

**A PROSPECTIVE STUDY ON INJECTION TRAMADOL
HYDROCHLORIDE AS A LABOUR ANALGESIC AND
ITS EFFECT ON DURATION OF LABOUR**

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in partial fulfillment of requirements for*

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CERTIFICATE

This is to certify that the dissertation entitled “**A PROSPECTIVE STUDY ON INJECTION TRAMADOL HYDROCHLORIDE AS A LABOUR ANALGESIC AND ITS EFFECT ON DURATION OF LABOUR**” is a bonafide work done by **DR.V.S. VAISHNAVI** in the Institute of Obstetrics and Gynaecology (Madras Medical College) Egmore, Chennai in partial fulfillment of the university rules and regulations for award of MS degree in Obstetrics and Gynaecology under my guidance and supervision during the academic year 2011-2013.

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DECLARATION

I hereby declare that the study titled “**A PROSPECTIVE STUDY ON INJECTION TRAMADOL HYDROCHLORIDE AS A LABOUR ANALGESIC AND ITS EFFECT ON DURATION OF LABOUR**” was done by me in the Institute of Obstetrics and Gynaecology (IOG), Madras Medical College, Chennai – 600 003, during the period of my PG study for M.S Obstetrics and Gynaecology from 2011-2013, under the guidance and supervision of, **Prof.Dr. P.MEENALOCHANI M.D., DGO.**

This dissertation is submitted to the TamilNadu **Dr. M.G.R. Medical University**, Chennai in partial fulfillment of University regulations for the award of M.S. Degree Examination in Obstetrics and Gynaecology.

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INTRODUCTION

“The Delivery of the infant into the arms of a conscious and pain free mother is one of the most exciting and rewarding moments in medicine” - Moir ¹

Pain is the single most sentinel for the beginning of labor. The pain of labour is unique in that it is a normal physiological process. Labour may be the most painful experience many women may encounter.

Pain relief in labour has always been surrounded with myths and controversies. Hence providing effective and safe analgesia during labour has remained as an on going challenge.

“For all happiness mankind can gain is not in pleasure but in rest from pain” – John Dryden.

Read (1944) has emphasised that the intensity of pain during labour is related in large measure to emotional tension.

Pain and agony during childbirth is acute often unbearable and at times beyond description. In painful labour there is 25% reduction in the uteroplacental blood flow. Effective analgesia prevents the pain induced

hyperventilation and hypocapnia which can be severe enough to produce tetany in painful labour.

Adequate analgesia during labour is of benefit to the mother and has a positive influence on the course of labor and the state of newborn child, thus making obstetrical analgesia an essential part of modern obstetrics.

The American college of Obstetricians and Gynaecologists (2002) has stated that a “woman’s request for labor pain relief is sufficient medical indication for its provision”.²

Adequate analgesia during labor is beneficial to the mother and has a positive influence on the course of labor and the newborn child. The experience of labourpain is modified by emotional, motivational cognitive, cultural and social circumstances. Choice among a variety of methods and individualization of pain relief is describable.

An ideal analgesic should be easy to administer, should not affect the consciousness level of the parturient, provide reversible, predictable and good analgesia. It should allow the parturient to ambulate at least during early stages of labour and not interfere with uterine contractions.

It should not be toxic to mother and fetus and not produce cardiorespiratory depression in the foetus.³

Tramadol is a weak opioid agent, which has an analogous analgesic efficacy to meperidine (pethidine). It causes less neonatal respiratory depression and less sedative effect.

In the present study, the efficacy of intramuscular tramadol hydrochloride as a labour analgesic and its effect on the duration of labour and its effect on the mother and newborn were studied.

AIM OF THE STUDY

1. To study the effect of intramuscular tramadol hydrochloride for pain relief in labour in primigravid patients.
2. To study the effect of the drug on duration of labour.
3. To study effect of the drug on the mother and newborn.

REVIEW OF LITERATURE

“The experience of labour pain is a highly individual reflection of variable stimuli that are uniquely received and interpreted by each woman” – Lowe (2002)²

Melzack determined that about 60-80% of parturients rated their labour pain as severe in nature while about 23% of primipara and 11% of multipare rated their pain as horrible.⁵

Babyloneans were the first to use various methods for pain control in labour. Opioids were used 5500 years ago. Early days, in the mythology of china, Egypt, Greece and troy, concoctions, decoctions, herb extracts or wines were used, for relief of labour pain. Physical methods like jumping over mother’s abdomen to hasten delivery were used. Psychological methods using hymns, rings, talisman and hypnosis were tried.

Alcohol was kept beside maternity bed for self administration according to the persons. Morphine was used which though was useful in labour pain relief caused foetal distress.

January 19, 1847, James young Simpson, a Scottish obstetrician used ether for a woman with deformed rickety pelvis during childbirth. Charles D Meigs, a Philadelphian obstetrician criticised this and hypothesized the concept of ‘no drug labour’. Simpson proposed that “medical men may oppose for a time the super induction of anaesthesia in parturition, but they will oppose it in vain, for certainly our patients themselves will force use of it upon the profession”.⁶

John Snow in 1853, administered chloroform to the Britain Queen Victoria for the birth of her eighth child, Prince Leopold. This method ‘Narcose a la reine’ received warm approval from the queen.

Emil fischer and Vommering introduced Barbiturate in 1908. Phenobarbitone was used in 1912. Pethidine was used since 1940. It was used by 68.9% of laboring women by 1970, but has been superseded by other agents now. Clark in 1971, first used the opioid antagonist, naloxone.

Regarding regional techniques, the first pudendal block was given by Dr. Mueller. First paracervical block was given by Gelut in 1926. In 1927, Dellapiane used the first lumbar sympathetic block. In 1935, the

first epidural block was performed by Graffignino. First continuous epidural analgesia was given by Flower et al in 1946.

NORMAL LABOUR

It is the spontaneous onset of regular painful uterine contractions associated with effacement and dilatation of the cervix and descent of the presenting part, with or without a show or ruptured membranes. This process culminates in the birth of a healthy baby followed by expulsion of the placenta and membranes.

PAIN IN PARTURITION

Pain is a word for which it is difficult to find a satisfactory definition. Beecher has proposed that pain can be divided into two components. The first part is the original pain sensation (i.e; the sensory aspect). The second part is the behavior response to pain (i.e; the motor aspect). Pain threshold is the level at which discomfort reaches sufficient intensity to be interpreted by the subject as a painful sensation. This sensory appreciation of pain can be slightly altered by various factors such as fatigue and distraction. The pain threshold varies in the same person from time to time and differs in different individuals. Sensory

pain also has the quantitative property of intensity or amount and severity. The amount of pain experienced in labour has never been proved to be related to the general pain threshold of the individual.

The motor component or reaction to pain by the patient can be modified by many influences. Personality and cultural background and drugs are examples of these factors. There is no correlation between the amount of pain that a patient experiences and her reaction to it.⁷

Melzack using the multidimensional McGill pain questionnaire found that the total pain rating index (PRI) was 34% for primi and 30% for multiparas.⁵

MECHANISM OF THE PAIN OF LABOUR

First Stage of Labour:

Pain in the first stage of labour arises from the uterus and adnexae during contraction and is visceral in nature. Pain is largely due to the formation of lower uterine segment (LUS) and cervical dilatation with subsequent mechanical distention, stretching and tearing during contraction. Chemical nociception mediators contribute to pain including bradykinin, substance P, leukotrienes, lactic acid, prostaglandin, 5 hydroxy tryptamine.

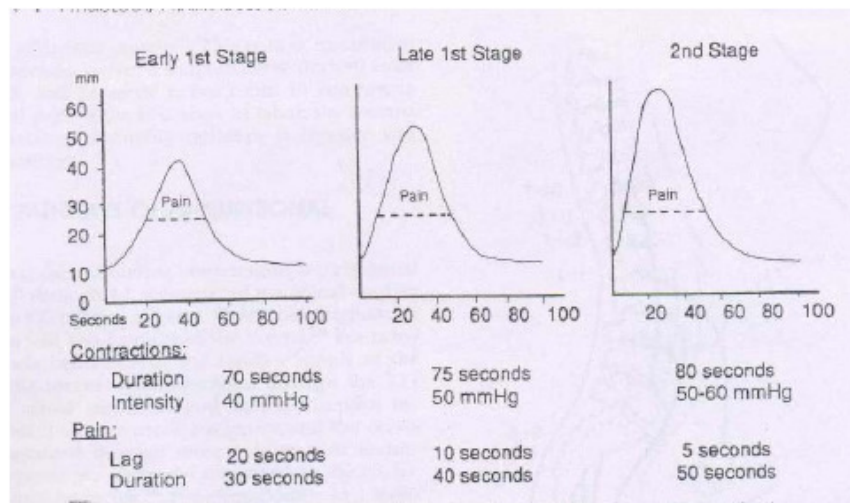


Figure-1: Relation between duration of uterine contraction and duration of pain associated with the contraction. Intensity of contraction must reach 25 mm Hg before pain is perceived and there is a lag of 20 seconds during the early phase of the first stage of labour when the buildup of the contraction is slower. As labour progresses, the contraction reaches its peak more rapidly and the lag is shortened.⁹

Hypothesis of Uterine Nociception Origin:

Time of onset of uterine contractions is related to time of onset of pain (figure-1). The observed lag time between the two reflects the time needed for a contraction to generate an increase in amniotic fluid pressure

to 15 mm Hg above baseline. To initiate cervical dilatation typically, intrauterine pressure must exceed 25 mm Hg before pain is experienced.¹⁰ During early labour less than 45% of contraction time is associated with pain, whereas during late first stage 60% of contraction time is associated with pain. The unanesthetized uterus can be incised and gently palpated without discomfort to the patient undergoing cesarean delivery under abdominal field block, whereas forceful palpation and stretching of the cervix and lower uterine segment under the same conditions provide pain similar in quality and location to that occurring during labour. Though the postpartum uterine contractions are 2-3 times greater in magnitude the intensity is less.¹¹

Second Stage of Labour:

Afferent transmission from the vagina and pelvic outlet is via A δ and C fibres, but with the parasympathetic bundle in the pudendal nerves (S2,S3,S4). There is also a minor contribution from the ilioinguinal, genitofemoral and the perforating branch of the posterior cutaneous nerve of thigh. It is important to appreciate that pain-sensitive structures in the pelvis are also involved, that is, the adnexae, the pelvic parietal

peritoneum, bladder, urethra, rectum and roots of the lumbar plexus. Therefore, the second stage pain is somatic in nature and best relieved by a local anesthetic.

NEURAL PATHWAYS OF PARTURITIONAL PAIN

Head and Cleland concluded that nociceptive impulses from the body of the uterus are transmitted through T11 and T12 nerves and the pain from the LUS and the cervix is transmitted through the pelvic nerve to the S2,S3,S4 spinal segments.

Parturition pain has two components

- 1.Visceral components
- 2.Somatic components

VISCERAL COMPONENT

From the uterus, the visceral component reaches T10 through L 1 segments of the spinal cord. Bonica⁹ demonstrated conclusively that the lower uterine segment and upper part of the cervix are in fact supplied by afferents that supply the body of the uterus and accompany the sympathetic nerves and not by any of the sacral nerves. Parasympathetic

innervation of the uterus does not appear to have a role in uterocervical pain mediation.

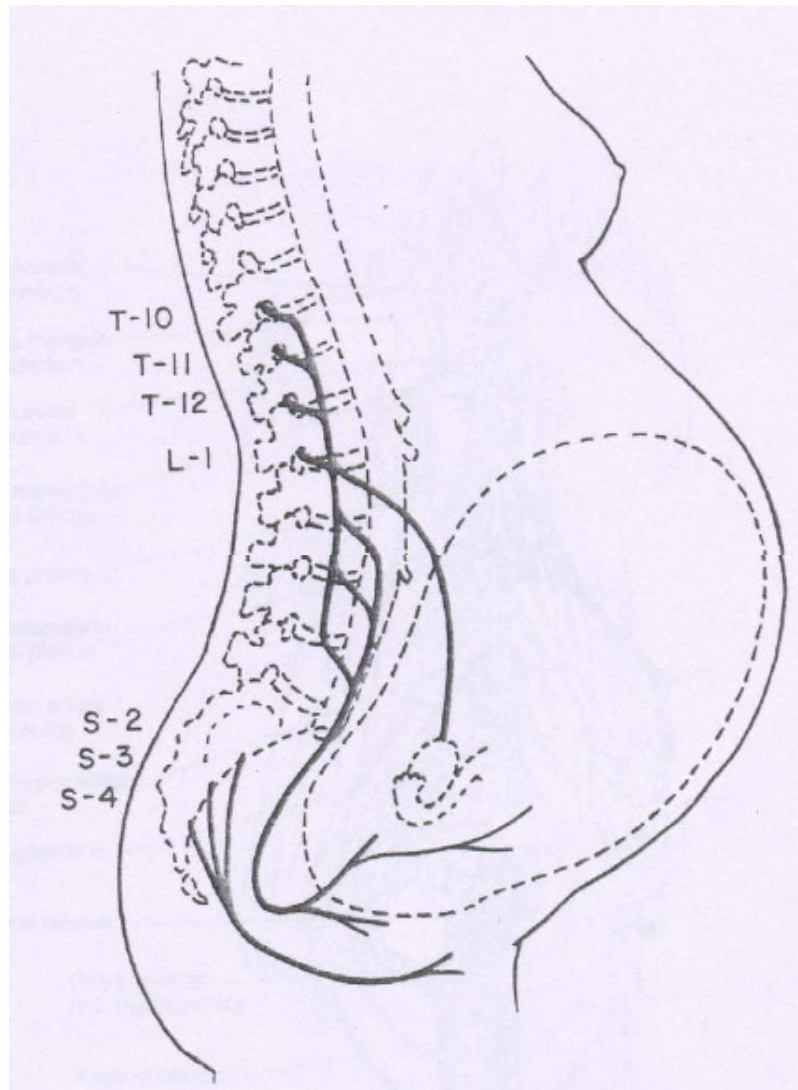


Figure-2: Schematic representation of the peripheral nociceptive pathways involved in the pain of childbirth

SOMATIC COMPONENT

Somatic pain is due to stretching of the perineum. Painful impulses are transmitted primarily through pudendal nerve, which is derived from anterior division of sacral nerves S 2 -S 4. In addition to innervating the vagina, vulva and the perineum, the pudendal nerve supplies motor fibers to various skeletal muscles of the pelvic floor and perineum. The ilioinguinal nerve and genital branch of the genitofemoral nerve provide peripheral innervation of the perineum anteriorly, the posterior cutaneous nerve supplies lateral innervation.

Following transmission of nociceptive information from the uterus, cervix and perineum to the dorsal horn, as with other acute pain states, this information is then relayed to other parts of the spinal cord. The multidimensional response to pain (sensory, affective and evaluative dimension) is determined at higher centers of the brain through spinothalamic and other ascending pathways and limbic system.

CAUSES OF PAIN DURING LABOUR

There are a variety of noxious stimuli that lead to the pain of labour. They give rise to subjective discomfort, as well as objective alterations in cardiorespiratory function and autonomic nervous system.

- Myometrial hypoxia : Contraction of a muscle during a period of hypoxia causes pain. When uterine relaxation between contractions is insufficient to allow adequate oxygenation, the severity of the pain is increased.
- Stretching of the cervix: The pain is mainly felt in the back.
- Pressure on the nerve ganglia adjacent to the cervix and vagina.
- Traction on the tubes, ovaries and peritoneum.
- Traction on and stretching of the supporting ligaments.
- Pressure on the urethra, bladder and rectum.
- Distension of the muscles of the pelvic floor and perineum.¹²

EFFECTS OF LABOUR PAIN

Pain has deleterious effect on both mother and foetus¹³. The effects are mediated at three levels

- Cortical
- Suprasegmental
- Segmental

CORTICAL

It is mediated by impulses arriving in the somatosensory cortex through neospinothalamic tract. Its effect includes anxiety, fear, emotional, arousal, behavior changes like verbalization and motor activity. Anxiety itself can produce in-coordinate uterine contraction and total depression.

SUPRASEGMENTAL

It is mediated by the connections of the paleospinothalamic tract with the reticular formation. Its effects include hyperventilation and endocrine response increasing the ACTH, cortisol and aldosterone levels. This increases oxygen consumption. They reach a peak at or after delivery¹⁴. In a study in a group of unmedicated, unprepared

primiparas, ventilation increased from normal mean of 10 litres/minute between contractions to a mean 23-35 litres/minute during contraction, causing marked increase in tidal volume and minute ventilation.

SEGMENTAL

Local neuronal connection at the spinal dermatome is responsible for this effect. Its effect includes decreased gastric motility, delayed gastric emptying, ileus, nausea and vomiting.

Clinical Characteristics of Labour and Delivery Pain

The clinical characteristics of uterine contraction pain (i.e., first stage labour pain) are distinct from those associated with delivery pain (i.e., 2nd stage labour pain) suggesting use of distinct neural pathways.

Peripheral visceral afferents branch considerably, overlap at the dorsal roots and convey on the dorsal horn over a wide number of segments. Hence visceral pain is described clinically as being dull and vague. It is poorly localized. Referred pain during labour is explained partly by the convergence of visceral and somatic nociceptive afferents on the same dorsal horn neuron. Visceral pain of uterine contractions has a delayed

transmission . Aching, cramping, pain during the latent phase of labour is referred and limited to T 11, T 12 dermatomes(lower back). Pain becomes severe in active phase of first stage of labour (cervix dilated 3-4 cm) with increasing intensity of uterine contraction spreading to involve the T 10 and L 1 dermatomes. Low back pain is the result of nociceptive transmission in the T 10 -L 1 segments.

30% of women during the first stage of labour experience severe lumbar low back pain which is the result of referred pain via dorsal rami of nerve root T 10 -L 1, the lateral branches of which travel caudally before becoming superficial and supplying the skin over the lower back and posterior pelvic rim. Descent of the fetal presenting part during the late first stage and second stage of labour produces sharp, well localized somatic pain in the region innervated by the pudendal nerve. Pain is perceived most acutely in the lower part of the sacrum, the perineum, vagina, rectum and thighs (L 2 to S 1 spinal cord segments).¹⁶

Pressure on and traction of pain sensitive structures in the pelvic cavity including pressure on nerve roots of the lumbosacral plexus, stretching of ligaments, fascia, muscles, traction on pelvic parietal

peritoneum and uterine ligaments and tension of the bladder, urethra and rectum and it may be referred to the sacral segments and lower lumbar segments.

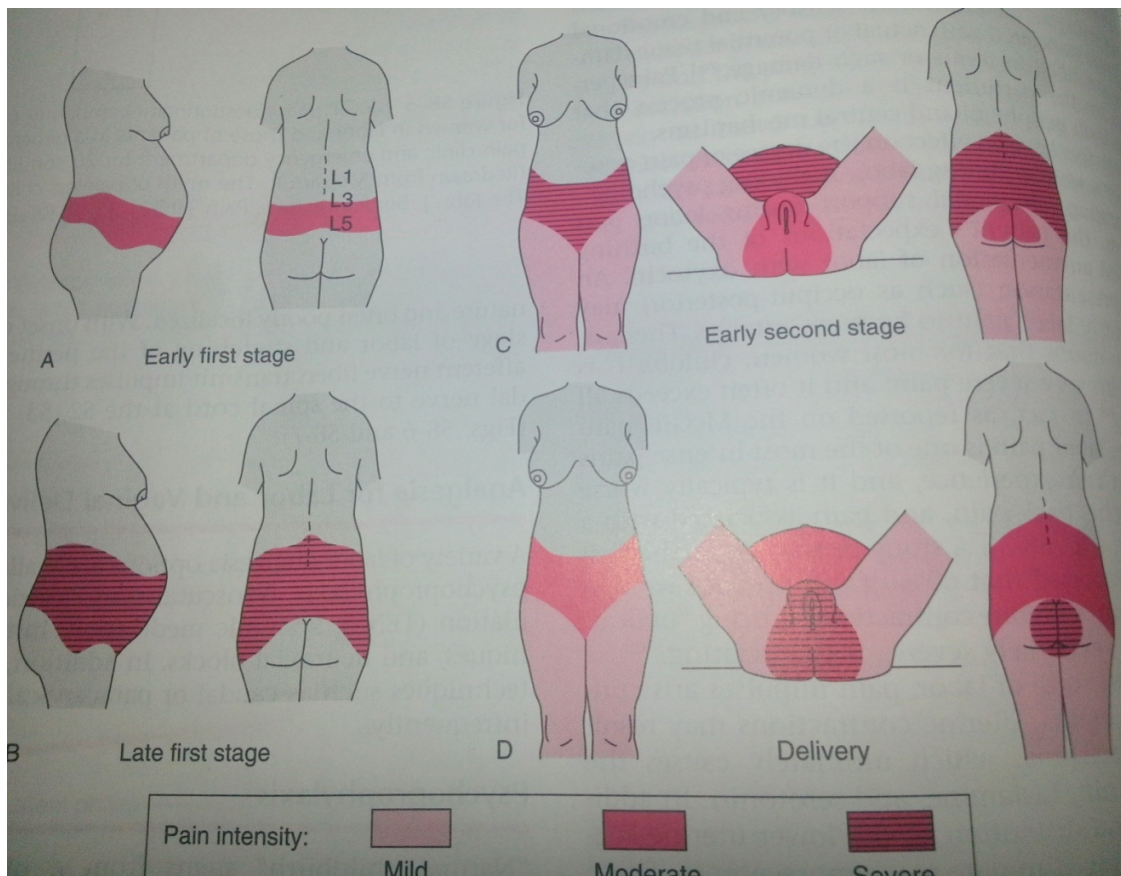


Figure:3: Distribution and intensity of labor pain during each stage of labor and delivery

A – In the early first stage, pain is referred to the T11 and T12 dermatomes.

B – In the late first stage, however, the severe pain is also referred to the T10 and L1 dermatomes.

C – In the early second stage, uterine contractions remain intense and produce severe pain in the T10 to L1 dermatomes. At the same time the presenting part exerts pressure on pelvic structures and thus causes moderate pain in the very low back and perineum and often produces mild pain in the thighs and legs.

D – Intensity and distribution of pain during the late phase of the second stage and during actual delivery. The perineal component is the primary cause of pain, whereas uterine contractions produce moderate pain¹⁵

Other factors that influence the pain of childbirth include physical, psychologic, emotional and motivational, ethnocultural and neurohumoral factors.

Physical Determinants: Factors identified as influencing the degree of labour pain experienced by the parturient include her age, parity and physical condition and size of the infant in relation to the size of the birth canal. Primiparae appear to suffer more pain than multiparous women. There appears to be a differential pattern of the progression of labour

pain, with nulliparae reporting more pain during early and active labour and less pain during second stage than multiparae. It follows that a short first stage of labour with rapidly dilating cervix should therefore involve more pain than a longer first stage.

Melzack and associates found that pain scores were increased in heavier women. The heavier the primipara was per unit of height, more was the pain score. Position during labour appears to influence the amount of pain experienced. Some evidence suggest that women feel less pain when their labour and delivery was in an upright position. The actual intensity of labour contractions is more important with the perception of pain than contraction duration.

Psychologic consideration

Psychologic factor include attitude towards labour, fear and anxiety, expectations of pain, prior experience of pain and knowledge of the process of pregnancy and parturition. A frequent cause of fear and anxiety is lack of knowledge of or misinformation about process of labour and delivery.

During the first stage of labour, fear of pain has a high correlation with pain levels. In second stage of labour concerns about pain shift to

concerns regarding the potential for self injury during birth and the neonate's well being.

Neurohormonal Factor

Neurohormonal changes in pregnancy may modify the responses to pain. Uterine distention and cervical stretching occurring in later stages of pregnancy and parturition result in stimulation of afferent fibres in the pelvic and hypogastric nerves activating pregnancy induced hypoalgesia via a spinal, probably κ opioid system.

Dawson Basoa and Gin Tzler indicate that δ opioid receptor activity is a prerequisite for the manifestation of a substantial portion of gestational and hormone simulated pregnancy analgesia whereas the potent spinal μ opioid analgesia system does not participate. Increased progesterone during pregnancy is thought to increase sensitivity to analgesic agents.

In addition to the classic opioid receptor ($\mu, \delta,$ and κ) cloning studies have revealed an atypical opioid receptor with 50% homology to μ, δ and κ opioid receptor termed ORL (opioid receptor like)- 1 and is found in CNS areas involved in pain perception.

PHYSICAL	PSYCHOLOGIC AND ETHNOCULTURAL	PROPOSED NEUROHUMORAL MECHANISMS
Age and parity	Attitude toward labor	Endogenous opioids
Physical condition	Fear and anxiety	Hormones
Size of infant/birth canal	Expectations of pain	Placental ± amniotic fluid substance
Abnormal fetal presentation	Prior experience of pain	Substance P
Stage of labor	Knowledge of childbirth	Nociceptin/ORL-1 receptor system
Speed and degree of cervical dilatation	Environment and support	Spinal cord noradrenergic-cholinergic system
Frequency of contractions	Confidence to cope with labor	
Maternal position in labor	Education and social class	
Menstrual history	Culture and beliefs	

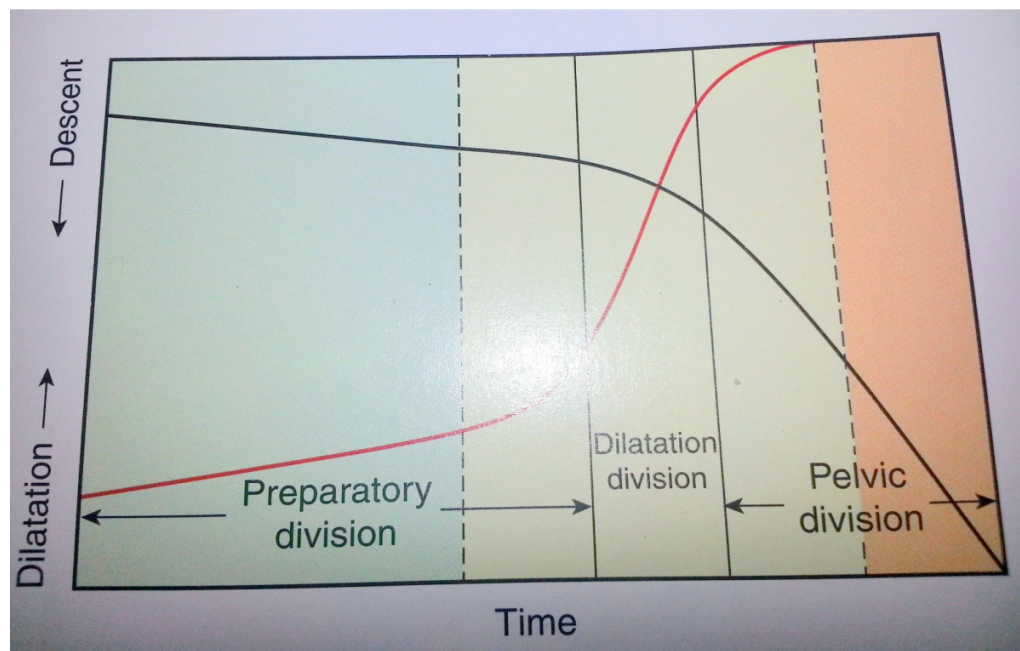
Table-2: Summary of some of the factors that may influence the pain of childbirth

STAGES OF LABOUR

First stage of labour

Friedman divided labour into 3 functional divisions.

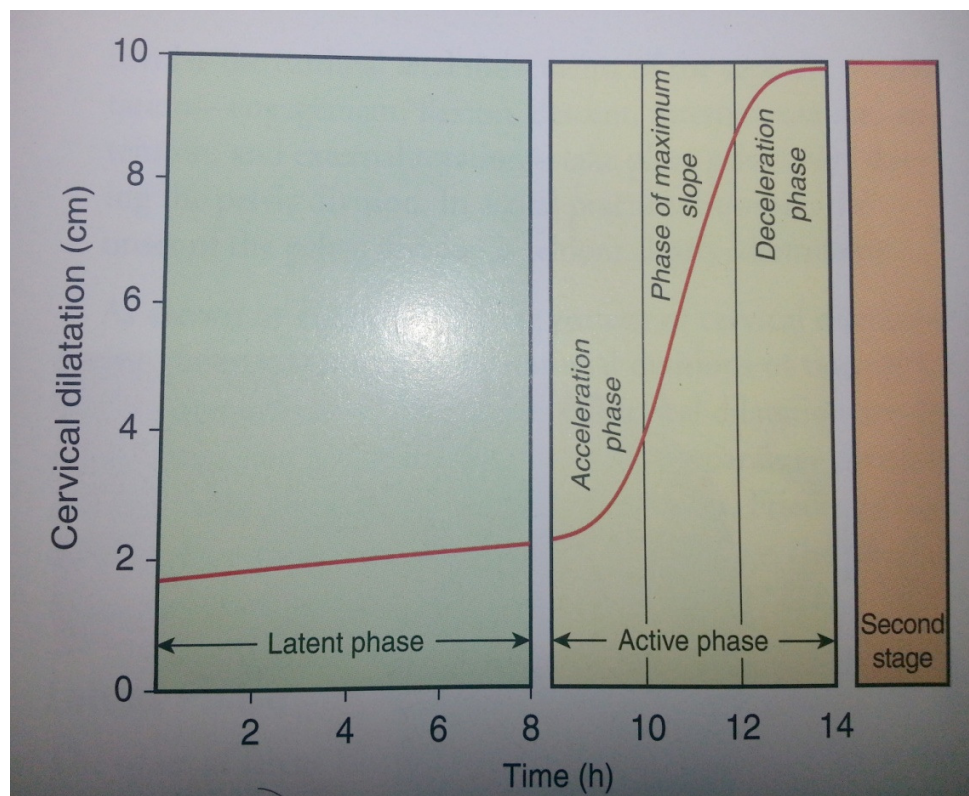
1. Preparatory Division – during which cervix dilates a little with considerable change in its connective tissue components. Sedation and conduction analgesia are capable of arresting this division of labour.
2. Dilatation division- during which dilatation is rapid and is unaffected by sedation or conduction analgesia.
3. Pelvic division.



Cervical Dilatation is divided into 2 phases.

1. The latent phase – Corresponds to the preparation division .
2. Active phase – Corresponds to the dilatational division.

Friedman sub divided this active labour in to acceleration phase, phase of maximum slope and deceleration phase.



The latent phase may last for upto eight hours in nulliparas and upto six hours in multiparas. During the peak of the active phase of labour, the rate of cervical dilatation is 1 cm per hour in

both nullipara and multipara. Descent is expected to occur at the rate of 1 cm/hour in primipara and 2 cm/hour in multipara.

Second Stage of labour

Begins when cervical dilatation is complete and end with fetal delivery. It is divided into two phases

Phase 1- passive phase (phase of descent, pelvic phase)

The passive phase is from full cervical dilatation until the fetal head reaches the pelvic floor. Major portion of fetal descent occurs in this phase and is highly variable.

Phase 2 – Active phase (expulsive phase, perineal phase)

It is marked by the maternal urge to bear down.

The median duration is variable. It is approximately 50 minutes in primipara and 20 minutes in multipara. The length of second stage varies and is influenced by position of the mother, fetus, uterine contraction, use of oxytocin, pushing efforts of the women and type of analgesia used.

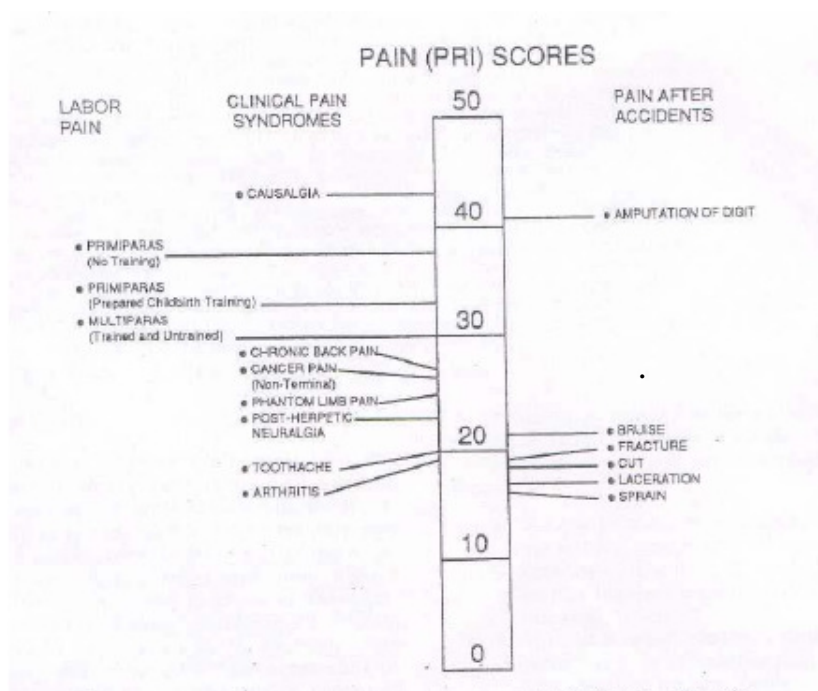
Duration of labour

The mean length of first & 2nd stage of labour was 9 hours in nulliparous women without regional analgesia and 6 hours in multiparas.

ACOG guidelines define “dystocia in nulliparous women as a second stage that lasts for more than three hours when regional anaesthesia is used and more than 2 hours when it is not. It is 2 hours and 1 hour for multiparae”.²

METHODS OF PAIN MEASUREMENT

Patients report of pain is recorded as pain score. The pain score used should be valid, reliable and geared to the patient. The instrument used to measure pain is dolorimeter.¹⁷



Pain rating index using Mc Gill pain questionnaire

McGill Pain Questionnaire

Patient's Name _____ Date _____ Time _____ am/pm

PRI: S _____ A _____ E _____ M _____ PRI(T) _____ PPI _____
 (1-10) (11-15) (16) (17-20) (1-20)

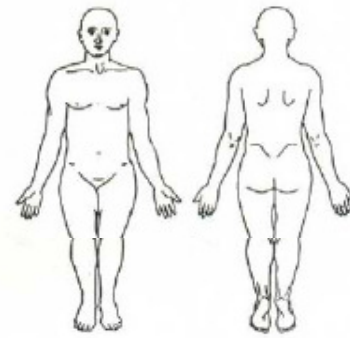
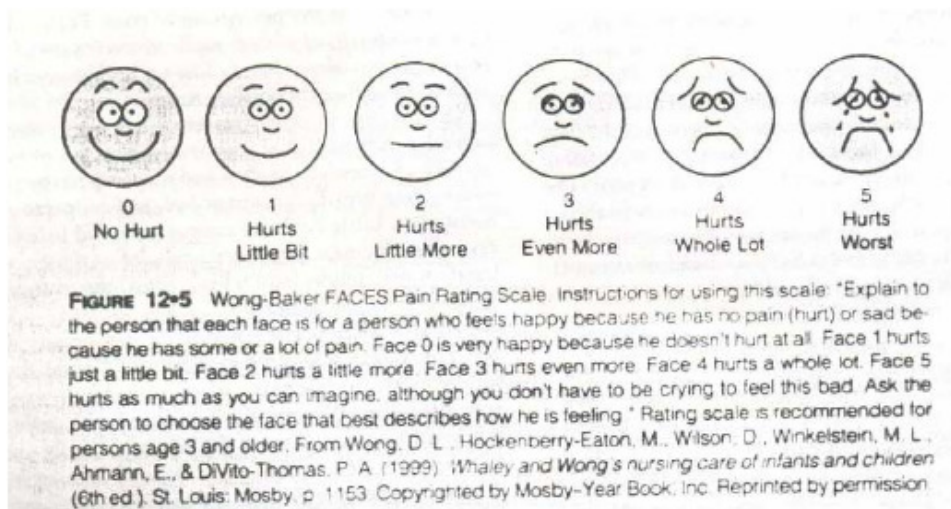
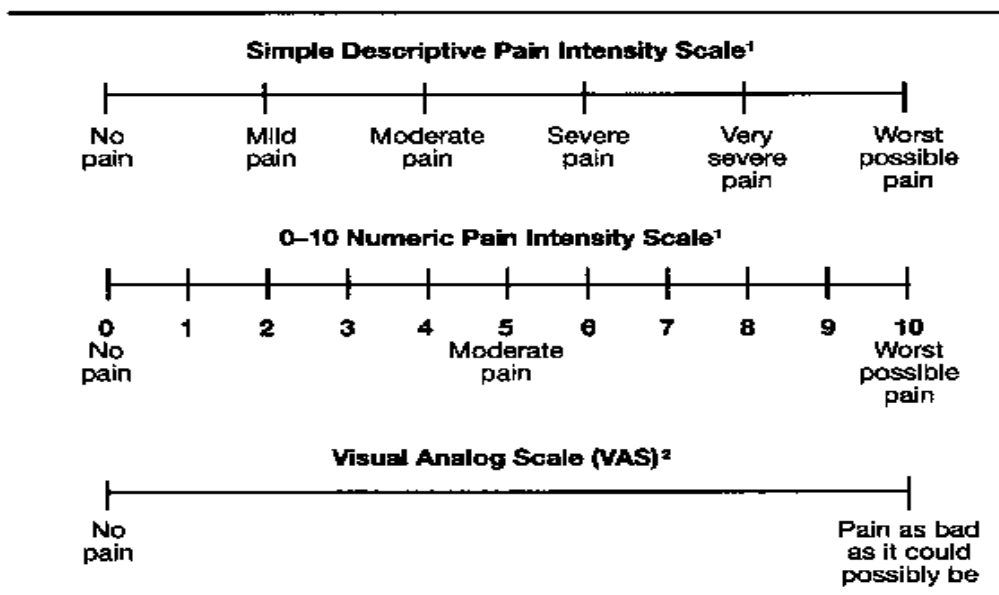
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FIG. 25-3. McGill Pain Questionnaire,²⁵ adapted for a study of narcotic drugs. Descriptors fall into four major groups: sensory, 1 to 10; affective, 11 to 15; evaluative, 16; and miscellaneous, 17 to 20. The rank value for each descriptor is based on its position in the word set. The sum of the rank values is the "pain rating index" (PRI). The "present pain intensity" (PPI) is based on a scale of 0 to 5.

WONG BAKER FACES PAIN RATING SCALE

Different facial expressions are used to describe the intensity of pain. It is specifically used in the paediatric age group.





¹If used as a graphic rating scale, a 10 cm baseline is recommended.

²A 10-cm baseline is recommended for VAS scales.

VISUAL ANALOGUE SCALE

Has a 10 cm line denoting pain intensity by adjectives or number. These are graphic rating scales. The patients indicate a point on the line depending on its intensity.¹⁸

METHODS OF LABOUR ANALGESIA

NON PHARMACOLOGICAL

1. Psychoprophylaxis – hypnosis, prepared child birth, breathing exercises.
2. Modifications of labour room environment – presence of relatives, soothing music, etc.
3. Physical modalities – acupuncture , massaging heating pads, warm bath, and intradermal injection of sterile water.
4. Transcutaneous electrical nerve stimulation (TENS)

PHARMACOLOGICAL

1. systemic opioids – Pethidine i.v / i.m
Tramadol i.m
Fentanyl i.v / i.m
Remifentanyl i.v/ i.m
Pentazocine

2. Inhalational agents – Entonox - 50% nitrous oxide in 50% oxygen

(PCIA)

Desflurane

Isoflurane

Sevoflurane

3. Regional analgesia - Paracervical block

Pudendal block

Subarachnoid block

Continuous lumbar epidural analgesia

Patient controlled epidural analgesia

Combined spinal epidural block

Lumbar sympathetic block¹⁹

SYSTEMIC ANALGESIA

Systemic drugs have been used to decrease the pain of childbirth.

systemic analgesic drugs is used especially in

1. Some conditions (e.g., hemorrhages, coagulopathy) that contraindicate the administration of epidural and spinal anesthesia.
2. Epidural anesthesia is not available in all hospitals especially smaller facilities.
3. Epidural anesthesia is not without risk, and some women decline this technique.
4. Alternatively, some women choose to receive a systemic analgesic during early labour and opt for epidural anesthesia as pain becomes more intense.

Parenteral Opioids

Opioids are the most widely used systemic medications for labour analgesia. Use of these drugs does not require the use of specialized equipment or personnel. These drugs allow the parturient to better tolerate the pain of labour but typically they do not provide complete analgesia. Although systemic opioids have long been used for labour

analgesia, there is little scientific basis to suggest that one drug is intrinsically better than another for this use. Most often the choice of opioid is based on institutional condition and or personal preference. The efficacy of analgesia and the incidence of side effects are largely dose dependent rather than drug dependent. Because of their lipid solubility and low molecular weight (<500 daltons), all opioids easily cross the placenta by diffusion and are associated with the risk of neonatal respiratory depression and neurobehavioral changes. Neonatal metabolism and elimination of drugs are prolonged. There may be subtle changes in the neuro behavior of the neonate, the clinical significance of which is unclear.

Modes of Administration:

Intermittent Bolus Doses:

Opioids may be given subcutaneously or intramuscularly. More often opioids are administered intravenously either intermittently or by continuous intravenous infusion. The route and timing of administration influence maternal uptake and placental transfer. Subcutaneous and intramuscular injections have the advantage of simplicity. Of course intramuscular injection is painful. Absorption varies with the site of

injection and injection is followed by a delay in the onset of analgesia. Subcutaneous or intramuscular injection results in analgesia of variable onset, quality and duration. Advantages of intravenous administration include (1) less variability in the peak plasma concentration of drug (2) faster onset of analgesia (3) the ability to titrate dose to effect.

Patient Controlled Analgesia (PCA)

PCA is a cost-effective technique that produces superior analgesia with very high patient satisfaction. Patients are able to self administer precise dose of drug. Purported advantages of PCA include

- Superior pain relief with lower doses of drugs.
- Less risk of maternal respiratory depression (compared with bolus intravenous administration).
- Less placental transfer of drug.
- Less need for anti-emetics.
- Higher patient satisfaction.

PCA for labour is not without limitation despite frequent administration, small doses of opioid may not always be effective for the fluctuating intensity of labor pain. Also the risk to the fetus and neonate remains unclear. PCA can be used if epidural analgesia is unavailable,

contradicted or unsuccessful. Although, PCA may result in higher patients administration, most studies have not demonstrated either reduced use of drug or improved analgesia with PCA when compared with IV administration by the obstetric nurse.

CLASSIFICATION OF OPIOID ANALGESICS

1. Natural opium alkaloid : Morphine, codeine.
2. Semi-synthetic opiates: Diacetyl morphine (Heroin), Pholcodeine.
3. Synthetic opioids : Pethidine (Meperidine), fentanyl, methadone, dextropropoxyphene, tramadol, ethoheptazine .²¹

OPIOID RECEPTORS:

Morphine and other opioids exert their action by interacting with specific receptors present on neurons in the central nervous system and in peripheral tissues. Radioligand binding studies have divided the opioid receptors into three types: μ, κ, δ each has a specific pharmacological profile and pattern of anatomical distribution in brain, spinal cord and peripheral tissues. Subtypes of μ and κ receptor have been identified.

Actions ascribed to different types of opioid receptor

μ (mu)	κ (kappa)	δ (delta)
Analgesia (supraspinal μ 1 + spinal μ 2)	Analgesia (spinal κ 1) (supraspinal κ 3)	Analgesia (spinal + affective component of supraspinal)
Respiratory depression (μ 2)	Respiratory depression (lower ceiling)	Respiratory depression
Euphoria	Miosis (lower ceiling)	Affective behaviour
Miosis	Dysphoria	Reinforcing actions
Reduced GI motility	Hallucinations	Reduced GI motility
Physical dependence (morphine type)	Physical dependence (Nalorphine type)	
Sedation	Sedation	

TRAMADOL HYDROCHLORIDE

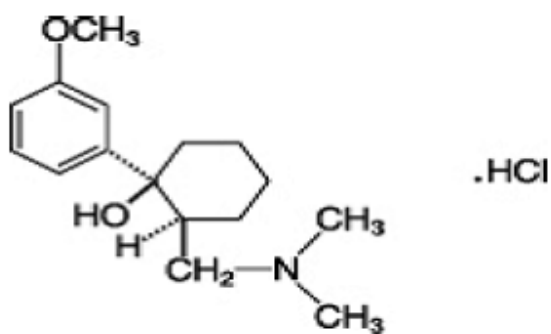
Tramadol hydrochloride is a narcotic drug introduced in 1971 in Germany and is now available throughout the world. Tramadol hydrochloride is a synthetic 4-phenyl-piperidine analogue of codeine with a dual mechanism of action.²⁰

Tramadol hydrochloride is a centrally acting synthetic codeine analogue that is a weak opioid receptor agonist. Its affinity for μ opioid receptor is modest while that for κ and δ is weak. Its affinity for the opioid receptor is only 1/6000 that of morphine. Unlike other opioids, it inhibits reuptake of nor-adrenaline and 5-hydroxytryptamine and thus activates monoaminergic spinal inhibition of pain. Its analgesic action is only partially reversed by opioid antagonist naloxone.

It is a racemic mixture of 2 enantiomers (+) tramadol and (-) tramadol and has chemical structure: (1R, 2R)-2-[(dimethylamino) methyl]-1-(3-methoxyphenyl) cyclohexanol hydrochloride.

Chemical structure

Molecular formula : C 16 H 25 NO 2 HCl



Characteristics:

- White to off white crystalline
- odourless
- Soluble in water and ethanol
- Characteristic unpleasant taste which is mildly bitter
- Molecular weight-299.84
- pH 6-6.8
- pKa value is 9.3 at 293 K

Available as capsules, drops, suppositories and injections. Solution for injection contains 50 mg/ml of tramadol hydrochloride in an adequate sodium acetate buffered solution without preservative.



Mechanism of Analgesia:

The antinociceptive action of tramadol hydrochloride is mediated by two components:

- 1. Opioid pathway:** Tramadol interacts with μ , κ and δ receptors where it exhibits purely agonist effects. It has moderate affinity for μ receptors and weak affinity for δ and κ receptors. The duration of antinociceptive is relatively long being comparable

to morphine and longer than that of codeine and dextropropoxyphene. The opioid component of analgesia is reversed by naloxone.

2. Non-opioid pathway: Tramadol hydrochloride inhibits the reuptake of nor-adrenaline and 5-hydroxy tryptamine (serotonin) and activates monoaminergic spinal inhibition of pain by elevating the pain threshold.

It is also 5 HT_{2C} receptor antagonist and Nicotinic ,M₁ and M₃ Muscarinic receptor antagonist,NMDA antagonist and GABA-A receptor inhibitor.

Pharmacokinetic properties

Absorption :

The bioavailability following oral administration of the drug is 68 to 100%.It is 100% available when administered intramuscularly²²

Distribution:

The drug is 20 % protein bound in the plasma. 80% of the administered dose crosses the placenta

Metabolism:

85% of the administered dose is metabolized by demethylation in liver via cytochrome P450 isozyme. The metabolite O-desmethyl tramadol is active and has 200 times μ affinity of that of tramadol. It binds to μ opioid receptor and exerts its effects on GABAergic transmission.

Excretion:

Excretion is 90% through the kidneys. Remaining is excreted in the faeces. The $T_{1/2}$ is 5 hours. The elimination half-life is 5-6 hours. The elimination half life is doubled in patients with hepatic or renal impairment. So it is not recommended in patients with end stage renal failure.

Therapeutic Efficiency:

Intramuscular tramadol 50-150 mg is found to be equal to 50-100mg IM pethidine and 100 mg Tramadol equal to 10 mg morphine.

Dose:

50 -150mg or 1-2 mg/kg 4-6 hourly.

A daily dose of 400 mg is sufficient.

Administration:

Oral ,intramuscular, intravenous ,per rectal or as a part of patient controlled analgesia.

Actions:

Respiratory System: Therapeutic doses of tramadol has no significant effect on respiratory rate, tidal volume, arterial carbon dioxide tension, ventilatory carbon dioxide response. A decrease in respiratory rate is due to effective analgesia rather than respiratory depression. Over dosage may cause respiratory depression.

Cardiovascular System: In therapeutic doses tramadol has no significant effect on the cardiovascular system except for transient reduction in pulmonary artery pressure. Hence, it is suitable for pain relief in cardiac patients e.g., acute myocardial infarction and in diagnostic cardiac catheterizations.

Central nervous system: It has an analgesic potency equivalent to pethidine.

Other Effects: Tramadol has minor direct action on smooth muscle, hence it is likely to cause cholestasis, urinary retention and constipation. It produces dose dependent mydriasis and antitussive effect. In contrast to morphine, it does not produce dependence, tolerance and addiction even after long-term use.

Indication: Tramadol can be used for treating moderate to severe acute pain and chronic pain resulting from cancer, surgical procedure, trauma, myocardial infarction, obstetric pain, painful diagnostic procedures.

Interaction with other Drugs: Tramadol should not be combined with MAO inhibitors (e.g., anti-depressants).

Contraindications: Contraindicated in cases of acute intoxication with alcohol, hypnotics, analgesics or CNS acting drugs. Seizures are particularly likely during tramadol intravenous injection in patients with epilepsy.

Side effects: Dry mouth, nausea, vomiting, fatigue, hot flushes, transient tachycardia, sweating, dizziness.

Overdose and Intoxication: Symptoms are restlessness, salivation, ataxia, cyanosis, prostration, mydriasis, dyspnoea, cramps, tremor, vomiting.

Opioid Antagonists: Naloxone (Nurcan) is the opioid antagonist of choice for reversing neonatal asphyxia due to opioid use during labour. Giving naloxone to the mother before delivery has not showed any benefit. This antagonizes maternal analgesia during labour or at delivery without causing a decrease in opioid related maternal side effects. When maternal administration of opioids is anticipated to result in neonatal respiratory depression, about 10µg/kg of naloxone is given in the cord. Other routes are subcutaneous, intramuscular and intravenous. Naloxone reverses opioid depression of newborn minute ventilation and increases the slope of carbon dioxide response curve in infants affected by maternal administration of an opioid. The recommended dose is 0.1 mg/Kg of a 1 mg/ml or 0.4 mg/ml solution.

REVIEW OF CLINICAL TRIALS WITH TRAMADOL AS LABOUR ANALGESIC

Maryam khooshideh and Ali shahriari in 2009, studied in hundred and sixty full-term parturients, the effect of Intramuscular tramadol 100mg versus 50 mg of intramuscular pethidine. Lower incidence of maternal side-effects and shorter duration of labour was seen in the tramadol group . Both the drugs provide moderate analgesia in first stage of labour but pethidine is more effective in the second stage.⁴

Rao ZA et al, in 2010 conducted a non randomized controlled trial to compare the duration of labour and mode of delivery between routine labour practice and walking epidural analgesia with 0.5% tramadol with 0.1% Bupivacaine .They showed that it markedly reduces the duration of labour.

Fieni S, Angeri F et al (2000) studied the efficacy and tolerability of parenteral tramadol and meperidine as labour analgesics and concluded that tramadol gives an analogous analgesic effect with better tolerability without maternal and neonatal complications.²³

Bitsch M et al (1980) compared parenteral tramadol used in 23 normal deliveries and pethidine. Both demonstrated identical analgesic effects. The tramadol group did not have any labour or neonatal complications. Thus, he recommended tramadol for obstetrical analgesia since it does not exert inhibitory effects on the respiration centre.²⁴

Hussein P et al, in 1987 compared tramadol 100 mg with pethidine 100 mg on 40 women asking for pain relief during labour. The pethidine group showed a slightly but not significantly shorter duration of labour. Tramadol had a similar analgesic effect but less side effects.²⁵

Lehman KA (1994) studied the use of tramadol in the management of labour pains, MI, trauma associated pain and found that it has good results for control of pain associated with labour²⁶.

In 1996, Radbrach L et al studied on management of pain with tramadol and found that it has good labour analgesic property but no neonatal respiratory depression.²⁷

In 1997 Sarkar B, Mukhopadhyay AK compared the effect of IM tramadol hydrochloride and pethidine in patients with dysfunctional labour and normal labour. The analgesic effect was comparable in both

groups. But the incidence of FD, CS, duration of labour was significantly less in the tramadol group .²⁸

Claahsen-Vander Grinten HL et al (2005) investigated the pharmacokinetic profile of neonates whose mothers were given tramadol hydrochloride. 22 mothers who requested for pain relief in labour were given IM tramadol hydrochloride (100-250 mg) At the time of birth, maternal venous and cord blood samples were drawn. Post partum samples at 1, 2, 3, 6 and 12 hours were taken from both the mother and baby. They concluded that IM tramadol given to mothers during labour almost freely reaches the neonates. The neonate has a reduced renal elimination of its active metabolite. In spite of this, tramadol is an effective labour analgesic. They observed that with tramadol, pain relief was 38.92% with minimal changes in cardiorespiratory parameters, 22.22% had nausea, 11.11% had drowsiness. They found no effect of tramadol on the Apgar score. They concluded that tramadol 1 mg/ Kg caused mild to moderate relief of labour pain .³⁰

Usha Rani Sharma, Verma RS (1997), compared tramadol to a no drug group. They concluded that tramadol was an effective analgesic

without any significant maternal or neonatal complications and that it can be safely administered during labour.²⁹

Parasertsawat et al in 1986, studied 135 parturients and compared the analgesic effects of tramadol, morphine and pethidine. They observed that analgesic effect in tramadol group was good in 24.5%, satisfactory in 53.3% and no response in 22.2%. They found the differences in response in all three groups were statistically insignificant. The side effects in all the three groups were minimal consisting of drowsiness, nausea, vomiting, palpitation. There was no respiratory depression in the neonates.³¹

In 2001 Singh S studied 60 women and compared 100 mg tramadol with 30 mg Pentazocine used as labour analgesics. They observed that pain relief with tramadol was 80% and pentazocine was 60%. The maternal and fetal complications were slightly more in the pentazocine group.³²

In 2004, Nagesh Kumar conducted a randomized, prospective study on 100 women in labour. 50 women received tramadol, 50 women were given distilled water. He concluded that IM tramadol can be used as safe

labour analgesic in any health centre even with least monitoring facilities unlike other opioids because of negligible side effects at therapeutic dose either on mother or fetus. There was also significant shortening of duration of labour in the tramadol group .³³

Elbourne D, Wiseman RA (2000) studied sixteen trials to assess the effect of intramuscular opioids as labouranalgesic. Interval to delivery, pain relief or instrumental or operative delivery did not differ between tramadol and pethidine.³⁴

Meena Jyothi, Singhal Prabha, Choudary Devika (2006) evaluated the various effects of programmed labour protocol in primi parae. They concluded that programmed labour provides effective labour analgesia, augments the process of labour and reduces third stage blood loss. It has no adverse effects on the foetus.³⁵

Nagaria tripti, Acharya Jyotsna in 2006 compared intramuscular tramadol hydrochloride and pentazocine as an analgesic during labour in 200 term parturients. They found that pain relief was satisfactory in 37% and moderate in 38% and mild in 16% in tramadol group, and satisfactory in 14%, moderate in 34% and mild in 42% of penatzocine

group. The total duration of labour and interval between injection and delivery, side effects were less in tramadol group.³⁶

Sudha patil et al (2012) studied the efficacy and safety of intramuscular tramadol hydrochloride 100mg as analgesia for labour in 100 primigravida. Good pain relief was noted in 58% of parturients, moderate pain relief in 30% and mild pain relief in 12%.³⁷

Viegus OA et al in 1993 compared in 90 labouring primiparae the analgesic efficacy and safety of intramuscular pethidine 75mg, tramadol 50mg, tramadol 100mg. Pain relief is similar with both 100mg tramadol and pethidine 75mg. Adverse effects and respiratory depression are common in the pethidine group. Thus tramadol has a superior safety profile than pethidine.³⁸

MATERIALS AND METHODS

Type of study: This is a prospective comparative interventional study.

Population under study: Primigravida with full term singleton pregnancy admitted in labour at Institute of Obstetrics & Gynaecology, Egmore from August 2011 to August 2012.

Methodology:

400 primigravid women with singleton term gestation admitted in labour were selected according to inclusion and exclusion criteria.

INCLUSION CRITERIA:

Primigravid women with

1. Singleton live foetus with satisfactory admission CTG.
2. Gestational age between 37 – 42 weeks.
3. Vertex presentation with no evidence of CPD.
4. In active phase of labour.

Criteria for active phase of labour: well effaced cervix, dilatation more than 4 cm, good uterine contractions i.e. 3 contractions in 30 minutes each lasting for atleast 35-40 seconds.

EXCLUSION CRITERIA:

1. History of hypersensitivity to the drug.
2. Women with associated medical conditions like heart disease, chronic hypertension, epilepsy, respiratory and renal diseases.
3. Associated obstetric complications like APH, GDM, hypertension in pregnancy, CPD, multiple gestation.

Informed consent was obtained from the patients and allocated in 2 groups, Group A and Group B.

GROUP A: Study group: 200 women in study were given 100mg Intramuscular injection Tramadol hydrochloride

GROUP B: Control group: 200 women in active labour who did not receive tramadol.

Study group A

In patients with 4 cm cervical dilatation and in established active phase of labour,

- vital signs were recorded
- pain score noted before drug administration.
- Severity of labour pains assessed by NPI scale .
- Intramuscular injection Tramadol 100mg given.

- Vital signs and pain score were recorded after drug administration.
- Partogram was maintained and progress of labour assessed.
- Injection syntocinon for augmentation of labour if contractions were inadequate.
- Another 100mg tramadol was given after 4 hours if the patient complained of increasing pain except in patients who had already reached the second stage.
- Routine neonatal care given.

Study group B

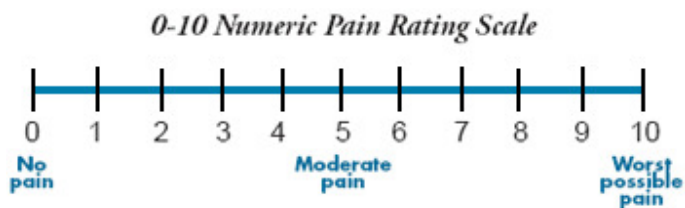
In patients in active phase of labour,

- Vital signs were recorded
- Pain score recorded.
- Partogram to assess the progress of labour.
- Labour augmented with syntocinon if required.

The pain score of the patients, onset of drug action, progress of labour, duration of labour, mode of delivery, APGAR scores of the new born, complications during the course of labour, associated side effects, change in vital parameters, fetal heart rate were noted in both the groups.

PAIN ASSESSMENT

The pain score was measured by numeric pain intensity scale.



0-1: NO PAIN

2-4:MILD PAIN

5-7:MODERATE PAIN

8-10:SEVERE PAIN

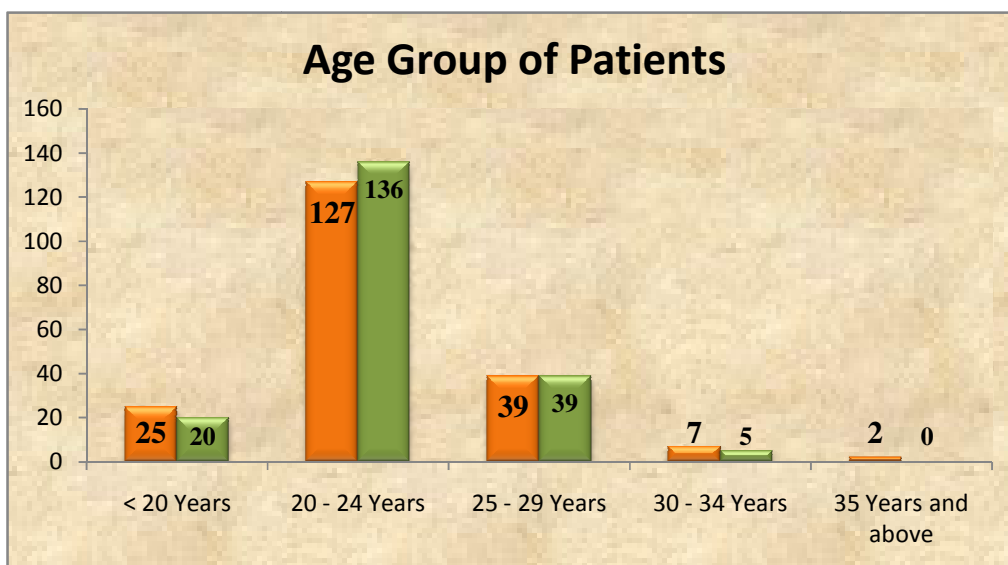
During labour, after administration of drug, if patients had pain score of 0-1(no pain), they were considered to have good pain relief. When patients had pain score between 2 and 4 (mild pain) they considered to have moderate pain relief. When pain score was from 5-7 and 8-10, patients were considered to have mild pain relief and no pain relief respectively.

RESULTS AND ANALYSIS

Continuous variables are presented as mean with standard deviation. Comparisons between groups and within groups were made using Pearson Chi Square Test or t-test as appropriate. Differences in the compared groups were considered as statistically significant if, P value is <0.05.

AGE DISTRIBUTION (Table-1)

AGE IN YEARS	STUDY	CONTROL
19	25 (12.5%)	20 (10%)
20-24	127 (63.5%)	136 (68.0%)
25-29	39 (19.5%)	39 (19.5%)
30-34	7 (3.5%)	5 (2.5%)
>35	2 (1%)	0 (0%)



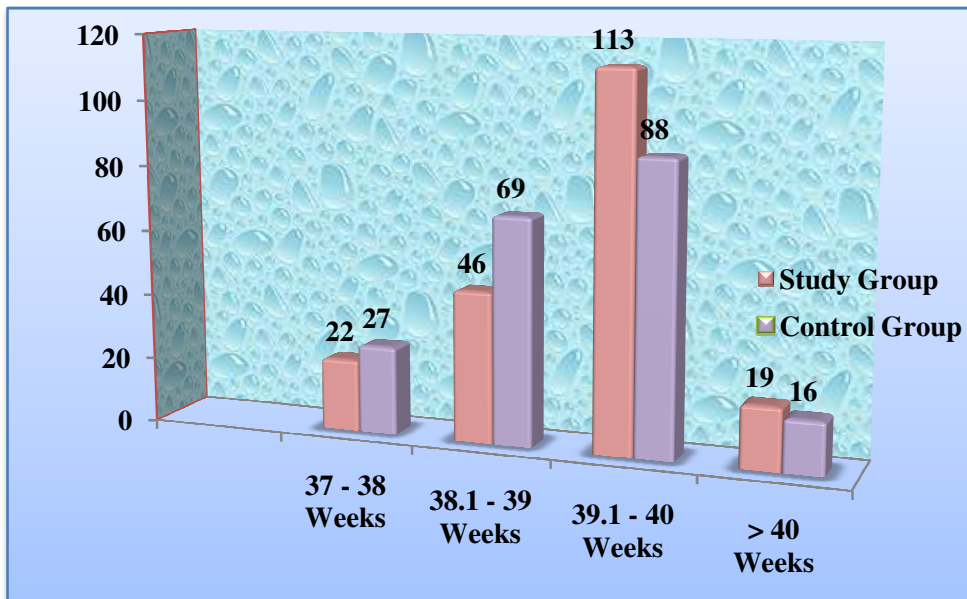
Mean age of the study group: 22.81 with SD 3.27

Mean age in the control group: 22.54 with SD 2.81

There is no statistically significant difference in age between the two groups (p value 0.38).

GESTATIONAL AGE (Table -2)

GESTATIONAL AGE IN WEEKS	STUDY	CONTROL
37-38	22(11%)	27(13.5%)
38.1-39	46(23%)	69(34.5%)
39.1-40	113(56.5%)	88(44%)
>40	18(9.5%)	16(8%)



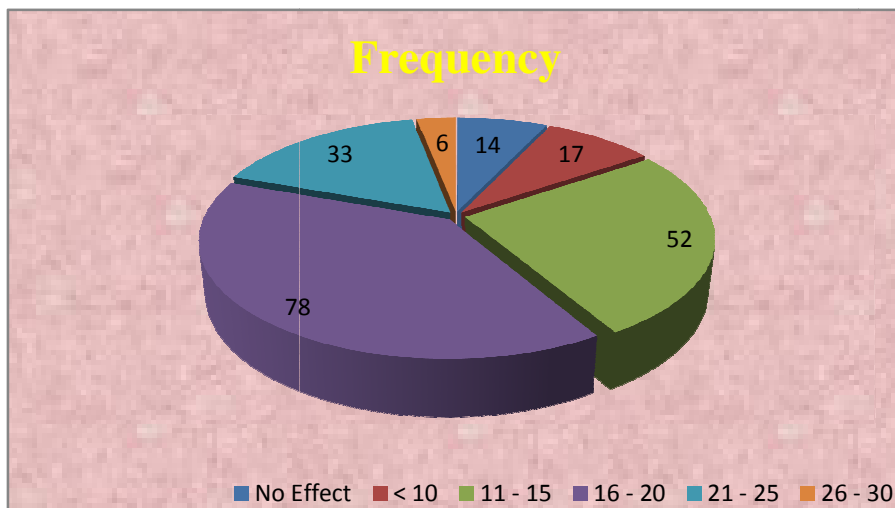
The Mean gestational age in the study group is 38weeks 4 days.

The Mean gestational age in the control group is 38weeks 5days.

The gestational age in both groups is comparable.

ONSET OF DRUG ACTION (Table -3)

ONSET OF DRUG ACTION (ODA) IN MINUTES	NUMBER OF PATIENTS	PERCENTAGE
No Effect	14	7.0%
< 10	17	8.5%
11 - 15	52	26.0%
16 - 20	78	39.0%
21 - 25	33	16.5%
26 - 30	6	3.0%



Mean duration of onset of drug action is 18.31 ± 6.5 minutes.

PAIN IN STAGE I (Table – 4)

DEGREES OF PAIN	STUDY	CONTROL
NO PAIN (0-1)	0	0
MILD(2-4)	0	0
MODERATE(5-7)	25(12.5%)	15(17.5%)
SEVERE(8-10)	175(87.5%)	185(92.5%)

In stage I, 87.5% of the patients in the study group and 92.5% of the control group had severe pain and 12.5% of patients in study group and 17.5% of the control group had moderate pain.

The pain score before drug administration is comparable in both groups (p value-0.368).

PAIN IN STAGE I BEFORE AND AFTER DRUG

ADMINISTRATION (Table – 5)

DEGREES OF PAIN	STAGE I BEFORE DRUG	STAGE I AFTER DRUG
NO PAIN	0	0
MILD PAIN(0-1)	0	136(68%)
MODERATE(2-4)	25(12.5%)	27(13.5%)
SEVERE(8-10)	175(87.5%)	11(5.5%)

There is a significant decrease in the pain score after drug administration in stage I (p value < 0.0001).

There was moderate pain relief in 68% of patients and mild pain relief in 13.5% of patients and no pain relief in 5.5% of patients.

PAIN IN STAGE II IN STUDY AND CONTROL GROUP

(Table – 6)

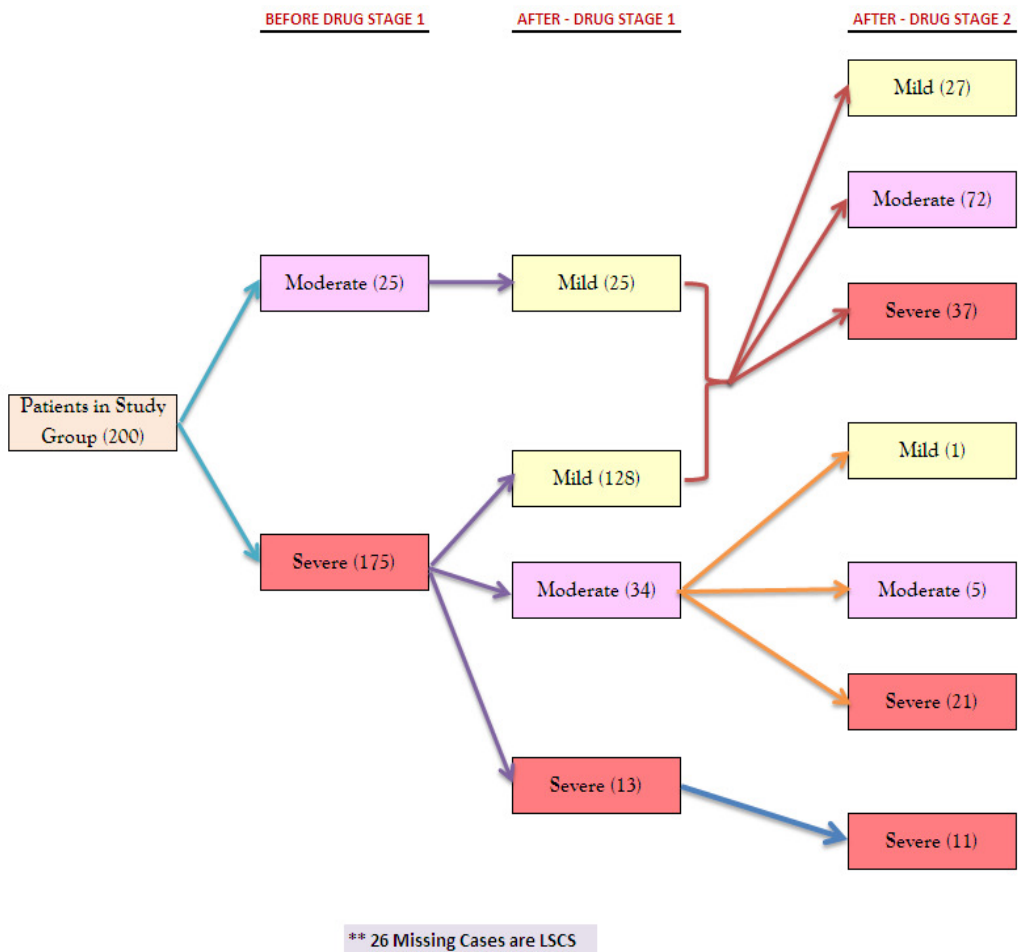
DEGREES OF PAIN	STUDY	CONTROL
MILD(2-4)	28(16.1%)	0
MODERATE(5-7)	77(44.25%)	0
SEVERE(8-10)	69(39.7%)	172(100%)
TOTAL	174	172

(26 Cases In Study Group and 28 Cases in Control Group had LSCS)

In the study group 39.7% patients had severe pain,44.25% had moderate pain and 16.1% had mild pain.

In the control group all patients had severe pain.

The pain in stage II in study group was less than control group which is statistically significant.(p value < 0.001).



This shows the distribution of pain scores before administration of the drug in stage 1 and after drug in stage 1 and stage 2.

MEAN PAIN SCORE IN LABOUR (Table – 6)

PAIN	GROUP	MEAN	STANDARD DEVIATION
STAGE 1	STUDY	9.13	1.11
BEFORE DRUG	CONTROL	9.16	0.97
STAGE 1	STUDY	4.05	1.77
AFTER DRUG	CONTROL	-	-
STAGE 2	STUDY	6.65	1.81
	CONTROL	9.61	0.59

The mean pain score before drug administration in stage I was 9.13 ± 1.11 in study group and 9.16 ± 0.97 in the control group which is comparable. (p value 0.37)

The mean pain in stage I in study group decreased to 4.05 ± 1.77 which is statistically significant. The mean score in stage II in study group is 6.65 ± 1.81 and in control group it is 9.61 ± 0.59 .

DURATION OF LABOUR (Table – 7)

DURATION OF LABOUR (min)	GROUP	NUMBER	MEAN	SD	P value
STAGE 1	STUDY	200	251.05	57.21	0.0005
	CONTROL	200	272.49	59.44	
STAGE 2	STUDY	174	27.49	13.16	0.575
	CONTROL	172	26.72	12.81	
STAGE 3	STUDY	174	8.66	3.17	0.11
	CONTROL	172	9.2	3.19	

The mean duration of stage I in study group was 251.05 ± 57.21 minutes. In the control group it was 272.49 ± 59.44 minutes. The mean duration of stage I is less in the study group compared the control group (p value 0.0005).

The mean duration of stage II in study group was 27.49 ± 13.16 minutes and in control group was 26.72 ± 12.81 minutes. There is no statistically significant difference between the two groups in the mean duration of stage II (p value 0.575). The mean duration of stage III in both groups is comparable (p value 0.11).

TOTAL DURATION OF LABOUR (Table – 8)

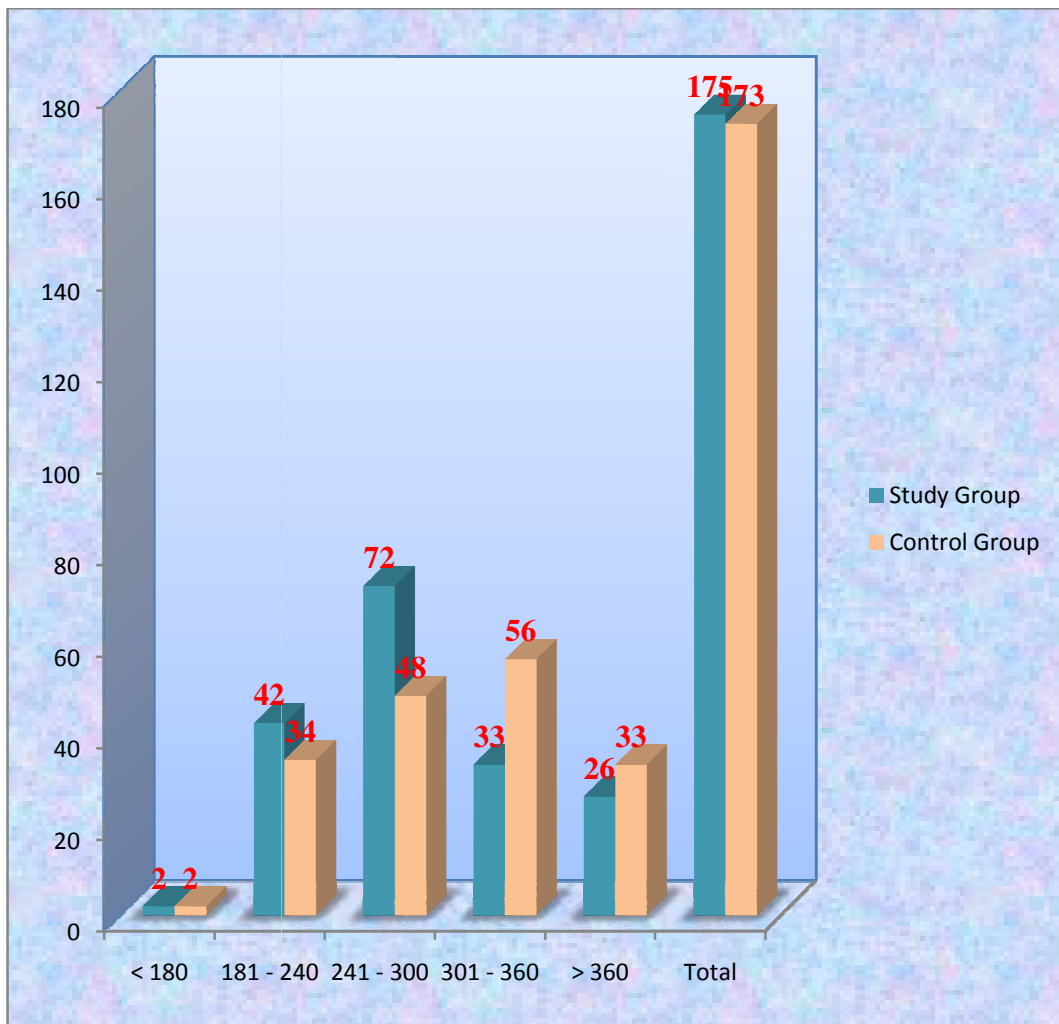
TOTAL DURATION OF LABOUR (min)	Study Group	Control Group
< 180	2 (1.1%)	2 (1.2%)
181 – 240	42 (24.0%)	33 (19.1%)
241 – 300	72 (41.1%)	47 (27.2%)
301 – 360	33 (18.9%)	57 (32.9%)
> 360	26 (14.9%)	34 (19.7%)
Total	175	173

The average total duration of labour in the study group is 287.21±65.43minutes.

The average total duration of labour in the control group is 307.55±68.31minutes.

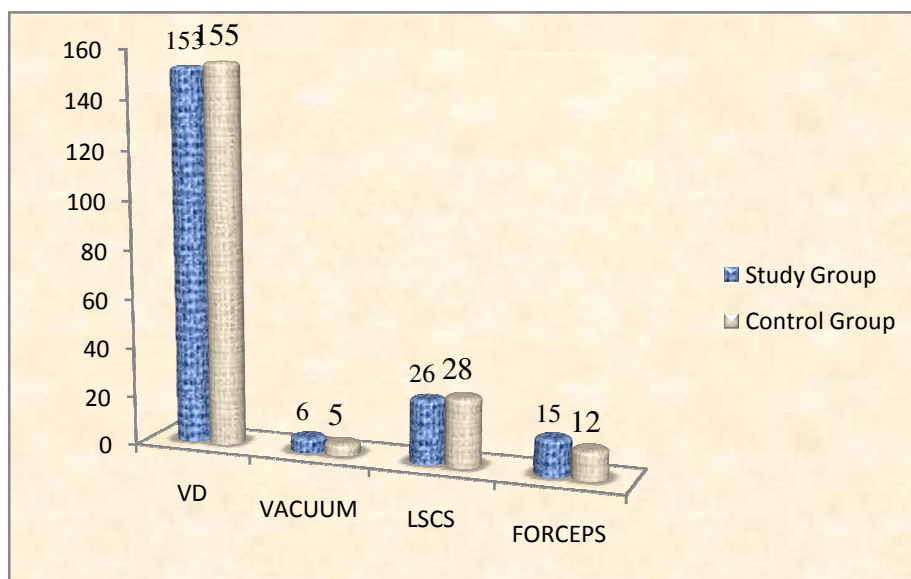
The total duration of labour is significantly less in patients who were given tramadol than in patients in the control group(p value 0.0063).

TOTAL DURATION OF LABOUR



MODE OF DELIVERY (Table – 9)

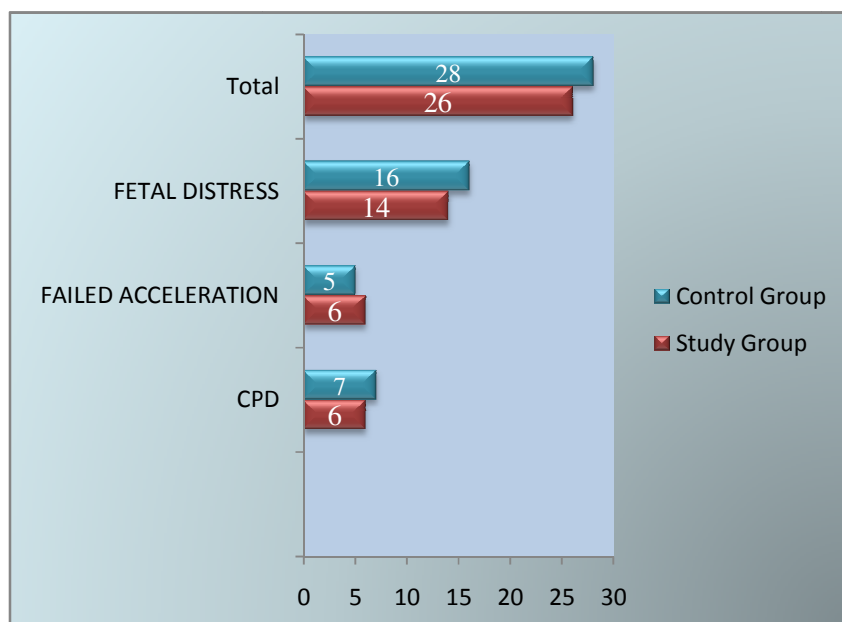
MODE OF DELIVERY	Study Group	Control Group
NVD	153 (76.5%)	155 (77.5%)
VACUUM	6 (3%)	5 (2.5%)
LSCS	26 (13%)	28 (14%)
FORCEPS	15 (7.5%)	12 (6%)



76.5% of the study group and 77.5% of the control group had normal vaginal delivery. There was no difference between the two groups in terms of the mode of delivery.

INDICATIONS FOR LOWER SEGMENT CAESAREAN SECTION (Table - 10)

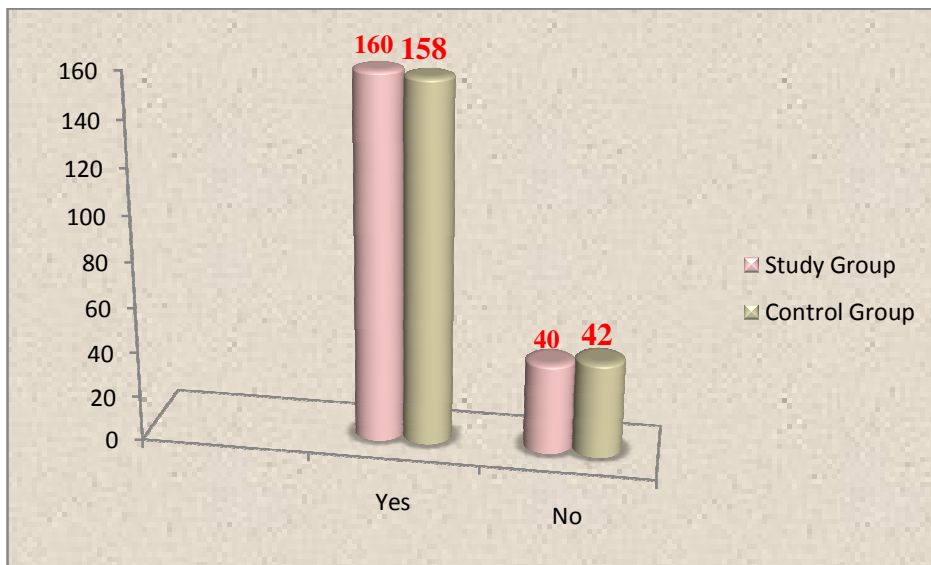
CAESAREAN INDICATIONS	Study Group	Control Group
CPD	6 (23.1%)	7 (25.9%)
FAILED ACCELERATION	6 (23.1%)	5 (18.5%)
FOETAL DISTRESS	14 (53.8%)	16 (59.3%)
Total	26	28



Foetal distress is the most common indication for LSCS in both study group (53.8%) and control(59.3%) group. There is no statistically significant difference.

**PATIENTS REQUIRING OXYTOCIN FOR AUGMENTATION
OF LABOUR (Table -11)**

PATIENTS REQUIRING OXYTOCIN	Study Group	Control Group
Yes	160 (80.0%)	158 (79.0%)
No	40 (20.0%)	42 (21.0%)
Total	200	200



There is no statistically significant difference between the two groups in terms of oxytocin requirement.

ADVERSE EVENTS (Table -12)

ADVERSE EVENTS	Study Group	Control Group	P Value
NAUSEA	37 (18.5%)	10 (5.0%)	<0.0001
VOMITING	19 (9.5%)	11 (5.5%)	0.075
DROWSINESS	5 (2.5%)	0	0.024
PALPITATION	0	0	-
HYPER SENSITIVITY	0	0	-
RESPIRATORY DISTRESS	0	0	-
FETAL TACHYCARDIA	0	0	-

There is statistically significant increase in nausea (P <0.0001) and drowsiness (P 0.024) in the study group than in the control group. Though incidence of vomiting was higher in the study group, it is not statistically significant.

NEONATAL OUTCOME BASED ON APGAR SCORE (Table – 13)

APGAR SCORE 1 MIN	STUDY	CONTROL	P VALUE
3-5	0	1(0.5%)	0.317
6-7	25(12.5%)	23(11.5%)	0.758
8-10	175(87.5%)	176(88%)	0.879

APGAR SCORE 5 MIN	STUDY	CONTROL	P VALUE
3-5	0	0	-
6-7	2(1%)	2(1%)	1
8-10	198(99%)	198(99%)	1

FOETAL HEART RATE (Table – 14)

FHR	MEAN	SD
ONSET OF LABOUR	139.23	5.98
AT TIME OF INJ	138.92	4.95
30 MIN AFTER	139.4	8.68

There is no significant change in the mean fetal heart rate before and after administration of drug.

**CARDIORESPIRATORY PARAMETERS AT THE ONSET OF
LABOUR IN STUDY AND CONTROL GROUP (Table – 15)**

	STUDY GROUP		CONTROL GROUP		P VALUE
	MEAN	SD	MEAN	SD	
PULSE RATE	79.34	4.18	79.75	3.59	0.254
RESPIRATORY RATE	16.01	1.42	17.45	1.96	0.37
SYSTOLIC BP	111.41	5.96	112.69	5.42	0.25
DIASTOLIC BP	72.18	5.23	71.78	4.64	0.419

The cardiorespiratory parameters are similar in both groups at the onset of labour.

MATERNAL CARDIORESPIRATORY PARAMETERS IN THE STUDY GROUP (Table – 16)

MATERNAL PARAMETERS	TIME	MEAN	SD
PULSE RATE	Onset of labour	79.34	4.18
	Time of injection	79.67	3.97
	30 min after inj	79.41	3.99
	After delivery	79.37	4.18
RESPIRATORY RATE	Onset of labour	16.015	1.423
	Time of injection	16.015	1.633
	30 min after inj	16.24	3.16
	After delivery	16.355	1.698
SYSTOLIC BLOOD PRESSURE	Onset of labour	111.41	5.96
	Time of injection	111.79	4.21
	30 min after inj	111.685	4.38
	After delivery	110.735	4.79
DIASTOLIC BLOOD PRESSURE	Onset of labour	72.18	5.23
	Time of injection	72.13	3.97
	30 min after inj	72.53	3.82
	After delivery	72.89	3.6

There was no significant change in the vital parameters after drug administration in the study group.

DISCUSSION

The American Academy of Paediatrics and American college of Obstetricians and Gynaecology (2007) have specified that it is the responsibility of the obstetrician or certified midwife in consultation with an anaesthesiologist to formulate pain relief . In the present study, 400 patients were studied. Study group: 200 patients in active labour who received 100mg tramadol hydrochloride Control group:200 patients in active labour who did not receive the drug.

AGE

The mean gestational age in the study group was 22.81 ± 3.27 years and 22.54 ± 2.81 years in the control group.76% of the study group and 78% of the control group were less than 25 years. This is comparable to the study by Thakur ratna *et al*⁴⁸ the mean age was 22 years.

GESTATIONAL AGE

Primiparous patients between 37 to 42 weeks were included in the study. The mean gestational age in study group was 38

weeks 4days and 38weeks 5days in the control group. In the study by Nagaria tripti *et al*³⁶ and sudha patil *et al*³⁷ the mean gestational age was 39 weeks.

In this study all patients were primigravidae. Similarly in a study by Jain *et al*, Viegas O A *et al*³⁸, Lie *et al*⁴⁹ all women were primigravida.

ONSET OF ANALGESIA

In the present study, time required for onset of analgesia was 18.31 ± 6.5 minutes.

It was 15.89 ± 6.61 minutes in a study by Nagaria tripti *et al*³⁶. In a study by Sudha Patil³⁷ the time for onset of analgesia was 15.35 ± 2.65 minutes.

DEGREE OF ANALGESIA ACHIEVED

Degree of pain relief	Nagaria Tripti	Thakur rathna	Meena Jyothi	Sudha Patil	Sarkar B, Mukhopadhyay	Present study
Complete pain relief	37%	15%	54%	58%	13%	0
Moderate pain relief	38%	55%	32%	30%	38%	68%
Mild pain relief	16%	16%	14%	12%	45%	13.5%
No pain relief	9%	14%	0%	12%	47%	5.5%

In the present study, 68% had moderate pain relief, 13.5% had mild pain relief and 5.5% had no pain relief at all after administration of tramadol. The mean pain score before the drug was 9.13 ± 1.11 . It was reduced after drug administration and was 4.05 ± 1.77 .

This is comparable to studies conducted by Nagaria Tripti *et al*³⁶ where 75% of patients had moderate to good pain relief and Thakur ratna *et al*⁴⁸ where 70% patients had good pain relief.

In a prospective blind randomized study Bajaj *et al*⁵⁰ noted that mean pain relief was 38.92% with tramadol .In a randomized control trial conducted by Jain *et al* compared the analgesic efficacy of intramuscular opioids,meperidine and tramadol with epidural analgesia, 65% patients rated analgesia as good in the tramadol group.

Li E and Weng *et al*⁴⁹ observed that effective pain relief was seen in 67% patients given 100mg tramadol hydrochloride in active labour.

O Kuti *et al*⁴⁰ in a study comparing tramadol hydrochloride and pentazocine in labour found that 30.9% patients had moderate pain relief and 66% patients had mild relief with tramadol.

Singh S *et al*³² in a study comparing 100 mg IM tramadol and pentazocine as labour analgesics observed that moderate pain relief with tramadol was 80%.

As shown in table, in stage II there is an increase in pain score, with 39.7% of patients experiencing severe pain and 44.25% experiencing moderate pain and 16.1% experiencing mild pain.

There is a significant increase in pain from stage 1 to stage 2 in the study group. However compared to the control group, where 100% experienced severe pain in stage II, the pain in stage II in study group is significantly reduced.

DURATION OF LABOUR

The average duration of labour in the study group was 287.21±65.43 minutes and 307.55 ± 68.31 minutes in the control group. The total duration of labour is significantly less in the study group (p value 0.0063)

Duration of labour	Thakur Rathna <i>et al</i> ⁴⁸	Nagaria Tripti <i>et al</i> ³⁶	Khooshid eh M, Ali Shahriari ⁴	Sudha Patil ³⁷	Present study
STAGE I	4.26±1.62 hours	4.28±2.22 hours	140 min	4.15 ±1.68 hours	251.05±57.21 min
STAGE II	11.95±5.8 min	0.30±0.05 hours	25 min	0.28 ±0.42 hours	27.49±13.16 min
STAGE III	5.5±1.5 min	0.04±0.015 hours		0.08±0.05 hours	8.66±12.81 min

The average duration of stage 1 in study group was 251.05 ± 57.21 minutes but in control group it was 272.49 ± 59.44 minutes. The duration of first stage is significantly less in the study group compared to the control group (p value < 0.0005). Though the duration of stage 2 and stage 3 were less in study group the difference is not statistically significant.

As shown in the table the duration of labour is significantly less in patients given tramadol in studies conducted by Nagaria Tripti *et al*, Ali shahriari and M.Khoosideh, Sudha patil.

Sarkar B and Mukhopadhyay A K and suvonnakote *et al* reported rapid progression in women receiving tramadol.

MODE OF DELIVERY

In the study group 76.5% had normal vaginal delivery, 13% underwent LSCS and 7.5% had forceps delivery and 3% had vacuum delivery. There was no significant difference in the mode of delivery when compared to the control group.

Mode of delivery	Thakur Ratna <i>et al</i> ⁴⁸	Nagaria Tripti <i>et al</i> ³⁶	O Kuti <i>et al</i> ⁴⁰	Sudha Patil ³⁷	Present study
NVD	98%	93%	88.1%	90%	76.5%
LSCS	0	3%	9.5%	4%	13%
Instrumental delivery	2%	4%	2.4%	6%	10.5%

Side Effects	Thakur Ratna <i>et al</i> ⁴⁸	Nagaria Tripti <i>et al</i> ³⁶	O Kuti <i>et al</i> ⁴⁰	Bajaj P <i>et al</i> ⁵⁰	Khooshideh <i>et al</i> ⁴	Present study
Nausea	7%	11%	-	22.2%	15%	18.5%
Vomiting	3%	4%	2.4%	-	-	9.5%
Drowsiness	2%	1%	14.3%	11.1%	29%	2.5%
Palpitation	1%	-	-	-	-	-
Hyper sensitivity	-	-	-	-	-	-
Dry mouth	10%	-	-	-	-	-

In the present study in comparison to the control group there is a statistically significant increase in nausea (p value < 0.0001) and drowsiness (p value 0.024). Vomiting is also increased in study group compared to the controls, but is not statistically significant.

FETAL HEART RATE

As shown in table, there is no significant change in the mean fetal heart rate before drug and 30 minutes after administration of the drug. Nagaria Tripti *et al* did not observe any change in the fetal heart rate after administration of tramadol.

NEONATAL OUTCOME

ANALYSIS OF THE APGAR SCORES

In the present study, there is no difference in the APGAR scores of the newborn between the study and control group. This shows that there is no effect of the drug on the neonatal outcome.

In the present study, 87.5% neonates had APGAR scores ≥ 8 at 1 minute and 99% neonates had APGAR score ≥ 8

Bajaj P *et al* reported 1 minute APGAR score >8 in all neonates in the tramadol group.

MATERNAL CARDIO RESPIRATORY PARAMETERS

In this study there is no significant change in the maternal cardio respiratory parameters after drug administration.

SUMMARY

This study is a prospective comparative interventional study.

200 patients were allocated to the study group and another 200 to the control group.

The study group received 100 mg of injection tramadol hydrochloride intramuscularly when they reached active labour.

Degree of pain relief was assessed using numeric pain relief score. Duration of all three stages were calculated in both the groups.

Other parameters like onset of drug action, mode of delivery, maternal cardio respiratory parameters, fetal heart rate and neonatal APGAR score were assessed.

There was a significant decrease in the pain score after drug administration in stage 1 (p value < 0.0001).

There was moderate pain relief in 68% of patients and mild pain relief in 13.5% of patients and no pain relief in 5.5% of patients. After drug administration in the study group 39.7% patients had severe pain, 44.25% had moderate pain and 16.1% had mild pain. In the control

group all patients had severe pain he pain. The second stage pain in the study group is lesser than in the control group which is statistically significant.(p value-<0.001).

The average duration of labour in the study group was 287.21±65.43minutes and 307.55±68.31 minutes in the control group. The total duration of labour is significantly less in the study group(p value 0.0063).

The duration of first stage is significantly less in the study group compared to the control group (p value <0.0005). Though the duration of stage 2 and stage 3 are less in study group the difference is not statistically significant.

In the present study in comparison to the control group there is a statistically significant increase in nausea (p value < 0.0001) and drowsiness (p value 0.024). Vomiting was also increased in study group compared to the controls, but is not statistically significant.

There was no respiratory depression in any of the new borns the study group. There was no alteration in the maternal cardio respiratory parameters with the drug.

CONCLUSION

Tramadol hydrochloride is a safe and effective drug for pain relief in active labour. It also causes a significant reduction in the duration of labour. The tolerance is good without any adverse effects on the mother and newborn.

Tramadol can be instituted as a safe and effective drug for pain relief in labour.

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ABBREVIATIONS

APH	ANTEPARTUM HAEMORRHAGE
ACOG	AMERICAN COLLEGE OF OBSTETRICS AND GYNAECOLOGY
ACTH	ADRENO CORTICO TROPIC HORMONE
BP	BLOOD PRESSURE
CPD	CEPHALO PELVIC DISPROPORTION
CTG	CARDIOTOCOGRAM
FD	FETAL DISTRESS
IM	INTRA MUSCULAR
I V	INTRA VENOUS
GDM	GESTATIONAL DIABETES MELLITUS
LSCS	LOWER SEGMENT CAESAREAN SECTION
NPI	NUMERIC PAIN INTENSITY SCALE

NSAIDS	NON STEROIDAL ANTI INFLAMMATORY DRUGS
ODA	ONSET OF DRUG ACTION
PCA	PATIENT CONTROLLED ANALGESIA
PIH	PREGNANCY INDUCED HYPERTENSION
PR	PULSE RATE
RS	RESPIRATORY RATE
SD	STANDARD DEVIATION
TDD	TOTAL DOSE OF DRUG
TENS	TRANS CUTANEOUS ELECTRIC NERVE STIMULATION
VAS	VISUAL ANALOGUE SCALE
VD	VAGINAL DELIVERY
VRS	VERBAL RATING SCALE

PROFORMA

S.NO

NAME :

IPNO:

AGE:

SE STATUS:

BOOKED/UNBOOKED:

DATE AND TIME OF DELIVERY:

CHIEF COMPLAINTS AND HISTORY OF PRESENTING ILLNESS:

H/O _____ AMENORHOEA

C/O LABOUR PAINS _____ HOURS

H/OLEAKING P/V OR BLEEDING P/V _____ HOURS

MENSTRUAL HISTORY:

LMP:

EDD:

REGULAR /IRREGULAR:

DAYS OF FLOW:

DURATION OF CYCLE:

OBETETRIC HISTORY: PRIMI

I TRIMESTER:

II TRIMESTER:

III TRIMESTER:

PAST HISTORY: HT/DM/TB/BA/HEART DISEASE/DRUG
HISTORY

FAMILY HISTORY: HT/DM/TB/BA/TWINS

PERSONAL HISTORY:

DIET: APPETITE: SLEEP: BLADDER: BOWEL:

GENERAL EXAMINATION

BUILT: NOURISHMENT:

HEIGHT: WEIGHT:

PALLOR: ICTERUS: PEDAL EDEMA:

LYMPHADENOPATHY: THYROID: BREAST:

VITALS

PULSE RATE: BP:

RR: TEMP:

SYSTEMIC EXAMINATION

CVS:

RS:

CNS:

OBSTETRIC EXAMINATION

P/A:UTERUS_____ WEEKS , ACTING

LONGITUDINAL LIE/CEPHALIC PRESENTATION

HEAD:

FHR:

SFH: EFW:

P/S

P/V CERVIX CONSISTENCY

EFFACEMENT

DILATATION

MEMBRANES

LIQUOR

VERTEX STATION : POSITION :

PELVIC ASSESSMENT

INVESTIGATIONS

Hb: TC: DC: BLOOD GROUPING: RBS:

URINE ROUTINE:

HIV: HbsAg:

MONITORING DURING LABOUR AFTER DRUG ADMINISTRATION

Date & time

Pulse

BP

RR

UT contraction

FHS

PV

Pain score

Tramadol dose
and time

OBSERVATIONS

- a) Degree of pain before administering the drug
- b) Degree of pain after administering the drug by NPI scale

Stage 1: stage 2

c) Effect on bearing down :satisfactory or not

d) Onset of drug action :

e) Duration of drug action :

f) Total dose of drug:

DELIVERY DETAILS

MODE OF DELIVERY:

VAGINAL: NORMAL/FORCEPS/VACUUM

LSCS: INDICATION :

ANY ADVERSE EFFECTS OF THE DRUG:

Nausea : Vomiting: Respiratory depression: Drowsiness:

BABY DETAILS

Sex: birth weight: Time of delivery:

APGAR:1'' 5''

NICU Admissions:

PATIENT CONSENT FORM

STUDY TITLE: **A PROSPECTIVE STUDY ON INJECTION TRAMADOL
HYDROCHLORIDE AS A LABOUR ANALGESIC AND
ITS EFFECT ON DURATION OF LABOUR**

STUDY CENTRE: Institute of Obstetrics and Gynaecology, Egmore, Chennai.

PARTICIPANT NAME: **AGE:** **I.D.NO:**

I confirm that I have understood the purpose of the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my complete satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.

I understand that investigator, the institution, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to the current study and further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

I hereby consent to, undergo complete physical examination, and diagnostic tests including haematological, and ultrasonogram examinations for me.

I hereby consent to participate in this study on “**A PROSPECTIVE STUDY ON INJECTION TRAMADOL HYDROCHLORIDE AS A LABOUR ANALGESIC AND ITS EFFECT ON DURATION OF LABOUR**”.

Place:

Signature of the Patient:

Date:

Address:

Signature of the witness:

Signature of Investigator:

PULSE RATE				RESPIRATORY RATE				SYSTOLIC BLOOD PRESSURE				DIASTOLIC BLOOD PRESSURE				FETAL HEART RATE		
AT ONSET OF LABOUR	AT TIME OF INJECTION	30 MIN LATER	AFTER DELIVERY	AT ONSET OF LABOUR	AT TIME OF INJECTION	30 MIN LATER	AFTER DELIVERY	AT ONSET OF LABOUR	AT TIME OF INJECTION	30 MIN LATER	AFTER DELIVERY	AT ONSET OF LABOUR	AT TIME OF INJECTION	30 MIN LATER	AFTER DELIVERY	AT ONSET OF LABOUR	AT TIME OF INJECTION	30 MIN LATER
76	78	80	78	16	17	17	16	112	118	116	112	68	72	74	74	138	134	140
80	82	82	82	17	15	15	15	110	116	112	112	70	74	78	74	140	138	142
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74	86	80	80	18	18	15	16	108	110	112	114	72	74	68	70	128	132	132
82	88	82	82	14	16	17	15	106	102	108	114	80	78	74	76	142	140	148
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82	76	80	80	16	17	14	16	108	114	112	106	68	70	66	68	144	140	138
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111	VANITHA MARY	30	21667	37+2	10	6	9	20	1	NO	240	22	10	272	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
112	JEEVA	19	21271	37+3	10	3	8	18	1	NO	280	35	15	330	VD		YES	YES	NO	NO	NO	NO	NO	NO	8	9
113	ARUNA	19	21700	37+6	8	3	7	19	1	YES	270	40	12	322	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
114	AMSA	19	21755	40+1	7	3	7	15	1	YES	200	30	10	240	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
115	SUKANYA	19	21759	39+6	10	3	3	10	1	YES	170	22	10	202	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
116	GNANAOLI	27	21720	40+1	10	4	-	25	1	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	NO	NO	8	9
117	CAROLIN	24	21668	40+1	10	4	-	18	1	YES	-	-	-	-	LSCS	CPD	YES	YES	NO	NO	NO	NO	NO	NO	8	9
118	BHUVANESHWARI	28	21577	40+3	7	4	4	10	1	NO	200	30	7	237	VD		YES	NO	NO	NO	NO	NO	NO	NO	8	9
119	RAJESHWARI	26	21807	38+5	9	3	8	24	1	YES	205	20	8	233	VD		NO	NO	NO	NO	NO	NO	NO	NO	6	7
120	ESTHER	20	21859	39+1	9	3	3	19	1	YES	260	25	10	295	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
121	REVATHI	21	21771	40+5	10	3	5	25	2	YES	320	30	15	365	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
122	VEDHAVALLI	25	21836	38+3	10	3	-	14	1	YES	-	-	-	-	LSCS	FA	NO	NO	NO	NO	NO	NO	NO	NO	8	9
123	SHAMINI	24	21870	39+2	10	4	8	13	1	NO	180	25	13	218	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
124	AMUDHA	27	21897	39+4	10	5	8	20	1	YES	240	70	15	325	OUT-FOR		NO	NO	NO	NO	NO	NO	NO	NO	8	9
125	GOWTHAMI	23	21909	39+3	10	9	9	NIL	1	YES	300	40	10	350	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
126	SEETHA	23	21884	39+5	10	3	6	15	1	YES	260	55	5	320	VACUUM		NO	NO	NO	NO	NO	NO	NO	NO	8	9
127	BHUVANESHWARI	24	21961	38+3	7	3	3	20	1	YES	220	20	10	250	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
128	DEVI	30	21984	38+2	10	9	9	NIL	1	YES	260	20	12	292	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
129	SUKANYA	19	21972	39+2	10	3	8	25	1	YES	320	35	12	367	VD		YES	YES	NO	NO	NO	NO	NO	NO	8	9
130	CHITRA	26	21375	38+3	10	3	-	20	1	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	NO	NO	8	9
131	SARANYA	22	21841	39+2	10	4	-	15	1	NO	-	-	-	-	LSCS	FA	YES	NO	NO	NO	NO	NO	NO	NO	8	9
132	MUNDIRA	20	22001	37+3	10	3	8	17	1	YES	280	25	10	315	VD		NO	NO	NO	NO	NO	NO	NO	NO	7	9
133	VIDHYA	19	22005	39	10	3	9	15	1	YES	300	40	18	358	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
134	JAYANTHI	29	22035	39+5	10	3	9	13	1	YES	200	10	8	218	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
135	SHANTHI	23	22114	39+1	10	9	-	NIL	1	YES	-	-	-	-	LSCS	FD	YES	YES	NO	NO	NO	NO	NO	NO	8	9
136	MARIYAMMAL	21	22136	38+1	9	3	4	15	1	YES	260	20	10	290	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
137	NANDHINI	20	22105	39+2	10	6	8	20	1	YES	270	22	10	302	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
138	ANANDHI	25	22104	40+5	9	4	-	25	1	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	NO	NO	8	9
139	PAVALAKODI	20	22102	39	9	4	6	25	2	YES	360	45	6	411	OUT-FOR		YES	YES	NO	NO	NO	NO	NO	NO	8	9
140	DHANA LAKSHMI	25	22222	37+3	10	5	8	15	1	NO	200	20	10	230	VD		YES	NO	NO	NO	NO	NO	NO	NO	8	9
141	BABY	23	21221	38	9	5	9	20	1	NO	170	25	10	205	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
142	NISHANTHINI	24	22122	39+1	9	5	-	18	1	YES	-	-	-	-	LSCS	CPD	NO	NO	NO	NO	NO	NO	NO	NO	8	9
143	GEETHA PRIYA	24	22278	39+2	10	6	7	25	1	YES	220	22	10	252	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
144	RAJESHWARI	30	22286	39+2	10	3	5	20	2	YES	380	50	10	440	OUT-FOR		NO	NO	NO	NO	NO	NO	NO	NO	8	9
145	MANJUULA	30	22230	39+4	7	3	6	23	1	YES	320	35	18	373	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
146	DURGA	21	22100	39+5	10	10	10	NIL	1	YES	260	20	10	290	VD		NO	NO	NO	NO	NO	NO	NO	NO	7	8
147	DIVYA BHARATHI	21	22108	39+4	7	3	5	14	1	YES	180	20	10	210	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
148	KAVITHA	21	22251	38+6	9	3	3	15	1	YES	240	22	7	269	VD		NO	NO	NO	NO	NO	NO	NO	NO	8	9
149	UDHAYA	23	21622	37+2	9	9	-	NIL	1	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	NO	NO	8	9
150	REVATHI	25	22396	37+4	10	7	-	30	2	YES	-	-	-	-	LSCS	FA	YES	YES	NO	NO	NO	NO	NO	NO	8	9

82	84	82	84	15	15	14	17	106	110	106	100	72	76	76	78	128	130	132
80	82	84	76	17	15	17	18	110	114	110	110	68	70	70	72	124	128	130
72	74	78	84	16	18	16	16	108	110	110	106	66	72	72	68	136	132	130
76	74	80	72	19	17	22	17	120	116	120	110	76	74	76	76	138	132	132
78	76	82	78	14	17	14	15	116	112	114	112	74	72	68	68	140	138	132
80	82	80	72	18	16	15	14	114	112	106	114	68	70	68	72	142	140	142
72	78	82	70	18	15	14	17	120	116	110	110	66	68	70	72	144	142	140
74	82	84	78	17	19	19	15	118	120	108	108	64	66	66	68	136	138	142
86	84	78	76	15	16	14	20	114	114	120	116	70	72	72	74	144	142	142
78	80	74	80	18	20	17	17	116	120	116	114	72	74	74	76	138	140	142
80	78	72	82	15	14	16	17	110	112	114	110	74	76	76	76	136	138	140
78	80	76	80	16	18	14	17	102	108	118	118	80	78	76	76	134	136	138
76	82	80	72	17	22	16	16	108	110	102	104	70	70	72	72	142	140	140
78	82	72	76	15	17	15	15	104	100	108	110	72	70	68	70	128	132	132
80	78	74	78	14	15	17	14	100	104	106	110	70	72	70	68	132	134	133
82	76	86	80	17	18	22	17	116	110	110	112	80	78	78	76	138	132	136
84	80	78	72	15	15	17	15	120	114	114	110	72	76	74	74	142	142	144
88	80	80	74	17	16	15	14	116	114	110	116	74	74	72	74	148	144	142
84	80	78	86	22	17	16	18	114	112	106	112	68	70	72	70	148	146	146
76	82	76	78	15	15	14	16	118	116	110	112	70	74	76	74	142	140	142
76	82	78	80	16	14	17	17	102	108	112	116	80	78	80	78	140	138	142
78	80	80	78	17	17	16	15	108	110	114	120	80	76	72	74	138	132	138
76	84	82	76	15	15	20	15	106	110	110	114	62	66	64	66	136	134	132
80	78	84	78	14	17	15	18	110	112	108	120	68	66	68	68	142	140	138
82	80	88	80	17	18	14	15	106	112	110	112	64	64	64	66	128	132	130
84	82	84	82	15	15	17	16	110	114	114	108	66	64	66	64	126	128	132
86	78	76	84	16	16	16	17	102	106	110	110	72	70	70	68	146	142	144
82	80	76	88	17	17	17	15	104	108	108	118	78	76	74	74	146	144	142
80	82	78	84	14	15	14	14	110	110	110	110	70	70	72	72	156	150	148
78	82	76	76	15	14	15	17	120	114	118	108	72	70	72	72	148	148	142
76	78	80	84	14	17	14	15	118	116	114	104	68	72	74	72	142	144	144
74	76	82	86	16	15	16	17	116	110	116	100	76	78	80	76	134	138	142
80	80	84	82	14	18	14	18	120	114	110	100	72	72	70	74	128	132	132
86	80	86	80	17	22	17	15	114	112	112	112	68	70	72	72	136	134	134
88	80	82	78	16	20	16	16	102	110	108	100	70	70	70	68	138	136	134
78	82	80	76	14	20	14	17	108	110	112	110	72	74	70	72	142	142	140
84	82	78	74	16	16	20	15	110	112	110	106	68	70	72	70	148	144	142
80	80	76	80	20	15	17	15	116	112	112	110	60	66	68	64	142	142	138
86	84	74	86	17	14	19	14	120	118	118	116	64	68	66	66	138	140	136
78	78	80	88	14	17	17	17	108	116	114	114	76	70	76	74	140	136	138

82	80	76	78	17	15	19	15	104	110	108	120	74	76	74	76	136	132	134
84	82	80	84	15	14	20	16	118	116	104	116	60	60	62	66	142	138	136
78	78	78	80	16	18	22	17	114	116	100	114	70	68	74	70	144	140	138
80	84	72	86	14	16	16	14	120	118	100	118	72	68	70	72	146	138	144
82	80	76	80	17	17	14	15	114	116	112	102	76	74	76	70	150	146	148
80	82	78	76	16	15	17	22	114	112	100	108	68	70	72	74	146	144	146
82	84	82	76	15	14	19	20	118	116	110	106	66	68	70	72	144	142	144
84	88	84	80	18	17	20	19	116	114	106	112	60	66	68	70	148	142	146
78	80	82	82	15	16	15	18	106	110	110	112	70	68	70	68	142	138	140
74	84	74	84	17	15	17	17	102	108	110	112	72	70	68	70	140	136	142
72	80	74	86	15	15	15	17	104	110	118	114	80	78	76	78	138	136	138
76	80	76	82	19	14	17	19	106	110	116	102	76	74	76	80	132	130	140
84	82	82	80	18	14	16	20	110	112	108	108	78	76	76	80	128	130	132
78	80	78	78	16	16	15	22	118	112	110	110	80	78	76	80	142	138	138
82	78	82	76	14	15	18	16	116	112	110	100	74	76	74	76	144	142	144
82	86	84	74	18	16	14	20	120	118	114	104	74	72	76	74	140	138	140
80	78	80	80	14	15	17	17	114	112	110	110	72	66	68	68	138	132	132
84	80	78	82	16	14	15	19	118	118	102	114	68	68	70	72	132	136	134
82	82	80	78	15	16	22	17	106	110	104	114	66	76	76	78	142	144	138
78	78	82	80	14	15	16	19	106	108	114	112	76	78	78	80	138	138	142
80	82	82	84	17	22	19	20	106	104	112	116	78	76	78	76	140	142	144
74	76	78	84	15	20	19	22	108	100	118	108	80	78	76	74	142	144	142
74	78	76	86	14	19	22	16	112	100	104	116	70	72	74	72	128	132	130
72	76	80	76	18	18	19	14	116	112	106	118	72	70	72	74	150	148	146
80	82	80	80	16	16	20	17	104	100	108	116	66	68	70	68	148	146	242
82	78	80	82	17	14	15	15	118	110	110	112	68	70	72	74	144	142	146
78	80	82	84	15	17	16	16	112	106	112	116	70	72	74	76	138	136	140
80	82	82	86	14	15	17	17	118	110	120	114	68	70	72	74	132	134	138
82	84	80	78	17	16	14	15	116	112	114	110	66	68	70	72	138	136	140
86	86	84	84	16	15	15	14	114	114	115	108	76	74	72	76	142	144	142
88	88	78	86	15	17	14	17	108	110	102	110	78	76	70	72	144	146	138
78	80	80	86	15	15	16	15	104	108	108	108	80	78	74	76	144	142	140
84	86	82	88	14	17	14	17	118	110	106	106	68	70	72	74	132	138	134
80	82	78	78	20	16	17	16	116	112	110	110	70	72	74	76	138	143	140
86	84	80	84	16	15	16	15	106	110	116	106	72	74	76	72	126	128	132
78	80	82	80	15	18	14	15	108	112	110	110	66	66	68	70	130	132	132
82	80	84	86	16	14	16	14	116	112	108	102	80	78	76	78	132	128	132
84	82	86	78	15	17	15	14	100	112	118	104	74	72	68	68	138	136	130
78	80	88	82	14	15	19	16	110	114	116	114	74	74	76	74	140	138	132
80	82	80	84	16	18	14	15	108	116	112	112	78	76	74	76	144	142	144

82	80	86	78	15	16	17	16	104	108	116	118	76	74	74	72	138	140	142
80	82	82	80	16	17	15	15	104	108	116	104	72	76	76	76	136	138	136
82	80	84	82	14	15	16	14	118	110	120	110	68	68	68	70	146	142	144
84	86	80	80	16	14	14	16	114	110	114	110	70	74	72	72	144	140	142
78	82	80	82	14	15	17	15	120	116	120	114	74	72	72	72	142	138	142
74	76	82	84	15	15	16	16	118	114	112	110	74	76	76	74	138	136	140
72	78	80	78	17	14	15	19	110	110	118	116	70	72	74	74	130	132	132
76	78	82	74	15	14	18	20	100	104	108	110	66	70	68	68	136	128	134
76	80	80	72	16	16	15	16	104	108	106	106	80	78	72	76	144	138	138
72	78	82	76	14	15	17	20	116	108	110	108	80	76	76	78	142	144	138

MASTER CHART – CONTROL GROUP

S.NO	NAME	AGE	IP.NO	G.A	DEGREES OF PAIN		OXYTOCIN	DURATION OF ACTIVE LABOUR			TOTAL DURATION OF LABOUR	MODE OF DELIVERY	LSCS INDICATION	ADVERSE EVENTS						APGAR SCORE		PULSE RATE	BLOOD PRESSURE		RESPIRATORY RATE	FETAL HEART RATE
					STAGE 1	STAGE 2		STAGE 3	NAUSEA	VOMITTING				DROWSINESS	PALPITATION	RESPIRATORY DISTRESS	FETAL TACHYCARDIA	1 MIN	5 MIN	SYSTOLIC	DIASTOLIC					
1	SARAL	23	18766	39+4	9	9	YES	220	30	5	255	VD		NO	NO	NO	NO	NO	NO	8	9	80	110	68	16	138
2	PRIYA	26	16704	39+6	9	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	7	9	86	120	70	14	130
3	SANGEETHA	20	18851	37+2	9	10	YES	300	49	7	356	VD		NO	NO	NO	NO	NO	NO	8	9	82	114	64	16	144
4	JENEFFER	23	18909	38+1	10	10	NO	420	40	10	470	VD		NO	NO	NO	NO	NO	NO	8	9	74	116	68	18	142
5	RAJALAKSHMI	21	18885	39+2	8	9	YES	180	10	10	200	VD		NO	NO	NO	NO	NO	NO	8	9	88	120	80	14	144
6	DURGA	21	18872	37+3	10	10	NO	360	31	17	408	VD		NO	NO	NO	NO	NO	NO	8	9	84	108	74	18	134
7	CHITRA	25	18927	38+4	10	9	YES	280	24	12	316	VD		NO	NO	NO	NO	NO	NO	8	9	74	112	72	14	132
8	MAHALAKSHMI	25	19034	40	9	9	YES	240	20	5	265	VD		NO	NO	NO	NO	NO	NO	8	9	72	114	66	18	130
9	SAMUNDESHWARI	21	19237	39+3	10	10	YES	375	65	10	450	OUT-FOR		NO	NO	NO	NO	NO	NO	8	9	82	108	68	16	140
10	DIVYA	20	19501	39+4	10	10	YES	180	15	10	205	VD		NO	NO	NO	NO	NO	NO	8	9	84	100	70	18	148
11	ANURADHA	21	19576	38+5	9	10	YES	360	30	10	400	VD		YES	YES	NO	NO	NO	NO	8	9	84	120	78	15	152
12	ARUNA	20	19686	39+2	10	10	NO	210	20	10	240	VD		NO	NO	NO	NO	NO	NO	8	9	82	118	80	17	144
13	SHARMILA	20	19768	39+2	8	10	YES	380	45	20	445	VD		NO	NO	NO	NO	NO	NO	8	9	78	114	78	19	142
14	GOMATHI	21	19864	38+3	9	10	YES	380	28	10	418	VD		NO	NO	NO	NO	NO	NO	9	9	74	108	76	22	138
15	LAKSHMI	24	19818	38+4	10	10	YES	260	22	10	292	VD		NO	NO	NO	NO	NO	NO	8	9	80	110	68	21	136
16	LATHA	21	19874	38+5	10	10	YES	400	38	18	456	VD		NO	NO	NO	NO	NO	NO	7	8	84	120	70	18	136
17	DURAISANI	20	19971	37+5	8	10	NO	420	40	10	470	VD		NO	NO	NO	NO	NO	NO	8	9	80	114	72	16	144
18	DHANA LAKSHMI	23	19892	39+2	9	9	YES	320	46	8	374	VD		NO	NO	NO	NO	NO	NO	9	9	78	118	80	17	142
19	THAEN MOZHI	23	19984	37+3	10	10	YES	240	30	10	280	VD		NO	NO	NO	NO	NO	NO	8	9	74	110	74	18	142
20	YESU MANI	22	20086	39	8	10	YES	290	26	5	321	VD		NO	NO	NO	NO	NO	NO	8	9	78	120	68	16	140
21	MAHALAKSHMI	20	20168	39+2	10	10	YES	280	20	10	310	VD		YES	YES	NO	NO	NO	NO	8	9	80	108	70	17	140
22	SARANAYA	21	19795	39+2	8	9	YES	320	65	10	395	OUT-FOR		NO	NO	NO	NO	NO	NO	8	9	82	104	70	18	138
23	MANJULA	21	20031	39+5	8	8	NO	240	19	7	266	VD		NO	NO	NO	NO	NO	NO	6	8	76	110	66	19	142
24	RAMA LAKSHMI	25	20179	39+2	7	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	8	9	78	112	68	20	144
25	VIDHYA LAKSHMI	22	2846	39+4	7	10	YES	200	26	8	234	VD		NO	NO	NO	NO	NO	NO	8	9	82	118	78	22	134
26	SANGEETHA	20	2784	39+2	10	10	YES	220	20	10	250	VD		NO	NO	NO	NO	NO	NO	8	9	88	104	64	19	138
27	RAMYA	23	2939	39+5	10	10	NO	270	21	17	308	VD		NO	NO	NO	NO	NO	NO	8	9	78	106	64	15	142
28	KANAKA	22	2937	38+2	10	10	YES	335	48	10	393	VD		NO	NO	NO	NO	NO	NO	8	9	84	120	78	16	144
29	GANGA BHAVANI	27	3023	38+6	10	10	YES	300	24	6	330	VD		NO	NO	NO	NO	NO	NO	8	9	80	108	80	17	134
30	PONNAMMAL	20	3071	39+5	10	10	YES	280	20	10	310	VD		NO	NO	NO	NO	NO	NO	8	9	78	110	78	15	136
31	KAVITHA	21	3109	39+6	8	9	YES	200	33	7	240	VD		NO	NO	NO	NO	NO	NO	8	9	76	116	68	17	148
32	GEETHA	22	3132	38+1	10	10	NO	260	15	10	285	VD		NO	NO	NO	NO	NO	NO	8	9	74	118	68	18	146
33	VUJAYA	22	3142	39+5	9	9	NO	230	20	10	260	VD		NO	NO	NO	NO	NO	NO	8	9	78	108	70	17	128
34	PARVATHI	23	3308	38+5	9	9	YES	260	15	5	280	VD		NO	NO	NO	NO	NO	NO	8	9	80	110	72	15	130
35	BOOMA DEVI	26	3381	37+3	9	9	YES	240	35	5	280	VD		NO	NO	NO	NO	NO	NO	8	9	84	108	74	16	144
36	MEENAKSHI	20	3255	39+2	10	10	YES	320	30	10	360	VD		NO	NO	NO	NO	NO	NO	7	8	88	106	72	20	142
37	SARTAJ	22	3489	39+1	10	10	YES	240	15	5	260	VD		NO	NO	NO	NO	NO	NO	8	9	82	108	70	22	140
38	VENNILA	26	3562	38+1	7	9	YES	300	40	20	360	OUT-FOR		NO	NO	NO	NO	NO	NO	8	9	80	110	72	21	142
39	RAJALAKSHMI	25	3674	38+3	9	10	YES	260	25	10	295	VD		NO	NO	NO	NO	NO	NO	8	9	78	112	70	19	138
40	DHATCHAYANI	21	3552	38+6	8	10	YES	310	25	10	345	VD		YES	NO	NO	NO	NO	NO	8	9	76	116	74	18	136
41	SAMUNDESHWARI	22	3812	39+2	10	10	YES	300	55	10	365	OUT-FOR		NO	NO	NO	NO	NO	NO	8	9	74	114	72	17	142
42	VASANTHI	25	3892	38+6	10	-	YES	-	-	-	-	LSCS	CPD	NO	NO	NO	NO	NO	NO	8	9	86	110	78	15	140
43	GANGA	20	4098	39+2	10	10	YES	220	17	13	250	VD		NO	NO	NO	NO	NO	NO	8	9	80	100	68	19	138
44	THAEN MOZHI	21	4092	38+3	7	9	NO	360	38	12	410	VD		NO	NO	NO	NO	NO	NO	8	9	88	120	70	17	138
45	NIRMALA DEVI	20	3846	37+6	10	10	YES	240	28	12	280	VD		NO	NO	NO	NO	NO	NO	7	8	76	108	70	18	136
46	ISHWARYA	19	4236	38+5	9	10	YES	300	19	13	332	VD		NO	NO	NO	NO	NO	NO	8	9	80	110	70	19	132
47	SARALA	23	4413	38+3	7	9	YES	320	30	10	360	VD		NO	NO	NO	NO	NO	NO	8	9	86	116	72	20	128
48	RAJESHWARI	29	4304	39+1	10	10	YES	200	20	10	230	VD		NO	NO	NO	NO	NO	NO	8	9	84	118	74	21	152
49	RADHIKA	19	4705	38+4	9	NL	NO	180	25	10	215	VD		NO	NO	NO	NO	NO	NO	8	9	88	108	68	21	150
50	NOORJAHAN	24	4569	38+4	10	10	NO	360	26	14	400	VD		NO	NO	NO	NO	NO	NO	8	9	80	114	64	18	152

51	MENAKA	26	21501	40	7	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	7	8	78	108	62	17	148
52	SUMITHRA	22	21391	38+6	9	-	YES	-	-	-	-	LSCS	CPD	NO	NO	NO	NO	NO	NO	8	9	84	120	78	17	144
53	SUMATHI	18	21535	38+4	10	9	YES	300	28	12	340	VD		NO	NO	NO	NO	NO	NO	8	9	86	110	80	18	142
54	ALAMELU	21	21420	39+4	10	10	NO	360	20	10	390	VD		YES	YES	NO	NO	NO	NO	8	9	78	112	78	16	142
55	MALAR	26	21661	39+4	8	10	YES	280	10	5	295	VD		NO	NO	NO	NO	NO	NO	8	9	86	100	80	16	128
56	SUDHA	22	21645	38+6	8	10	NO	340	30	10	380	VD		NO	NO	NO	NO	NO	NO	8	9	82	108	68	17	126
57	RADHIKA	19	20931	37+1	10	NIL	YES	220	10	10	240	VD		NO	NO	NO	NO	NO	NO	8	9	80	110	78	17	138
58	JOTHI	21	21679	39+2	10	8	YES	270	30	15	315	VD		NO	NO	NO	NO	NO	NO	8	9	80	108	72	15	142
59	LAKSHMI	23	21737	40+5	10	-	YES	-	-	-	-	LSCS	FA	NO	NO	NO	NO	NO	NO	8	9	82	120	74	19	144
60	ANNA LAKSHMI	25	21745	38+1	7	-	YES	-	-	-	-	LSCS	CPD	NO	NO	NO	NO	NO	NO	8	9	86	118	76	18	138
61	ARUL SELVI	19	21752	40+1	10	10	NO	270	25	5	300	VD		NO	NO	NO	NO	NO	NO	8	9	84	116	76	22	142
62	USHA	30	20892	37+3	10	-	YES	-	-	-	-	LSCS	CPD	NO	NO	NO	NO	NO	NO	8	9	86	108	68	19	136
63	MENAKA	24	21754	39+5	10	-	NO	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	8	9	80	120	72	21	136
64	SUJATHA	33	21778	39+4	10	10	YES	260	24	6	290	VD		NO	NO	NO	NO	NO	NO	7	8	76	104	72	19	138
65	HEMA LATHA	23	21834	38+6	8	-	YES	-	-	-	-	LSCS	FA	NO	NO	NO	NO	NO	NO	8	9	80	108	68	18	140
66	RAMYA	20	21811	39+1	10	10	NO	240	25	10	275	VD		NO	NO	NO	NO	NO	NO	8	9	84	110	66	19	128
67	JAYANTHI	21	21866	38+2	9	10	YES	310	17	5	332	VD		NO	NO	NO	NO	NO	NO	8	9	82	112	64	16	138
68	EZHIL ARASI	32	21883	37+2	10	-	YES	-	-	-	-	LSCS	CPD	NO	NO	NO	NO	NO	NO	8	9	76	118	74	15	148
69	SUGANTHI	24	21875	37+6	9	9	YES	200	25	5	230	VD		NO	NO	NO	NO	NO	NO	8	9	74	104	78	14	142
70	UMA	22	21893	39+2	10	10	YES	320	60	10	390	VD		NO	NO	NO	NO	NO	NO	8	9	72	120	78	18	144
71	BHARATHI	20	21879	37+2	10	10	NO	400	25	5	430	VD		NO	NO	NO	NO	NO	NO	6	8	78	112	68	19	146
72	MANJULA	21	21921	38+4	9	9	YES	240	12	8	260	VD		NO	NO	NO	NO	NO	NO	8	9	80	116	68	17	148
73	SHALINI	25	21946	38+4	10	10	YES	280	30	7	317	VD		NO	NO	NO	NO	NO	NO	8	9	72	100	64	17	144
74	DAISY	23	21773	38+6	9	9	YES	220	25	10	255	VD		NO	NO	NO	NO	NO	NO	8	9	74	120	78	19	148
75	DEVIKA	22	21927	40+2	10	NIL	NO	280	15	10	305	VD		NO	NO	NO	NO	NO	NO	8	9	80	108	68	17	144
76	RATHI KUMARI	25	21994	37+2	9	9	YES	290	13	5	308	VD		NO	NO	NO	NO	NO	NO	8	9	76	116	68	16	148
77	SARANYA	19	21995	39	10	-	NO	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	8	9	78	110	66	19	136
78	SHANTHI	26	22012	38+2	10	10	YES	200	10	5	215	VD		NO	NO	NO	NO	NO	NO	7	8	72	118	64	16	128
79	CHANDRA KALA	26	21711	39+4	10	10	YES	180	10	4	194	VD		NO	NO	NO	NO	NO	NO	8	9	74	108	70	15	132
80	ANGALA PARAMESWARI	28	22023	37+2	8	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	8	9	80	106	66	17	138
81	TAMIL MOZHI	20	22070	40	10	10	YES	280	30	10	320	VD		NO	NO	NO	NO	NO	NO	8	9	82	118	68	19	136
82	JENEFFER	21	21958	39+1	10	10	NO	290	18	5	313	VD		NO	NO	NO	NO	NO	NO	8	9	80	120	70	17	152
83	RANJITHA	18	19807	38+2	9	NIL	YES	280	15	5	300	VD		NO	NO	NO	NO	NO	NO	8	9	84	118	72	18	148
84	NOORJAHAN	21	22173	39+1	8	10	YES	270	15	5	290	VD		NO	NO	NO	NO	NO	NO	8	9	80	108	74	16	142
85	PRAMILA	21	22146	37+5	9	10	YES	320	65	10	395	OUT-FOR		NO	NO	NO	NO	NO	NO	8	9	84	112	78	15	148
86	KAVITHA	28	22171	38+3	10	10	YES	300	18	12	330	VD		NO	NO	NO	NO	NO	NO	8	9	80	120	78	19	150
87	VUJAYA LAKSHMI	24	22247	39+6	10	10	NO	320	25	5	350	VD		NO	NO	NO	NO	NO	NO	7	8	78	108	70	15	148
88	GAYATHIRI	19	22140	39	9	10	YES	200	15	5	220	VD		NO	NO	NO	NO	NO	NO	8	9	80	110	68	17	142
89	SIRISHA	30	22276	38+2	10	10	YES	320	45	10	375	VD		NO	NO	NO	NO	NO	NO	8	9	82	118	64	17	148
90	CHITRA	21	22083	40+2	10	10	YES	200	18	10	228	VD		NO	NO	NO	NO	NO	NO	8	9	84	120	66	18	146
91	SURYA	21	22277	40	10	10	NO	220	20	10	250	VD		NO	NO	NO	NO	NO	NO	8	9	78	108	70	16	132
92	DHANA LAKSHMI	20	22185	39+4	9	10	YES	190	10	5	205	VD		NO	NO	NO	NO	NO	NO	8	9	80	114	68	16	130
93	RAMYA	19	22347	39+3	10	10	YES	180	15	5	200	VD		NO	NO	NO	NO	NO	NO	8	9	74	116	68	14	138
94	BHAVANI	21	21804	39+2	9	9	YES	260	10	5	275	VD		NO	NO	NO	NO	NO	NO	8	9	78	120	78	15	134
95	SAMSUNEESHA	20	22041	39+2	10	-	YES	-	-	-	-	LSCS	CPD	NO	NO	NO	NO	NO	NO	8	9	82	118	70	15	138
96	MAHAESHWARI	24	22309	40+2	10	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	7	9	82	120	78	19	130
97	STELLA MARY HEART	24	22419	39+1	8	9	YES	240	15	10	265	VD		NO	NO	NO	NO	NO	NO	7	8	78	108	70	17	144
98	USHA	29	22366	38+2	9	-	YES	-	-	-	-	LSCS	FA	NO	NO	NO	NO	NO	NO	8	9	76	108	68	18	142
99	HEPSIBA BEULA	22	22221	39	10	10	NO	260	10	10	280	VD		NO	NO	NO	NO	NO	NO	8	9	80	110	68	16	148
100	AYSHA BEEBI	21	22527	40+2	10	10	YES	280	60	10	350	OUT-FOR		YES	YES	NO	NO	NO	NO	8	9	84	118	70	14	144
101	KESARI	20	22443	40+1	10	10	YES	240	10	4	254	VD		NO	NO	NO	NO	NO	NO	8	9	82	100	60	18	142
102	PADMAVATHI	20	22541	39+4	9	NIL	NO	320	15	10	345	VD		NO	NO	NO	NO	NO	NO	8	9	76	108	70	15	138
103	SALOMI	18	22649	39+5	8	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	8	9	84	106	74	18	136
104	LAKSHMI	26	22301	39+6	10	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	8	9	80	116	76	16	138

105	SASI REKHA	26	21609	38+1	8	9	YES	280	63	7	350	OUT-FOR	NO	NO	NO	NO	NO	NO	8	9	78	114	68	15	140	
106	SUKANYA	21	22753	39+2	10	10	NO	270	33	7	310	VD	NO	NO	NO	NO	NO	NO	8	9	82	120	70	18	142	
107	DEEPA	20	22863	38+1	8	8	YES	250	23	10	283	VD	NO	NO	NO	NO	NO	NO	8	9	76	120	72	17	144	
108	UMA	22	22786	38+6	10	10	NO	240	10	5	255	VD	NO	NO	NO	NO	NO	NO	8	9	80	116	74	17	146	
109	PARAMESHWARI	24	22805	38+4	8	10	YES	280	20	5	305	VD	NO	NO	NO	NO	NO	NO	5	7	76	114	72	18	146	
110	NAFILA BEGUM	21	22798	40+5	8	10	YES	420	65	15	500	VACUUM	NO	NO	NO	NO	NO	NO	8	9	82	108	68	15	132	
111	SELVI	20	22785	40	8	10	YES	420	60	10	490	OUT-FOR	NO	NO	NO	NO	NO	NO	8	9	78	116	66	16	138	
112	SELVI	24	22810	39+1	10	10	YES	270	30	10	310	VD	NO	NO	NO	NO	NO	NO	8	9	84	114	64	19	136	
113	DHANA LAKSHMI	24	22872	39+5	9	-	YES	200	20	8	228	LSCS	FD	NO	NO	NO	NO	NO	7	8	78	110	72	16	142	
114	SUDHA	21	22821	39+1	10	10	YES	280	21	8	309	VD	NO	NO	NO	NO	NO	NO	9	9	80	108	68	17	148	
115	RAJEE	24	22866	37+2	7	9	YES	225	29	7	261	VD	NO	NO	NO	NO	NO	NO	8	9	82	110	66	17	138	
116	PREMALATHA	22	22919	38+2	9	-	YES	220	20	8	248	LSCS	NO	NO	NO	NO	NO	NO	8	9	82	108	64	18	148	
117	FARIDA	25	22938	39+2	10	10	NO	170	20	10	200	VD	NO	NO	NO	NO	NO	NO	8	9	78	118	68	15	146	
118	RUBINI	20	22932	38+1	9	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	8	9	78	108	72	18	146
119	IMANJULA	20	23046	40+1	8	-	YES	-	-	-	-	LSCS	FA	NO	NO	NO	NO	NO	NO	8	9	82	110	68	16	130
120	KAVITHA	23	22904	39+2	9	10	YES	320	42	10	372	OUT-FOR	NO	NO	NO	NO	NO	NO	8	9	80	118	78	20	148	
121	RADHA	26	23071	39+2	10	10	YES	200	60	10	270	VACUUM	NO	NO	NO	NO	NO	NO	8	9	80	114	74	21	134	
122	SUMATHI	23	23002	38	8	10	YES	320	28	12	360	VD	NO	NO	NO	NO	NO	NO	6	7	76	112	76	20	136	
123	SUDHA	23	20360	38+4	10	10	YES	250	38	12	300	VD	NO	NO	NO	NO	NO	NO	8	9	72	112	68	18	144	
124	REKHA	21	20102	39+5	9	10	YES	300	44	18	362	VD	YES	YES	NO	NO	NO	NO	8	9	82	120	78	19	142	
125	HEMALATHA	23	20335	38+6	10	-	YES	-	-	-	-	LSCS	CPD	NO	NO	NO	NO	NO	8	9	78	112	80	21	138	
126	SHANTI	24	20404	39+3	9	9	NO	210	21	7	238	VD	NO	NO	NO	NO	NO	NO	8	9	80	104	78	18	144	
127	VITHEEYA	21	20293	37+2	9	9	NO	300	18	6	324	VD	NO	NO	NO	NO	NO	NO	8	9	74	118	74	17	132	
128	SAVITHA	21	19968	37+5	10	9	YES	230	32	10	272	VD	NO	NO	NO	NO	NO	NO	8	9	78	114	68	15	138	
129	SELVI	18	20489	38+2	9	9	YES	200	20	5	225	VD	NO	NO	NO	NO	NO	NO	8	9	82	120	78	17	144	
130	KANKKADEVI	21	20683	37+2	10	10	YES	190	23	10	223	VD	NO	NO	NO	NO	NO	NO	8	9	86	112	74	19	146	
131	SHANTI	25	20723	39+1	10	9	YES	300	29	14	343	VD	YES	YES	NO	NO	NO	NO	8	9	88	114	72	20	148	
132	GEETHA	24	20750	37+1	9	9	NO	230	22	6	258	VD	NO	NO	NO	NO	NO	NO	8	9	76	118	74	21	144	
133	NITHYA	19	20792	39+1	7	10	YES	250	15	5	270	VD	NO	NO	NO	NO	NO	NO	8	9	78	108	68	18	132	
134	IRUDHYA MARY	21	20845	38+1	8	8	YES	330	31	7	368	VD	NO	NO	NO	NO	NO	NO	8	9	78	110	70	16	138	
135	KRISHNAVENI	30	20819	39+1	10	10	YES	270	25	10	305	VD	NO	NO	NO	NO	NO	NO	9	9	82	110	74	19	142	
136	SRIMATHI	23	20672	40	8	8	YES	360	55	10	425	VACUUM	NO	NO	NO	NO	NO	NO	8	9	82	120	78	18	138	
137	KUMUDHA	19	20882	39+2	10	10	NO	310	23	7	340	VD	NO	NO	NO	NO	NO	NO	8	9	80	100	76	19	144	
138	REKHA	20	20833	39+2	9	9	YES	280	27	10	317	VD	NO	NO	NO	NO	NO	NO	8	9	84	116	70	20	142	
139	GAYATHIRI	19	20946	39+1	10	10	YES	140	20	10	170	VD	NO	NO	NO	NO	NO	NO	8	9	78	114	74	19	148	
140	MAHESHWARI	25	20790	38+6	9	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	7	8	82	110	68	17	146	
141	INDIRA	21	20992	37+4	10	10	YES	400	50	10	460	VACUUM	NO	NO	NO	NO	NO	NO	8	9	78	118	66	21	142	
142	GEETHA	19	21129	39+4	10	10	NO	260	20	10	290	VD	NO	NO	NO	NO	NO	NO	8	9	78	116	64	15	138	
143	RADHA	23	21160	37+5	7	8	YES	250	18	7	275	VD	NO	NO	NO	NO	NO	NO	8	9	78	108	66	18	142	
144	PRIYA	24	21209	39+1	9	10	YES	320	28	10	358	VD	NO	NO	NO	NO	NO	NO	8	9	82	110	78	15	144	
145	AKILA	20	20956	39+6	8	10	YES	180	10	4	194	VD	NO	NO	NO	NO	NO	NO	8	9	82	120	74	16	146	
146	JOTHI	24	21346	40+1	10	10	YES	270	22	8	300	VD	NO	NO	NO	NO	NO	NO	8	9	80	112	70	19	136	
147	MEGHALA	24	19278	40+3	10	10	YES	200	23	10	233	VD	NO	NO	NO	NO	NO	NO	8	9	82	116	72	17	138	
148	AMALA	28	21400	39+6	9	9	NO	190	20	10	220	VD	NO	NO	NO	NO	NO	NO	6	8	84	118	74	14	132	
149	SANGEETHA	24	21376	40+5	10	9	YES	220	10	5	235	VD	NO	NO	NO	NO	NO	NO	8	9	78	120	68	18	142	
150	KAVITHA	23	21491	39+8	7	9	YES	240	23	7	270	VD	NO	NO	NO	NO	NO	NO	8	9	82	120	78	21	132	
151	GEETHA	23	21319	39+2	8	9	YES	200	20	10	230	VD	YES	YES	NO	NO	NO	NO	6	8	86	114	70	22	146	
152	VASANTHA MANJU	23	21597	37+2	10	9	YES	290	35	7	332	VD	NO	NO	NO	NO	NO	NO	8	9	84	118	72	19	132	
153	POONGODI	19	23052	38+5	10	-	YES	-	-	-	-	LSCS	FA	NO	NO	NO	NO	NO	8	9	78	108	68	18	132	
154	PRAKHA	28	23121	39+1	8	10	NO	280	25	10	315	VD	NO	NO	NO	NO	NO	NO	8	9	80	106	66	14	138	
155	DIIVA	20	23036	37	10	10	NO	270	30	10	310	VD	NO	NO	NO	NO	NO	NO	8	9	78	110	68	22	144	
156	SHOBANA	19	23048	37+6	10	9	YES	340	20	10	370	VD	NO	NO	NO	NO	NO	NO	8	9	78	116	78	15	146	
157	AARTHI	27	23145	38	10	10	YES	320	20	7	347	VD	NO	NO	NO	NO	NO	NO	8	9	80	100	70	18	142	
158	LATHA	25	23156	38+3	10	10	YES	360	30	10	400	OUT-FOR	NO	NO	NO	NO	NO	NO	7	8	82	120	78	19	148	

159	CHITRA	24	23153	38+2	9	10	YES	280	55	15	350	VD		NO	NO	NO	NO	NO	NO	8	9	80	118	74	20	146
160	KIRTHIKA	22	23158	39+1	9	10	NO	200	20	10	230	VD		NO	NO	NO	NO	NO	NO	8	9	82	108	68	16	144
161	VANITHA	25	23211	39+5	9	9	YES	320	35	15	370	VD		NO	NO	NO	NO	NO	NO	8	9	80	116	76	19	132
162	VIDHYA	27	23225	40+5	10	10	YES	280	23	7	310	VD		NO	NO	NO	NO	NO	NO	6	8	78	106	70	17	138
163	VENNILA	20	23228	39+3	9	10	YES	240	24	10	274	VD		NO	NO	NO	NO	NO	NO	8	9	80	104	70	15	148
164	RAJAKUMARI	21	23249	39+1	9	9	YES	300	23	10	333	VD		NO	NO	NO	NO	NO	NO	8	9	78	118	72	16	142
165	AMUDHA	23	23259	39+2	7	8	YES	210	15	7	232	VD		NO	NO	NO	NO	NO	NO	8	9	80	116	74	19	134
166	PREMA	22	23267	38+1	9	9	YES	340	35	10	385	VACUUM		NO	NO	NO	NO	NO	NO	8	9	82	120	76	17	136
167	PRASANNA	23	23273	38+5	8	10	NO	280	25	5	310	VD		NO	NO	NO	NO	NO	NO	8	9	84	118	78	18	142
168	REKHA	19	23281	40	7	9	YES	300	21	7	328	VD		NO	NO	NO	NO	NO	NO	8	9	78	116	78	16	138
169	POORNIMA	20	23290	37+6	10	10	YES	200	15	5	220	VD		NO	NO	NO	NO	NO	NO	8	9	80	114	64	19	142
170	MYTHILI	22	23301	38+5	9	9	YES	190	20	8	218	VD		NO	NO	NO	NO	NO	NO	8	9	78	118	68	16	132
171	TAMILSELVI	21	23319	38+1	10	10	NO	280	38	10	328	VD		NO	NO	NO	NO	NO	NO	8	9	82	120	78	17	136
172	RANI	24	23328	39+3	10	10	YES	300	40	10	350	VD		NO	NO	NO	NO	NO	NO	8	9	80	110	70	15	142
173	MAHESHWARI	20	23308	39+1	9	10	YES	180	20	5	205	VD		YES	YES	NO	NO	NO	NO	8	9	84	106	76	19	144
174	KALAIYANI	19	23343	39+1	10	9	YES	210	25	10	245	VD		NO	NO	NO	NO	NO	NO	7	8	84	102	74	15	138
175	MUTHULAKSHMI	20	23352	38+5	9	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	6	8	88	100	68	17	132
176	VASUJI	22	23348	38+1	8	10	YES	250	23	10	283	VD		NO	NO	NO	NO	NO	NO	8	9	86	110	78	18	142
177	MERCULIN	23	23339	38+5	10	10	YES	310	20	10	340	VD		NO	NO	NO	NO	NO	NO	8	9	78	108	76	16	148
178	ILAVARASI	21	23367	38+1	9	9	YES	380	20	7	407	OUT-FOR		NO	NO	NO	NO	NO	NO	8	9	80	114	78	20	146
179	SINDHUJA	20	23349	39+4	8	9	NO	240	30	10	280	VD		NO	NO	NO	NO	NO	NO	8	9	82	116	74	18	136
180	SASIKALA	25	23350	39+5	10	10	YES	290	23	17	230	VD		NO	NO	NO	NO	NO	NO	8	9	86	120	78	19	136
181	SOWMYA	29	23376	39+3	8	8	YES	150	10	5	165	VD		NO	NO	NO	NO	NO	NO	8	9	78	110	80	17	142
182	SHANTHI	27	23358	38+5	9	9	YES	290	15	10	315	VD		NO	NO	NO	NO	NO	NO	8	9	84	108	78	14	148
183	ZEENATH	19	23365	39	10	10	YES	260	20	10	290	VD		NO	NO	NO	NO	NO	NO	8	9	80	118	76	18	142
184	GNAMAMBAL	22	23373	39+1	8	10	NO	215	15	10	240	VD		NO	NO	NO	NO	NO	NO	8	9	82	116	76	17	128
185	MALATHI	23	23394	39+4	10	10	YES	290	30	10	330	VD		NO	NO	NO	NO	NO	NO	8	9	78	110	70	18	150
186	PARVATHAM	22	23402	38+4	10	10	YES	320	20	10	350	VD		NO	NO	NO	NO	NO	NO	8	9	82	116	74	15	146
187	LALITHA	20	23471	38	10	10	YES	240	28	12	280	VD		NO	NO	NO	NO	NO	NO	8	9	80	118	72	14	144
188	VENI	25	23492	38+1	7	10	YES	200	10	10	220	VD		NO	NO	NO	NO	NO	NO	7	8	86	108	72	20	138
189	SIVAKAMI	26	23520	38+6	8	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	7	8	82	108	78	14	134
190	RADHIKA	20	23534	38+2	10	10	YES	300	25	10	335	OUT-FOR		NO	NO	NO	NO	NO	NO	8	9	78	116	68	15	144
191	KOUSALYA	24	23541	38+4	10	10	NO	180	25	10	215	VD		NO	NO	NO	NO	NO	NO	8	9	84	114	66	19	152
192	CHITRA	25	23452	39+1	8	8	YES	360	45	15	420	VD		NO	NO	NO	NO	NO	NO	8	9	78	114	64	20	148
193	DEVI RANI	27	23491	39+4	10	10	YES	280	30	10	320	VD		NO	NO	NO	NO	NO	NO	8	9	82	120	74	18	144
194	KAMALAVENI	22	23555	39	7	8	YES	320	30	10	360	VD		NO	NO	NO	NO	NO	NO	8	9	80	110	68	16	136
195	ROHINI	24	23561	40+2	9	9	YES	240	31	13	284	VD		YES	YES	NO	NO	NO	NO	8	9	78	118	74	17	144
196	SINDHUMATHI	23	23569	40+5	10	10	YES	220	30	15	265	VD		NO	NO	NO	NO	NO	NO	8	9	80	114	72	16	148
197	PADMAVATHI	23	23571	39+4	9	10	NO	270	24	8	302	VD		NO	NO	NO	NO	NO	NO	8	9	84	112	76	15	132
198	RAJAM	22	23578	39+5	10	10	YES	310	30	10	350	VD		NO	NO	NO	NO	NO	NO	8	9	88	118	74	19	142
199	KAVYA	20	23582	38+3	8	-	YES	-	-	-	-	LSCS	FD	NO	NO	NO	NO	NO	NO	8	9	78	110	74	17	138
200	KAVALVIZHI	21	23589	38+4	10	10	YES	320	20	5	345	VD		NO	NO	NO	NO	NO	NO	8	9	80	108	76	16	144

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. V.S. Vaishnavi
PG in MS Obstetrics & Gynaecology
Instt. of Obstetrics & Gynaecology
Egmore, Chennai 8

Dear Dr. V.S. Vaishnavi

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled "A prospective study on injection tramadol hydrochloride as a labour analgesic and its effect on duration of labour" No.1602082012.


The following members of Ethics Committee were present in the meeting held on 10/08/2012 conducted at Madras Medical College, Chennai -3.

- | | |
|--|---------------------|
| 1. Dr. S.K. Rajan. M.D.,FRCP.,DSc | -- Chairperson |
| 2. Prof. Pregna B. Dolia MD
Vice Principal, Madras Medical College, Chennai -3
Director , Institute of Biochemistry, MMC, Ch-3 | -- Member Secretary |
| 3. Prof. B. Vasanthi MD
Prof of Pharmacology ,MMC, Ch-3 | -- Member |
| 4. Prof. C. Rajendiran, MD
Director , Inst. Of Internal Medicine, MMC, Ch-3 | -- Member |
| 5. Prof. S. Deivanayagam MS
Prof of Surgery, MMC, Ch-3 | -- Member |
| 6. Thiru. S. Govindsamy. BABL | -- Lawyer |
| 7. Tmt. Arnold Soulina MA MSW | -- Social Scientist |

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.


Member Secretary, Ethics Committee

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