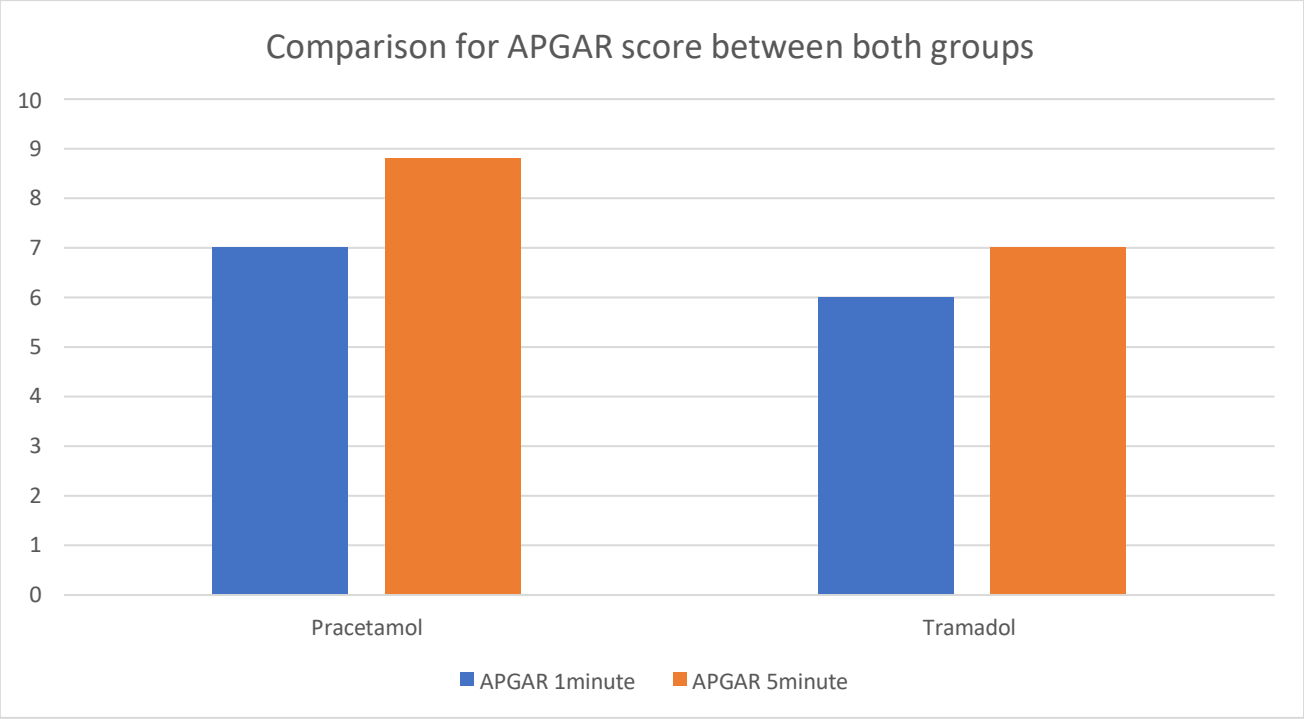


Figure 32: Comparison between both the groups for Apgar score at 1 minute and 5 minutes

According to the above data and bar diagram its seen that the average APGAR score at 1 minute for neonates born to parturient given paracetamol is 7 and at 5 minute its 8.8 with p value being 0.006 and <0.001 respectively , hence APGAR score being significant at 5 minutes for paracetamol group. But neonates born by emergency LSCS has been excluded from the study hence more studies with more sample sizes are needed for better result and outcomes.

6. DISCUSSION

Acetaminophen, often known as paracetamol, is the medicine that is used the most frequently in the world and is the first step for treatment for pain and pyrexia in practically all age groups. It also represents the first rung of the WHO analgesic ladder . The exact workings of the action are 1not entirely disclosed. Prostaglandin synthesis, serotonergic, opioid, nitric oxide, and cannabinoid pathways , as well as a variety of interconnected pathways, are just a few of the major mechanisms at play. It primarily inhibits the production of prostaglandins by acting as a COX and/or serotonergic system inhibitor. The efficacy and safety of 1intravenous paracetamol 1as 1an analgesic drug in a range of clinical diseases, including musculoskeletal pain , tension-type headaches, migraines, and across a range of surgical procedures , have been demonstrated in numerous trials [4-6]. It has reasonable side effects, is affordable, simple to administer, doesn't call for particular monitoring, and has helpful opioid-sparing benefits.

The synthetic counterpart of codeine tramadol hydrochloride has a distinct pharmacological profile. It combines the opioid and tricyclic antidepressant mechanisms of action. It blocks the transmission of pain impulses and

modifies pain perception. It is a modest -opioid receptor agonist. Additionally, it lessens norepinephrine and serotonin reuptake in the descending spinal inhibitory system , increasing the efficiency of the inhibitory route [7-10]. When treating a number of painful illnesses where treatment with potent opioids is not necessary, it has been demonstrated to be effective, well-tolerated, and constitutes Step 2 in the WHO ladder [9]. Its application as an obstetric analgesic in intramuscular [7] and intravenous formulations has received extensive research [8, 10].

In our study conducted we observed that there was not much change or difference in the intensity of labour pain prior to the administration of the drugs and after the administration of the drug , it was noted that paracetamol had a better pain analgesia compared to tramadol with better fetal outcome and mothers giving better efforts during labour and with no side effects. Pain score was scaled using the VAS score and it was seen that majority of the patients given paracetamol had moderate type of pain whereas tramadol patients had majorly severe pain , the mean VAS score being 4 for group paracetamol and score 7 for group tramadol with a significant p value of 0.0001 . According to the study done by Meenakshi Lallar et al [5] on 200 primigravida's pain intensity was measured using McGills pain intensity scale patients given paracetamol had distressing pain around 66%

of the patients,31% of the patients had horrible pain and in tramadol group around 78% of the patients had distressing pain,16% had horrible pain and hence the comparison between both the groups was statistically insignificant with a p value of 0.010.According to the study done by Aimakhu et al[3] after the administration of the first rescue dose there was no significant difference in the pain score between both the groups however at 120minutes , 180 minutes post rescue and 60 minute post partum there was an increase in the mean pain score and was not statistically significant.

In the study done by Meenakshi Lallar et al [5]94% of the paracetamol patients and 92% of tramadol patients had spontaneous vaginal delivery ,6% of paracetamol patients and 8% of tramadol patients went for LSCS and there was no instrumental delivery in both the groups , hence statistically insignificant .Also in the study conducted by Aimkahu et al [3]there was no significant difference the mode of delivery almost similar number of patients went for vaginal delivery and hence was statistically not significant. Similarly in our study , 1.8% of the patients given paracetamol had instrumental delivery one each of forceps delivery and vacuum assisted delivery and no patients in tramadol group had instrumental delivery , also 10.8% of patients belonging to tramadol groups in our study went for LSCS and 9% of the patients belonging to paracetamol group had also gone

for LSCS. Results obtained from our study was similar to various other studies conducted for the efficacy of paracetamol comparing to tramadol as labour analgesic.

Along with this in our study it was noted that paracetamol had fastened the progression of labour in many patients with better cervical dilatation and effacement and shortening the process of labour with better fetomaternal efforts with a significant p value of 0.0001, thus shortening the duration of active stage of labour in paracetamol group with a mean average duration of 3.9 hours and for second stage of labour with a mean average time of 14.3 minutes.

According to the study conducted by Neha Garg et al [(1)] the total duration of labour in paracetamol groups was found to be significantly shorter than in comparison to tramadol group , the mean duration of active phase of first stage of labour for paracetamol group was 4 hours , statistically significant with a p value of 0.0001 , the mean duration of second stage of labour with paracetamol was 36minutes with a significant p value of 0.0041.In the study done by Jeetinder Kaur et al [(7)] in primigravida's the duration of first stage of labour was shorter in the paracetamol group corresponding to an average time of 4.1 hours with a

significant p value of 0.003 but the second stage of labour was similar in both the groups in their study.

According to the study done by Aimakhu et al [3] there was no significant change in the duration of labour between paracetamol and tramadol groups and hence was not statistically significant. But in our study, there has been a significant reduction and shortening of both the first and second stage of labour in patients given paracetamol with significant p value in both.

Alongside this we had observed that all the neonates born to patients given intravenous paracetamol had better outcomes and were given mother side and all neonates had good Apgar score of more than 7 at 1 and 5 minutes respectively ;no neonates had to be intubated and no neonatal deaths were noted in both group of drugs , but neonates admitted in NICU were majorly belonging to tramadol category but , all neonates had good prognosis and speedy recovery. The mean Apgar score at 1 minute for neonates born to mothers given paracetamol is 7 where it is 8 for neonates born to mothers given tramadol as labour analgesics with a p value of 0.006 and the mean Apgar score at the end of 5 minutes for neonates born to mothers given paracetamol is 8.8 and that of tramadol is 7 with a significant p value of <0.001.

According to the study done by Meenakshi Lallar et al[5] the mean Apgar score of the neonates in the paracetamol group at 1 minute was 7.7 and at 5 minute was 9.6 and that of neonates born to the tramadol group at 1 minute was 7.8 and at 5 minute was 9.7 but not statistically significant . In the study done by Abida Rehman et al [4] they observed that there was more NICU admissions for neonates belonging to the tramadol group as compared to paracetamol group but the Apgar score for both the groups was not statistically significant , most neonates born to mothers given tramadol had similar Apgar score as paracetamol but they developed respiratory distress following delivery and needed NICU admissions.

Epidural analgesia is the method of choice for diminishing the labour pain efficiently without affecting other function , it lowers the risk of respiratory depression and unwanted sedation in comparison to inhalational and parenteral analgesia , but it increases the uteroplacental blood flow and improves the oxygenation of the fetus and the mother .

Thus from our study we can proudly say that paracetamol given intravenously 100ml or 1000mg can be used as a very simple, easily, economically friendly and safe drug available in developing country like ours where we have multiple primary and community health centres everywhere around each state , with limited resources and economical for feasibility for epidural analgesia.

7. SUMMARY

Some women breeze through giving birth, and some unfortunate women must go through the most painful moments for human beings. Epidural analgesia is the most effective analgesia for women in labour and is relatively safe. But epidural services are not routinely available in most obstetric units in developing countries because of the medical equipment, services and personnel cost. The basis of this study was to see whether paracetamol, regularly used analgesic offers better and safer labour analgesia compared to tramadol.

The study was conducted on 220 primigravida's admitted at our institute satisfying the inclusion criteria of the study and those who went for emergency LSCS was included for analysing the pain score and intensity but was excluded from the neonatal outcome and they were taken into the study after talking informed consent from the patients.

In our study 220 primigravida's were taken into the study but 22 cases who went for emergency LSCS were excluded from the fetal outcomes but included for pain score analysis. It was noted that majority of the patients given paracetamol had individual VAS score of 4 (42.70%) and tramadol had a score of 7 (55.5%), with a significant p value of 0.0001. Patients given paracetamol

had on an average moderate type of pain (90.90%) with a significant p value of 0.0001 compared to tramadol where patients experienced severe pain (82.7%).It was also observed that the duration of active labour was reduced in the paracetamol group with a significant p value of <0.0001 and the duration of second stage of labour was reduced in the paracetamol group with a significant p value of 0.003.Only around 6.4% neonates born to patients given paracetamol went to NICU compared to tramadol with a significant p value of 0.0001.

According to our study conducted, it can be concluded that Paracetamol is better and economically friendly, with better maternal and fetal outcomes in developing countries as compared to tramadol along with additional advantage of shortening the duration of labour.

8. CONCLUSION

Therefore, from our study we can conclude that paracetamol given is a better labor analgesic for patients in active labor as compared to tramadol given, it acts as a good pain reliefer along with less fetomaternal side effects and with additional advantage of shortening and progressing the duration of labor. Hence making paracetamol usage a regular labor analgesia for patients during active labor might decrease the LSCS rate due to intolerance to pain where epidural analgesia is not easily and readily available especially in resource limited and developing countries like ours. Therefore, paracetamol can be used as a safe and economically friendly and compliant drug for patients and neonates born to mothers in active labor.

Limitations of the study:

1. Sample size less, more sample size is needed to say that our results are more accurate as the cases that went for emergency LSCS were excluded from the study for neonatal outcomes.

2. More sample size is needed to comment on the rate of instrumental deliveries among both the groups.

3. More studies on comparison between paracetamol and epidural analgesics are needed to comment on the efficacy and safety of paracetamol over epidural analgesics in labouring patients for better fetomaternal outcomes and its effect on the progression of labour.

PROFORMA

COMPARATIVE STUDY BETWEEN INTRAVENOUS PARACETAMOL AND INTRAMUSCULAR TRAMADOL FOR LABOUR ANALGESIA

NAME:

AGE:

I.P. No:

DATE OF ADMISSION:

ADDRESS AND PHONE NUMBER:

DIAGNOSIS:

GENERAL PHYSICAL EXAMINATION:

PULSE:

BLOOD PRESSURE:

PALLOR:

TEMPERATURE:

CARDIOVASCULAR SYSTEM:

RESPIRATORY SYSTEM:

PER ABDOMEN:

LABOUR ANALGESIA: GROUP P GROUP T

DURATION OF ACTIVE LABOUR AFTER ANALGESIC:

DURATION OF SECOND STAGE:

EPISIOTOMY: YES / NO

PERINEAL TEARS: YES/NO

MODE OF DELIVERY :1) VAGINAL:

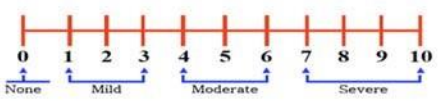
2) VENTOUSE (INDICATION):

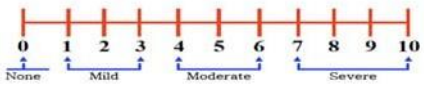
3) FORCEPS (INDICATION):

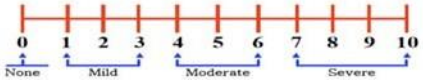
4) LSCS (INDICATION):

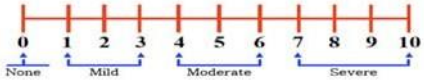
MECONIUM STAINED LIQUOR: YES / NO

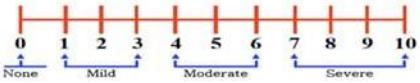
VAS SCORE

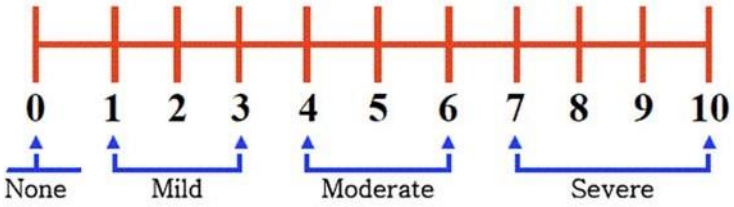
0 hr : 

1hr : 

3hr : 

2ns stage : 

1hr after delivery : 



NUMERIC PAIN INTENSITY SCALE

NEONATAL OUTCOME

1. APGAR SCORE: 1min 5min
2. Need for umbubagging:
3. Need for intubation:
4. NICU admission: a) for birth asphyxia:

b) death:

c) any other causes:

CONSENT FORM

B.L.D.E. (DEEMED TO BE UNIVERSITY) SHRI B.M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTER, VIJAYAPURA-586103

INFORMED CONSENT FOR PARTICIPATION IN DISSERTATION/RESEARCH

I, the undersigned,_____, D/O W/O_____, aged ____years, ordinarily resident of_____do hereby state/declare that Dr Priyanka Bhuvanendran of Shri. B. M. Patil Medical College Hospital and Research Centre has examined me thoroughly on _____ at _____ (place) and it has been explained to me in my own language that I am_____disease (condition) and this disease. Further Dr Priyanka Bhuvanendran informed me that he/she is conducting dissertation/research titled "Comparative study between intravenous paracetamol and intramuscular tramadol for labour analgesia: A Randomized Controlled Study" under the guidance of Dr. Neelamma Patil requesting my participation in the study. Apart from routine treatment procedure, the pre-operative, operative, post-operative and follow-up observations will be utilized for the study as reference data. Doctor has also informed me that during conduct of this procedure like adverse results may be encountered. Among the above complications most of them are treatable but are not anticipated hence there is chance of aggravation

of my condition and in rare circumstances it may prove fatal in spite of anticipated diagnosis and best treatment made available. Further Doctor has informed me that my participation in this study would help in evaluation of the results of the study which is useful reference to treatment of other similar cases in near future, and also, I may be benefited in getting relieved of suffering or cure of the disease I am suffering.

The Doctor has also informed me that information given by me, observations made photographs video graphs taken upon me by the investigator will be kept secret and not assessed by the person other than me or my legal hirer except for academic purposes. The Doctor did inform me that though my participation is purely voluntary, based on information given by me, I can ask any clarification during treatment / study related to diagnosis, procedure of treatment, result of treatment or prognosis. At the same time, I have been informed that I can withdraw from my participation in this study at any time if I want or the investigator can terminate me from the study at any time from the study but not the procedure of treatment and follow-up unless I request to be discharged.

After understanding the nature of dissertation or research, diagnosis made, mode of treatment, I the undersigned Smt_____under my full conscious state of mind agree to participate in the said research/dissertation.

Signature of patient: Date:

Signature of doctor: Place:

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ANNEXURE

S.No.	Age	D.O.A	Gestational age (weeks , days)	GPE	Pulse (bpm)	B.P systolic	Diastolic	Pallor	Temp Deg F	CVS	RS	Labour Analgesia	Duration of Active Labor (hrs)	Duration of 2nd Stage (mins)	Episiotomy	Perineal Tears	Mode of Delivery	Meconium Stained	VAS Score	Category	1 min 0/10	5min 0/10	Need for Umbugagging	Need for Intubation	NICU Admission
1	20	14/01/2021	39	nil	98	140	80	nil	afebrile	NAD	NAD	T	4	20	yes	no	ftnd	no	6	Moderate	07-Jan	8	no	no	no
2	23	16/01/2021	37	nil	80	110	70	nil	afebrile	NAD	NAD	P	3.5	20	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
3	21	03/03/2021	40	nil	80	110	70	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	3	Mild	7	9	no	no	no
4	25	05/03/2021	38	nil	96	120	70	nil	afebrile	NAD	NAD	P	3.5	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
5	20	05/03/2021	40	nil	84	110	70	nil	afebrile	NAD	NAD	T	6	20	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
6	20	09/03/2021	39	nil	96	130	90	nil	afebrile	nAD	NAD	P	4	15	yes	no	ftnd	no	3	Mild	6	8	no	no	yes oxygen hood
7	22	22/03/2021	38	nil	82	110	70	nil	afebrile	NAD	NAD	P	3.5	10	yes	no	ftnd	no	3	Mild	7	9	no	no	no
8	26	17/03/2021	39	nil	86	120	70	nil	afebrile	NAD	NAD	T	6	20	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
9	22	26/03/2021	37	nil	94	140	80	nil	afebrile	NAD	NAD	T	6.5	10	yes	no	ftnd	no	7	Severe	7	9	no	no	yes oxygen hood
10	21	02/03/2021	39	nil	80	110	70	nil	afebrile	NAD	NAD	T	6	15	yes	no	ftnd	no	7	Severe	7	8	no	no	yes oxygen hood
11	24	03/04/2021	38	nil	90	110	80	nil	afebrile	NAD	NAD	P	5	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
12	25	05/04/2021	37	nil	88	110	70	nil	afebrile	NAD	NAD	T	6	10	yes	no	ftnd	no	6	Moderate	7	8	no	no	no
13	20	08/04/2021	42	nil	92	110	80	nil	afebrile	NAD	NAD	P	3	15	yes	no	ftnd	yes	4	Moderate	7	8	no	no	yes oxygen hood
14	25	07/04/2021	39	nil	90	130	80	nil	afebrile	NAD	NAD	T	4.5	15	yes	no	ftnd	no	6	Moderate	7	8	no	no	no
15	20	10/04/2021	40	nil	92	120	80	nil	afebrile	NAD	NAD	P	4.5	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
16	21	10/04/2021	40	nil	90	110	90	nil	afebrile	NAD	NAD	T	5	20	yes	no	ftnd	no	7	Severe	7	8	no	no	yes oxygen hood
17	23	13/04/2021	38	nil	88	120	80	nil	afebrile	NAD	NAD	P	3	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
18	24	15/04/2021	38	nil	90	130	80	nil	afebrile	NAD	NAD	T	5	20	yes	no	ftnd	no	7	Severe	7	8	no	no	no
19	21	29/03/2021	39	nil	98	110	80	nil	afebrile	NAD	NAD	T	4	15	yes	no	ftnd	no	7	Severe	7	8	no	no	no
20	21	26/04/2021	37	nil	88	120	80	nil	afebrile	NAD	NAD	T	4	20	yes	no	ftnd	no	7	Severe	7	9	no	no	no
21	23	08/05/2021	38	nil	100	120	80	nil	afebrile	NAD	NAD	T	4	15	no	no	lscs (fetal	no	7	Severe	6	7	no	no	yes oxygen hood
22	24	05/06/2021	40	nil	98	130	80	nil	afebrile	NAD	NAD	P	4	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
23	22	31/07/2021	40	nil	90	140	70	nil	afebrile	NAD	NAD	P	8	NA	no	no	lscs(failed inductio	yes	3	Mild	7	8	no	no	no
24	21	31/07/2021	39	nil	102	130	80	nil	afebrile	NAD	NAD	P	4	25	yes	no	forceps delivery	no	4	Moderate	6	8	no	no	yes oxygen hood
25	24	24/08/2021	41	nil	88	110	70	nil	afebrile	nAD	nAD	P	2	10	yes	no	ftnd	no	3	Mild	7	9	no	no	no
26	21	24/08/2021	38	nil	90	110	70	nil	afebrile	NAD	NAD	P	3	10	yes	no	ftnd	no	4	Moderate	8	9	no	no	no
27	19	03/09/2021	39	nil	84	120	80	nil	afebrile	NAD	NAD	P	4	10	yes	no	ftnd	no	5	Moderate	7	8	no	no	no
28	22	14/09/2021	39	nil	86	110	80	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	6	Moderate	8	9	no	no	no
29	28	14/08/2021	37	nil	90	120	80	nil	afebrile	NAD	NAD	T	4	20	yes	no	ftnd	no	7	Severe	7	8	no	no	no
30	19	09/09/2021	37	nil	88	110	80	nil	afebrile	NAD	NAD	P	4	NA	no	no	lscs (fetal	no	5	Moderate	7	8	no	no	no
31	21	10/09/2021	41	nil	90	120	70	nil	afebrile	NAD	NAD	P	4.5	30	no	no	lscs (fetal	no	5	Moderate	6	8	no	no	no
32	22	11/09/2021	40	nil	88	130	80	nil	afebrile	NAD	NAD	T	3.5	NA	NO	NO	lscs (fetal	no	7	Severe	7	8	no	no	yes oxygen hood
33	19	14/09/2021	38	nil	90	120	80	nil	afebrile	NAD	NAD	P	3	10	yes	no	ftnd	no	5	Moderate	7	8	no	no	no

34	20	20/09/2021	38	nil	86	120	70	nil	afebrile	NAD	NAD	P	2	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
35	28	19/09/2021	40	nil	90	110	80	nil	afebrile	NAD	NAD	T	3	10	yes	no	ftnd	no	8	Severe	7	9	no	no	no
36	25	21/09/2021	39	nil	98	120	80	nil	afebrile	NAD	NAD	T	4.5	20	yes	no	ftnd	no	7	Severe	7	9	no	no	no
37	26	04/11/2021	40	nil	100	110	80	nil	afebrile	NAD	NAD	P	1	10	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
38	31	05/11/2021	38	nil	98	120	70	nil	afebrile	NAD	NAD	P	2	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
39	20	10/11/2021	40	nil	90	130	80	nil	afebrile	NAD	NAD	P	3	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
40	19	11/11/2021	38	nil	98	110	80	nil	afebrile	NAD	NAD	T	3	10	yes	no	ftnd	no	8	Severe	7	9	no	no	no
41	32	11/11/2021	38	nil	90	110	70	nil	afebrile	NAD	NAD	P	3	10	yes	no	ftnd	no	5	Moderate	7	8	no	no	no
42	22	12/11/2021	37	nil	88	120	70	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	7	Severe	7	9	no	no	no
43	23	14/11/2021	38	nil	90	110	80	nil	afebrile	NAD	NAD	T	6	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
44	22	14/11/2021	39	nil	98	120	80	nil	afebrile	NAD	NAD	T	3	20	yes	no	ftnd	no	7	Severe	7	9	no	no	no
45	21	19/11/2021	37	nil	88	110	80	nil	afebrile	NAD	NAD	T	7	20	yes	no	ftnd	no	7	Severe	7	8	no	no	no
46	19	18/11/2021	38	nil	90	130	70	nil	afebrile	NAD	NAD	P	2	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
47	21	02/11/2021	39	nil	86	120	80	nil	afebrile	NAD	NAD	P	4.5	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
48	19	22/11/2021	39	nil	90	120	80	nil	afebrile	NAD	NAD	P	2	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
49	22	19/11/2021	37	nil	88	110	70	nil	afebrile	NAD	NAD	T	5	20	YES	no	ftnd	no	7	Severe	7	9	no	no	no
50	21	22/11/2021	41	nil	90	120	70	nil	afebrile	NAD	NAD	T	6	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
51	23	22/11/2021	39	nil	92	110	80	nil	afebrile	NAD	NAD	T	10	NA	no	no	lscs (NPOL)	no	8	Severe	7	9	no	no	no
52	22	23/11/2021	37	nil	88	120	70	nil	afebrile	NAD	NAD	P	3	20	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
53	20	24/11/2021	39	nil	90	120	80	nil	afebrile	NAD	NAD	P	2.5	10	yes	no	ftnd	no	7	Severe	7	9	no	no	no
54	22	28/11/2021	39	nil	92	120	80	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	6	Moderate	7	8	no	no	no
55	20	29/11/2021	41	nil	90	110	90	nil	afebrile	NAD	NAD	T	8	NA	no	no	lscs (NPOL)	no	7	Severe	7	9	no	no	no
56	21	29/11/2021	40	nil	88	120	80	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
57	25	02/12/2021	39	nil	90	120	80	nil	afebrile	NAD	NAD	T	4	15	yes	no	ftnd	no	7	Severe	7	8	no	no	no
58	22	02/12/2021	38	nil	88	130	80	nil	afebrile	NAD	NAD	P	3	15	yes	no	ftnd	no	5	Moderate	7	8	no	no	no
59	24	03/12/2021	38	nil	96	120	80	nil	afebrile	NAD	NAD	P	2	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
60	22	05/12/2021	40	nil	90	120	70	nil	afebrile	NAD	NAD	P	4	20	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
61	24	08/12/2021	40	nil	92	120	80	nil	afebrile	NAD	NAD	P	2	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
62	26	07/12/2021	38	nil	88	110	80	nil	afebrile	NAD	NAD	P	5	NA	no	no	lscs (maternal	no	7	Severe	7	8	no	no	no
63	25	09/12/2021	38	nil	86	110	70	nil	afebrile	NAD	NAD	T	4	NA	NO	no	lscs (fetal	no	7	Severe	7	8	no	no	yes oxygen hood
64	20	10/12/2021	41	nil	90	120	70	nil	afebrile	NAD	NAD	P	4	10	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
65	23	11/12/2021	39	nil	92	110	80	nil	afebrile	NAD	NAD	P	3.5	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
66	26	02/12/2021	39	nil	90	120	80	nil	afebrile	NAD	NAD	P	2.5	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
67	22	01/12/2021	38	nil	88	130	80	nil	afebrile	NAD	NAD	T	4.5	15	yes	no	ftnd	no	7	Severe	7	8	no	no	no
68	24	01/12/2021	38	nil	90	130	70	nil	afebrile	NAD	NAD	T	3.5	10	yes	no	ftnd	no	7	Severe	7	9	no	no	no
69	26	05/12/2021	38	nil	86	110	90	nil	afebrile	NAD	NAD	T	4.5	15	yes	no	ftnd	no	7	Severe	7	8	no	no	yes oxygen hood
70	27	05/12/2021	37	nil	92	120	80	nil	afebrile	NAD	NAD	T	4.5	10	yes	no	ftnd	no	7	Severe	7	8	no	no	no
71	29	13/12/2021	38	nil	90	120	70	nil	afebrile	NAD	NAD	P	5	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
72	21	14/12/2021	37	nil	88	110	80	nil	afebrile	NAD	NAD	P	3	20	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
73	20	14/12/2021	39	nil	90	120	80	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
74	19	14/12/2021	37	nil	88	120	70	nil	afebrile	NAD	NAD	T	3	20	yes	no	ftnd	no	8	Severe	6	9	no	no	no
75	19	15/12/2021	39	nil	90	120	80	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
76	25	17/12/2021	39	nil	94	130	80	nil	afebrile	NAD	NAD	P	2	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no

77	24	17/12/2021	39	nil	90	120	70	nil	afebrile	NAD	NAD	T	6	20	yes	no	fnd	no	7	Severe	6	7	no	no	yes HFNC
78	24	16/12/2021	39	nil	86	120	80	nil	afebrile	NAD	NAD	P	4.5	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
79	27	17/12/2021	37	nil	88	110	80	nil	afebrile	NAD	NAD	T	3	10	yes	no	ftnd	no	6	Moderate	7	8	no	no	yes HFNC
80	20	17/12/2021	38	nil	90	120	80	nil	afebrile	NAD	NAD	T	5	20	yes	no	ftnd	no	7	Severe	7	9	no	no	no
81	21	25/12/2021	39	nil	86	130	80	nil	afebrile	NAD	NAD	P	3.5	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
82	23	25/12/2021	37	nil	90	130	70	nil	afebrile	NAD	NAD	P	4.5	10	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
83	31	16/12/2021	37	nil	92	120	80	nil	afebrile	NAD	NAD	T	5	NA	no	no	lscs (NPOL)	no	7	Severe	7	9	no	no	no
84	23	03/09/2021	39	nil	88	120	80	nil	afebrile	NAD	NAD	T	5	10	yes	no	ftnd	no	7	Severe	7	9	no	no	no
85	18	13/06/2021	38	nil	90	120	70	nil	afebrile	NAD	NAD	T	5	20	yes	no	ftnd	no	7	Severe	7	8	no	no	no
86	24	18/06/2021	39	nil	100	120	80	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
87	21	19/06/2021	39	nil	98	130	70	nil	afebrile	NAD	NAD	T	5	10	yes	no	ftnd	no	7	Severe	7	8	no	no	yes oxygen hood
88	24	26/12/2021	40	nil	100	130	70	nil	afebrile	NAD	NAD	T	3.5	NA	NO	NO	lscs (Meconium stained	no	7	Severe	6	7	no	no	yes oxygen hood
89	21	26/12/2021	38	nil	98	110	70	nil	afebrile	NAD	NAD	P	6	NA	no	no	lscs (maternal	no	7	Severe	7	9	no	no	no
90	20	20/12/2021	40	nil	96	120	80	nil	afebrile	NAD	NAD	T	7	15	yes	no	ftnd	no	8	Severe	6	8	no	no	no
91	25	26/12/2021	37	nil	88	130	80	nil	afebrile	NAD	NAD	P	5	15	yes	no	ftnd	no	5	Moderate	8	9	no	no	no
92	24	27/12/2021	40	nil	100	120	80	nil	afebrile	NAD	NAD	T	6.5	20	yes	no	ftnd	no	6	Moderate	6	8	no	no	yes oxygen hood
93	23	28/12/2021	38	nil	94	120	80	nil	afebrile	NAD	NAD	T	3.5	15	yes	no	ftnd	no	5	Moderate	7	8	no	no	no
94	23	29/12/2021	40	nil	92	130	70	nil	afebrile	NAD	NAD	P	3.5	10	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
95	27	29/12/2021	37	nil	98	120	70	nil	afebrile	NAD	NAD	T	3.5	20	yes	no	ftnd	no	8	Severe	6	8	no	no	yes oxygen hood
96	19	01/01/2022	38	nil	88	130	70	nil	afebrile	NAD	NAD	T	6	15	yes	no	ftnd	no	8	Severe	7	9	no	no	no
97	21	29/11/2021	40	nil	92	120	70	nil	afebrile	NAD	NAD	T	7	15	yes	no	ftnd	no	7	Severe	7	9	no	no	no
98	24	18/01/2022	38	nil	88	130	80	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	7	Severe	7	9	no	no	no
99	23	23/01/2022	37	nil	90	120	70	nil	afebrile	NAD	NAD	P	3	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
100	21	22/01/2022	38	nil	98	110	80	nil	afebrile	NAD	NAD	T	4	10	yes	no	ftnd	no	7	Severe	7	8	no	no	yes oxygen hood
101	22	23/01/2022	39	nil	90	130	80	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
102	20	21/02/2022	37	nil	92	130	70	nil	afebrile	NAD	NAD	T	5.5	10	yes	no	ftnd	no	7	Severe	7	8	no	no	yes oxygen hood
103	29	17/01/2022	39	nil	88	120	70	nil	afebrile	NAD	NAD	T	6.5	NA	no	no	lscs (NPOL)	no	7	Severe	7	9	no	no	no
104	20	03/01/2022	37	nil	100	110	70	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
105	26	03/01/2022	38	nil	88	120	80	nil	afebrile	NAD	NAD	T	4	15	yes	no	ftnd	no	7	Severe	6	7	no	no	yes oxygen hood
106	33	13/03/2022	37	nil	100	110	80	nil	afebrile	NAD	NAD	P	4.4	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
107	25	13/03/2022	39	nil	98	120	70	nil	afebrile	NAD	NAD	P	4	NA	no	no	lscs (non reactive NST)	no	6	Moderate	7	9	no	no	no
108	21	18/03/2022	39	nil	100	110	80	nil	afebrile	NAD	NAD	P	3	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
109	32	01/03/2022	37	nil	90	120	70	nil	afebrile	NAD	NAD	T	3	10	yes	no	ftnd	no	5	Moderate	7	8	no	no	yes (LBW)
110	23	01/03/2022	34	nil	100	120	70	nil	afebrile	NAD	NAD	T	6.5	15	yes	no	ftnd	no	7	Severe	7	8	no	no	no

111	24	02/03/2022	39	nil	98	110	80	nil	afebrile	NAD	NAD	P	4.5	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
112	29	02/03/2022	39	nil	88	120	80	nil	afebrile	NAD	NAD	P	3	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
113	27	03/03/2022	37	nil	86	110	80	nil	afebrile	NAD	NAD	P	4.5	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
114	24	04/03/2022	39	nil	90	120	80	nil	afebrile	NAD	NAD	T	3	15	yes	no	ftnd	no	7	Severe	7	9	no	no	yes oxygen hood
115	20	04/03/2022	37	nil	98	110	80	nil	afebrile	NAD	NAD	T	4.5	20	yes	no	ftnd	no	7	Severe	8	9	no	no	no
116	21	04/03/2022	38	nil	88	120	80	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	7	Severe	7	9	no	no	yes oxygen hood
117	27	05/03/2022	37	nil	90	110	80	nil	afebrile	NAD	NAD	T	4	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
118	28	05/03/2022	38	nil	88	110	90	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
119	23	06/03/2022	39	nil	90	120	70	nil	afebrile	NAD	NAD	P	5.5	20	yes	no	vaccum assisted delivery	no	7	Severe	7	8	no	no	yes HFNC
120	22	06/03/2022	37	nil	88	120	70	nil	afebrile	NAD	NAD	P	5.5	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
121	22	06/03/2022	38	nil	90	130	70	nil	afebrile	NAD	NAD	T	6.5	20	yes	no	ftnd	no	7	Severe	7	9	no	no	no
122	22	06/03/2022	39	nil	80	110	90	nil	afebrile	NAD	NAD	T	7	15	YES	no	ftnd	no	7	Severe	7	9	no	no	yes (LBW)
123	25	06/03/2022	39	nil	88	130	80	nil	afebrile	NAD	NAD	P	2	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
124	24	06/03/2022	38	nil	90	120	80	nil	afebrile	NAD	NAD	T	4	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
125	18	07/03/2022	39	nil	88	120	70	nil	afebrile	NAD	NAD	P	1	15	yes	no	ftnd	no	3	Mild	7	9	no	no	no
126	27	07/03/2022	38	nil	92	130	80	nil	afebrile	NAD	NAD	T	4	15	yes	no	ftnd	no	7	Severe	7	9	no	no	no
127	26	07/03/2022	37	nil	84	120	80	nil	afebrile	NAD	NAD	T	2.5	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
128	20	08/03/2022	39	nil	90	110	80	nil	afebrile	NAD	NAD	T	4.5	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
129	23	09/03/2022	38	nil	88	120	70	nil	afebrile	NAD	NAD	P	5	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
130	18	09/03/2022	37	nil	94	130	80	nil	afebrile	NAD	NAD	P	1.5	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
131	22	09/03/2022	38	nil	86	120	80	nil	afebrile	NAD	NAD	P	6	NA	no	no	lscs (NPOL)	no	5	Moderate	7	9	no	no	yes oxygen hood
132	25	10/03/2022	40	nil	90	110	80	nil	afebrile	NAD	NAD	T	6	15	yes	no	ftnd	no	7	Severe	7	9	no	no	yes oxygen hood
133	25	10/03/2022	40	nil	92	100	70	nil	afebrile	NAD	NAD	P	4	10	yes	no	ftnd	no	5	Moderate	8	9	no	no	no
134	20	11/03/2022	38	nil	90	110	80	nil	afebrile	NAD	NAD	P	5	15	yes	no	ftnd	no	4	Moderate	7	8	no	no	no
135	21	12/03/2022	40	nil	94	100	70	nil	afebrile	NAD	NAD	T	4	20	yes	no	ftnd	no	6	Moderate	6	7	no	no	yes oxygen hood
136	23	12/03/2022	40	nil	96	130	70	nil	afebrile	NAD	NAD	P	5	NA	NO	NO	lscs (maternal	no	6	Moderate	7	9	no	no	no
137	21	11/03/2022	39	nil	100	110	80	nil	afebrile	NAD	NAD	P	6	NA	NO	no	lscs (fetal	no	5	Moderate	7	8	no	no	yes oxygen hood
138	23	11/03/2022	40	nil	98	120	70	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
139	25	12/03/2022	40	nil	104	130	70	nil	afebrile	NAD	NAD	P	3	15	yes	no	ftnd	no	4	Moderate	7	8	no	no	no
140	25	12/03/2022	40	nil	98	120	70	nil	afebrile	NAD	NAD	P	3	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
141	25	12/03/2022	40	nil	100	120	80	nil	afebrile	NAD	NAD	P	3.5	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
142	23	12/03/2022	40	nil	98	110	80	nil	afebrile	NAD	NAD	P	4.5	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
143	23	13/03/2022	40	nil	98	120	70	nil	afebrile	NAD	NAD	P	4	20	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
144	25	13/03/2022	38	nil	100	130	70	nil	afebrile	NAD	NAD	P	4.5	20	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
145	25	14/03/2022	39	nil	94	120	80	nil	afebrile	NAD	NAD	T	6.5	20	yes	no	ftnd	no	8	Severe	7	9	no	no	yes oxygen hood
146	20	14/03/2022	37	nil	88	110	70	nil	afebrile	NAD	NAD	T	6	15	yes	no	ftnd	no	7	Severe	6	7	no	no	yes oxygen hood
147	23	14/03/2022	40	nil	100	110	90	nil	afebrile	NAD	NAD	T	5.5	20	yes	no	ftnd	no	6	Moderate	7	9	no	no	no

148	22	14/03/2022	40	nil	98	120	70	nil	afebrile	NAD	NAD	T	7	15	yes	no	ftnd	no	8	Severe	7	9	no	no	no
149	25	15/03/2022	42	nil	96	130	70	nil	afebrile	NAD	NAD	P	4	20	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
150	19	15/03/2022	40	nil	88	130	80	nil	afebrile	NAD	NAD	T	6.5	15	yes	no	ftnd	no	8	Severe	7	9	no	no	yes oxygen hood
151	20	15/03/2022	40	nil	90	120	80	nil	afebrile	NAD	NAD	P	5.5	20	yes	no	ftnd	no	6	Moderate	8	9	no	no	no
152	20	15/03/2022	39	nil	88	100	70	nil	afebrile	NAD	NAD	T	7	15	yes	no	ftnd	no	8	Severe	7	9	no	no	no
153	28	16/03/2022	40	nil	94	120	70	nil	afebrile	NAD	NAD	P	5.5	15	yes	no	ftnd	no	6	Moderate	7	9	no	no	no
154	29	17/03/2022	39	nil	90	110	90	nil	afebrile	NAD	NAD	T	6	20	yes	no	ftnd	yes thin meconium	8	Severe	7	8	no	no	yes oxygen hood
155	20	17/03/2022	40	nil	88	130	70	nil	afebrile	NAD	NAD	P	3.5	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
156	23	17/03/2022	40	nil	94	120	80	nil	afebrile	NAD	NAD	T	5.5	20	yes	no	ftnd	no	8	Severe	7	9	no	no	no
157	24	18/03/2022	39	nil	96	120	70	nil	afebrile	NAD	NAD	P	4.5	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
158	21	18/03/2022	39	nil	98	130	70	nil	afebrile	NAD	NAD	P	3.5	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
159	23	18/03/2022	36	nil	100	120	70	nil	afebrile	NAD	NAD	T	6	15	yes	no	ftnd	no	8	Severe	6	8	no	no	yes nasal prongs
160	21	18/03/2022	40	nil	96	130	70	nil	afebrile	NAD	NAD	T	7	10	yes	no	ftnd	yes thin meconium	7	Severe	7	8	no	no	yes oxygen hood
161	27	19/03/2022	39	nil	90	120	80	nil	afebrile	NAD	NAD	P	5.5	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
162	26	19/03/2022	38	nil	88	110	80	nil	afebrile	NAD	NAD	P	3.5	10	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
163	21	19/03/2022	38	nil	90	120	70	nil	afebrile	NAD	NAD	P	5	15	YES	no	ftnd	no	4	Moderate	7	9	no	no	no
164	25	20/03/2022	39	nil	88	110	80	nil	afebrile	NAD	NAD	P	4.5	20	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
165	21	21/03/2022	40	nil	92	130	70	nil	afebrile	NAD	NAD	T	5.5	20	yes	no	ftnd	yes thin meconium	7	Severe	7	8	no	no	yes oxygen hood
166	19	23/03/2022	38	nil	96	120	70	nil	afebrile	NAD	NAD	P	4	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
167	24	23/03/2022	40	nil	90	130	80	nil	afebrile	NAD	NAD	P	5	15	yes	no	ftnd	no	6	Moderate	8	9	no	no	no
168	25	23/03/2022	37	nil	88	120	70	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	8	Severe	7	9	no	no	no
169	25	24/03/2022	40	nil	90	130	80	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
170	20	26/03/2022	40	nil	86	110	70	nil	afebrile	NAD	NAD	T	6	10	yes	no	ftnd	no	7	Severe	7	9	no	no	no
171	28	26/03/2022	37	nil	90	120	70	nil	afebrile	NAD	NAD	T	6.5	10	yes	no	ftnd	no	7	Severe	7	9	no	no	no
172	26	25/03/2022	37	nil	98	120	80	nil	afebrile	NAD	NAD	T	7	15	yes	no	ftnd	no	8	Severe	7	9	no	no	no
173	26	26/03/2022	37	nil	88	110	90	nil	afebrile	NAD	NAD	P	3.5	15	yes	no	ftnd	no	5	Moderate	7	8	no	no	no
174	25	27/03/2022	37	nil	90	130	70	nil	afebrile	NAD	NAD	T	7	20	yes	no	ftnd	no	8	Severe	7	8	no	no	yes oxygen hood
175	24	28/03/2022	38	nil	86	110	80	nil	afebrile	NAD	NAD	T	5.5	20	yes	no	ftnd	no	7	Severe	7	9	no	no	no
176	27	28/03/2022	39	nil	92	120	80	nil	afebrile	NAD	NAD	T	6.5	15	yes	no	ftnd	yes thin meconium	8	Severe	6	8	no	no	yes oxygen hood
177	27	28/03/2022	37	nil	88	120	70	nil	afebrile	NAD	NAD	P	4.5	10	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
178	24	29/03/2022	38	nil	90	130	70	nil	afebrile	NAD	NAD	T	5.5	20	yes	no	ftnd	no	8	Severe	7	9	no	no	no
179	23	29/03/2022	38	nil	88	110	70	nil	afebrile	NAD	NAD	T	4.5	15	yes	no	ftnd	no	7	Severe	7	9	no	no	no
180	25	29/03/2022	39	nil	86	120	70	nil	afebrile	NAD	NAD	T	6.5	20	yes	no	ftnd	no	8	Severe	7	8	no	no	no
181	27	29/03/2022	37	nil	90	110	80	nil	afebrile	NAD	NAD	P	6	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
182	27	30/03/2022	37	nil	92	120	70	nil	afebrile	NAD	NAD	T	4.5	20	yes	no	ftnd	no	8	Severe	7	9	no	no	no
183	26	30/03/2022	37	nil	90	120	80	nil	afebrile	NAD	NAD	T	5.5	15	yes	no	ftnd	no	7	Severe	7	9	no	no	no
184	28	31/03/2022	40	nil	88	110	80	nil	afebrile	NAD	NAD	T	6.5	20	yes	no	fntd	no	7	Severe	7	9	no	no	no

185	20	31/03/2022	41	nil	90	130	70	nil	afebrile	NAD	NAD	T	6.5	15	no	no	lscs (fetal distress)	yes thick meconium	8	Severe	6	8	no	no	yes oxygen hood
186	21	31/03/2022	38	nil	92	120	80	nil	afebrile	NAD	NAD	P	5	NA	no	no	lscs (maternal	no	6	Moderate	7	9	no	no	no
187	21	01/04/2022	39	nil	90	120	80	nil	afebrile	NAD	NAD	P	5	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
188	23	03/04/2022	39	nil	86	130	70	nil	afebrile	NAD	NAD	T	8	NA	no	no	lscs (NPOL)	no	8	Severe	7	9	no	no	no
189	22	03/04/2022	40	nil	96	110	70	nil	afebrile	NAD	NAD	T	6	15	yes	no	ftnd	no	8	Severe	7	9	no	no	no
190	25	04/04/2022	37	nil	90	130	80	nil	afebrile	NAD	NAD	P	5	15	yes	no	ftnd	no	5	Moderate	6	8	no	no	yes oxygen hood
191	20	03/04/2022	38	nil	86	120	70	nil	afebrile	NAD	NAD	P	5	20	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
192	20	03/04/2022	38	nil	90	110	70	nil	afebrile	NAD	NAD	P	4.5	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
193	28	06/04/2022	38	nil	92	110	80	nil	afebrile	NAD	NAD	T	6	10	yes	no	ftnd	no	7	Severe	7	9	no	no	yes oxygen hood
194	21	11/04/2022	39	nil	90	130	80	nil	afebrile	NAD	NAD	P	5	20	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
195	19	11/04/2022	39	nil	88	130	70	nil	afebrile	NAD	NAD	T	7	15	yes	no	ftnd	no	8	Severe	7	9	no	no	no
196	19	11/04/2022	40	nil	90	110	70	nil	afebrile	NAD	NAD	P	4.5	10	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
197	27	13/04/2022	39	nil	86	110	90	nil	afebrile	NAD	NAD	T	7	NA	no	no	lscs (fetal	no	8	Severe	6	8	no	no	yes oxygen hood
198	23	13/04/2022	39	nil	90	120	70	nil	afebrile	NAD	NAD	P	4.5	10	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
199	22	14/04/2022	39	nil	92	130	70	nil	afebrile	NAD	NAD	T	4.5	15	yes	no	ftnd	no	7	Severe	8	9	no	no	no
200	24	14/04/2022	38	nil	88	120	70	nil	afebrile	NAD	NAD	T	5	10	yes	no	ftnd	no	8	Severe	7	9	no	no	yes oxygen hood
201	21	14/04/2022	38	nil	90	110	80	nil	afebrile	NAD	NAD	T	6	NA	no	no	lscs (non reactive NST)	no	8	Severe	7	8	no	no	yes oxygen hood
202	26	14/04/2022	37	nil	90	120	80	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	7	Severe	7	8	no	no	no
203	21	16/04/2022	37	nil	100	110	80	nil	afebrile	NAD	NAD	P	4.5	10	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
204	20	22/04/2022	40	nil	98	120	80	nil	afebrile	NAD	NAD	T	7	20	yes	no	ftnd	no	7	Severe	7	9	no	no	no
205	20	23/04/2022	38	nil	90	110	80	nil	afebrile	NAD	NAD	P	5.5	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
206	30	11/04/2022	39	nil	92	120	70	nil	afebrile	NAD	NAD	T	6.5	15	yes	no	ftnd	no	7	Severe	7	8	no	no	no
207	19	26/04/2022	40	nil	88	120	80	nil	afebrile	NAD	NAD	T	7	10	yes	no	ftnd	no	7	Severe	7	9	no	no	no
208	22	26/04/2022	40	nil	86	130	70	nil	afebrile	NAD	NAD	T	7	15	yes	no	ftnd	no	8	Severe	7	8	no	no	no
209	23	26/04/2022	40	nil	90	130	80	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	7	Severe	7	9	no	no	no
210	21	27/04/2022	40	nil	92	120	80	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	7	Severe	7	8	no	no	yes oxygen hood
211	26	26/04/2022	40	nil	90	110	70	nil	afebrile	NAD	NAD	P	5	10	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
212	21	28/04/2022	40	nil	88	100	70	nil	afebrile	NAD	NAD	T	6.5	15	yes	no	ftnd	no	7	Severe	7	8	no	no	no
213	18	28/04/2022	37	nil	90	110	70	nil	afebrile	NAD	NAD	T	5	15	yes	no	ftnd	no	8	Severe	7	8	no	no	no
214	22	28/04/2022	39	nil	88	110	90	nil	afebrile	NAD	NAD	P	5.5	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no
215	22	29/04/2022	40	nil	90	120	80	nil	afebrile	NAD	NAD	P	5	20	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
216	28	30/04/2022	38	nil	88	110	90	nil	afebrile	NAD	NAD	P	5	15	yes	no	ftnd	no	5	Moderate	7	8	no	no	no
217	26	30/04/2022	38	nil	90	120	70	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	4	Moderate	7	9	no	no	no
218	20	23/04/2022	39	nil	90	110	80	nil	afebrile	NAD	NAD	P	4	15	yes	no	ftnd	no	4	Moderate	7	8	no	no	no
219	27	24/04/2022	40	nil	88	120	80	nil	afebrile	NAD	NAD	T	6.5	15	yes	no	ftnd	no	7	Severe	7	9	no	no	no
220	28	23/04/2022	38	nil	90	110	70	nil	afebrile	NAD	NAD	P	5	15	yes	no	ftnd	no	5	Moderate	7	9	no	no	no