A Dissertation on

"EVALUATION OF MATERNAL AND FOETAL OUTCOME IN LOW DOSE EPIDURAL ANALGESIA FOR PAINLESS LABOUR"

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CERTIFICATE

This is to certify that the dissertation titled "EVALUATION OF MATERNAL AND FOETAL OUTCOME IN LOW DOSE EPIDURAL ANALGESIA FOR PAINLESS LABOUR" presented herein by Dr. P. SHANTHI is an original work done in the Department of Obstetrics and Gynecology, Govt. R.S.R.M Lying in Hospital, Stanley Medical College Hospital, Chennai for the award of the degree of M.D. (Branch) Obstetrics and Gynecology under our guidance and supervision during the academic year 2005 – 2008.

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DECLARATION

I, Dr. P. SHANTHI solemnly declare that the dissertation titled "EVALUATION OF MATERNAL AND FOETAL OUTCOME IN LOW DOSE EPIDURAL ANALGESIA FOR PAINLESS LABOUR" is a bonafide work done by me in the Department of Obstetrics and Gynecology, Govt. R.S.R.M Lying in Hospital, Stanley Medical College Hospital, Chennai, under the able guidance of PROF.DR. NALINI MD., DGO., The Superintendent, Department of Obstetrics and Gynecology, Govt. R.S.R.M Lying in Hospital, Stanley Medical College Hospital, Chennai- 600001.

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INTRODUCTION

"For all the happiness mankind can gain is not in pleasure but in rest from pain." JOHN DRYDEN.

The word pain is derived from the latin word "poena" meaning punishment. In the ancient times pain was considered to be punishment from god.

The distress and pain which women often endure while in labour, is beyond description and seems to be more than what human nature will be able to bear under any other circumstance.

James Simpson described the first obstetric analgesia 150 years ago.

Although not without risks epidural analgesia is the gold standard for pain relief in labour. There are side effects serious, and so serious, attached to all procedures carried out in medical practice and risk to benefit ratio with each of these procedure is the major determinant of its continuation.

Epidural analgesia, with lower concentration namely "WALKING EPIDURAL" where ambulation is possible is recently becoming popular.

AIM

- To determine the efficacy of epidural analgesia as a method of pain relief in labour.
- 2. To examine the effect of epidural analgesia on progress of labour.
- 3. To assess the effect of epidural analgesia on the outcome of labour.

PAIN OF PARTURITION

PAIN OF 1st STAGE

- Rhythmic uterine contraction and progressive cervical dilatation causes much of the pain in first stage.
- Afferent impulses from the cervix are transmitted to the spinal cord via segment T10 to L1.
- This usually produces pain over the lower abdomen, lower back, and the sacrum.
- More than two third of the women describe their pain as distressing, horrible, or excruciating.

PAIN OF 2nd STAGE

- Briefer than the first stage, but more intense.
- Perineal pain due to stretching of the vagina, vulva, and the perineum is superimposed on the uterine contractions.

 Second stage is primarily somatic in nature and transmitted via S2 to S4 segments.

EFFECT OF LABOUR PAIN AND MODIFICATION WITH ANALGESIA

(I) EFFECT ON MOTHER

A. RESPIRATORY SYSTEM :

Labour pain is a powerful ventilatory stimulator. So, parturient tends to hyperventilate. Following hyperventilation, Pa Co2 falls from 32 mmHg (to 16mmHg to 20mmHg) and pH raises to 7.55-7.60. During relaxation phase, pain no longer stimulates respiration so that hypocapnia causes a transient period of hypoventilation that decreases the maternal Pa O2 by 10 to 15%. When it falls below 70mmHg it has significant effect on foetus.

EFFECT OF ANALGESIA

Complete pain relief with epidural analgesia prevents transient period of hyperventilation and prevents hypoventilation during relaxation. So, Pa Co2 and PaO2 remain constant.

B. CVS

Uterine contractions cause 40 to 50% increase in the cardiac output above the prelabour value, due to extrusion of 250 to 300 ml of blood from the uterus into the maternal central circulation and due to the sympathetic activity provoked by pain. It increases systolic blood pressure by 20 - 30mmHg and that of diastolic by 15-20mmHg.

EFFECT OF ANALGESIA

Epidural analgesia by producing complete block of the nociceptive receptor pathway obviates the pain induced alterations in the cardiac output and blood pressure.

C. METABOLIC AND ENDOCRINE SYSTEM.

Work of labour, increases O2 consumption, increases metabolism, decreases GIT and urinary bladder motility and delays gastric emptying. It also increases maternal catecholamines, particularly noradrenaline and cortisol. Increase in O2 consumption causes maternal acidosis (metabolic) and foetal acidosis.

EFFECT OF ANALGESIA.

Decreases total work of labour, maternal metabolism and O2 consumption.

D. PSYCHOLOGICAL.

Severe labour pain produces serious long term emotional disturbances, where maternal health is affected. It creates negative influence on the baby and future pregnancy fear.

2) EFFECT ON UTERINE ACTIVITY AND LABOUR.

Pain produces incoordinate uterine actions manifested by a decrease in intensity, coupled with an increase in frequency and basal uterine tonus.

EFFECT OF ANALGESIA.

By decreasing the sympathetic induced hyperactivity, produces normal labour pattern and also decreases basal uterine tonus, thereby increases placental blood flow.

3) EFFECT ON FOETUS.

Uterine contractions cause intermittent reduction in the blood flow during their peak. This, with maternal alkalosis and hyperventilation shifts the Hb O2 curve to left, leading to maternal hypoxemia during relaxation phase and also umbilical vasoconstriction leading to foetal acidosis.

EFEECT OF ANALGESIA.

Epidural analgesia through its vasomotor blocking effect increases the intervillous blood flow in the placenta and decreases foetal acidosis.

METHODS OF PAIN MEASUREMENT.

Pain is personal, subjective, experience influenced by cultural learning, the meaning of the situation, attention and other psychological variables. Melzack and Casey et al., suggested a 3 dimensional view of pain which comprises of sensory- discriminative, motivational- affective and cognitive – evaluate components.

Methods of pain measurements.

- 1. Verbal rating scale.
- 2. Visual analogue pain scale.
- 3. Mc.Gill pain questionnaire.
- 4. The descriptor differentiating scale.

VAS – Advantages:

- 1. Simple, efferent, minimally intrusive measure of pain intensity.
- 2. Widely used in research.
- 3. Has ratio scale property.

4. Provided, adequate clear instructions are given to the patients, it's conceptual simplicity.

VAS – Disadvantages:

- 1. Bias of expectancy for change and reliance on memory.
- 2. Its assumption that pain is a uni-dimensional experience.

METHOD OF LABOUR PAIN RELIEF.

SYSTEMIC

- Narcotic analgesia
- Sedatives
- Ketamine
- Inhalational agents- Entonox.

REGIONAL

- Lumbar epidural block.
- Caudal epidural block.
- Sub arachnoid block.
- Combined spinal epidural.

- Lumbar sympathetic block.
- Paracervical block.
- Pudendal block.

Non-pharmacological methods.

- Psycho prophylaxis
- Hypnosis.
- Acupuncture
- Audio analgesia.
- Electro analgesia.
- TENS (trans cutaneous electrical nerve stimulation)

EPIDURAL SPACE

ANATOMY AND CHANGES IN PREGNANY.

The epidural space is the interval between the periosteum lining the vertebral canal and the duramater surrounding the canal in its extension from the foramen magnum to the lower end of dural sac.

It is also referred as extradural or peridural space.

BOUNDARIES

Superiorly:	Foramen magnum.
Inferiorly :	Sacro coccygeal membrane.

- Anteriorly : Posterior longitudinal ligament covering Vertebral bodies and discs.
- Posteriorly : Anterior surfaces of lamina connecting Ligaments , roots of spina ligamentum Flavum.

CONTENTS

- •Dural sac
- •Spinal nerve roots
- •Extradural plexus of veins
- •Spinal arteries
- •Lymphatics and fat.

SIZE

- Anterior portion 1mm (throughout the length) Posterolateral - at cervical level 1.5 -2 mm. - at thoracic level 3 -5 mm.
 - at lumbar level 4-6 mm.

CHANGES DURING PREGNANCY

• The lumbar lordosis associated with pregnancy, increases the technical difficulty in performing epidural or subarachnoid puncture when midline method is carried out.

• Increased elastic tissue and softening of the connective tissue and increased water content, leads to difficulty in identifying the epidural space by loss of resistance technique.

• Intermittent obstruction of the Inferior vena cava by the enlarged uterus encourages the venous drainage through alternate pathways and so the vertebral or azygos system dilates the epidural internal vertebral plexus which reduces the internal volume of the epidural space. Hence, segmental doses are reduced in pregnancy.

• During the uterine contraction, sudden efflux of blood from the contracting uterus into the venous system increases the epidural pressure, so the spread of the anaesthetic solution in the epidural space will be exaggerated during a contraction, so injection should not be made at this

time. The risk of venous puncture by needle or catheter will be increased if either is inserted into the epidural space during a contraction, because of engorged vertebral plexus. In the non pregnant state, the pressure in the lumbar epidural space is normally -1cm of H2O. In early labour, between contractions, pressure in the lateral position averages 1.63 cm H2O and raise to 4 - 10 cm H2O by the end of first stage of labour during contractions. Assuming that, the supine position will increase the epidural pressure further proportional to the degree of IVC obstruction and there is a positive pressure inside the epidural space in pregnancy, methods of identifying the space which depends on the presence of negative pressure are not recommended.

PHARMACOLOGY

BUPIVACAINE

Bupivacaine is a synthetic drug and was prepared by A.F.Ekenstam in 1957.The molecular weight of the chloride salt is 325 and that of the base is 288. The pH of the solution containing epinephrine is 3.5. It is an anilide compound .Chemical name is 1-nbutyl- DL-piperidine-2- carboxylic acid 2, 6 dimethyl anilide hydrochloride.

MECHANISM OF ACTION

The base form is in equilibrium with cationic form outside the axoplasmic membrane. It prevents Na+ ions moving intracellularly. It also affects the second messenger system such as adenylate cyclase and guanylate cyclase and also inhibits the synaptic transmission by modification of post or presynaptic Calcium channel blockade in epidural or subarachnoid block.

PHARMACOKINETICS

The drug is rapidly absorbed after epidural administration and enters the circulation after the local anaesthetic has been taken up into local tissues such as epidural fat. Distribution of local anaesthetic has special emphasis in the pregnant patient because one of the organs that will be exposed to the absorbed drug is the foeto-placental unit. The protein binding to the maternal tissues is 95% and to the foetus is 66%. The anaesthetic index is 3.0 - 4.0. The elimination half life is 162 mins and the liver is the site of metabolism.

CLINICAL CHARACTERISTICS

Penetrance	- Moderate.
Duration	- 6 to 8 hrs.
Infiltration	- 0.05%
Field block	- 0.1%
Pudendal / Paracervical	- 0.125%
Extradural analgesia	- 0.125 % to 0.25%
Extradural motor	- 0.5% to 0.75%
Maximal dose	- 2 mg / kg body weight.

EPIDURAL BLOCK

For obstetrical analgesia and perineal surgeries 20 ml of 0.25% solution is effective whereas recent studies using 0.1%, 0.075%, and

0.0625% solution are coming out with promising results, with least effect on mother and foetus, especially no motor blockade.

SIDE EFFECTS AND COMPLICATIONS

CNS TOXICITY

Potentially toxic blood levels can occur when the drug is injected intravenously, intra arterially or a large dose is given into a highly vascularised area. Risks of CNS toxicity is more because bupivacaine is a highly protein bound drug. Pregnancy is associated with 30% reduction in the protein binding. This allows for higher brain levels for a given dose. The symptoms of CNS toxicity include slow speech, jerky movements, tremors, hallucinations and seizures. As such these complications can be very well avoided by enduring correct technique and by avoiding inappropriately larger doses.

CVS TOXICITY

It causes dose dependent depression of contractility and this may cause progressive prolongation of ventricular conduction and ventricular fibrillation due to reentry phenomenon. Toxic plasma concentration is 4-5 mcg/ml.

FENTANYL

Fentanyl citrate is a synthetic phenyl piperidine derivative. M μ 2 receptor agonist .It is a chemical congener of reversed ester of pethidine and 80-100 times as potent as morphine.

PHARMACOKINETICS

Fentanyl has a rapid onset and shorter duration of action. It is highly lipid soluble and redistributed. It is metabolized in liver by demethylation and excreted by kidneys.

Since 1980 Fentanyl is used in epidural analgesia.

- Dose 50-200 mcg
- Onset 5-15 mins
- Duration 2-4 hrs after a single dose.

SIDE EFFECTS

- Pruritus
- Sedation
- Urinary retention
- Nausea and vomiting

- Apnea
- Seizures

SYNERGISTIC ACTION OF EPIDURAL L.A / OPIOD MIX

- Local anesthetics reduce the afferent input to spinal cord via A delta and C fibers.
- Opiods modulates C and some A delta fibres at substantia gelatinosa.
- Both reduce central transmission via spinothalamic tract.

OPIATES IN OBSTETRIC ANALGESIA

- Synergistic effect with Local anesthetics reduces the dose of the same, with less motor block.
- Reduced incidence of one sided and missed segment blocking.
- Alleviates persistent back and perineal pain.
- Reduces incidence and severity of shivering.
- Less hypotension with less L.A dose.
- Post operative and delivery pain optimized.

EPIDURAL ANALGESIA IN LABOUR PRELIMINARY CONSIDERATION

American society of Anaesthesiology published guidelines for regional anaesthesia in obstetrics.

INDICATION

American college of O&G and American society of anesthesiologists have collectively published the opinion that-

"Maternal request is sufficient justification for pain relief in labour."

All they point out is that

"There is no other circumstance, where it is considered acceptable for a person to experience severe pain, amenable to safe intervention, while under physician's care.

SPECIAL INDICATIONS

- Unusually painful labour
- Preeclampsia
- Incoordinate uterine contractions
- Premature labour
- Cardiac and respiratory diseases
- Diabetes mellitus
- Trial of scar

• Recent abdominal surgery

CONTRAINDICATION

- Patients refusal
- Active maternal hemorrhage
- Maternal septicemia, febrile illness, local sepsis
- Maternal coagulopathy
- Hypersensitive to drugs
- Anatomical defects of spine
- Previous spinal surgery

PROS & CONS

PROS

- Superior pain relief
- Facilitates patients co-operation
- Provides anaesthesia for episiotomy or forceps delivery
- Allows extension of anaesthesia for caesarean section
- Avoids opiod induced maternal & neonatal respiratory depression
- Close monitoring by hospital staffs gives mother sense of confidence

CONS

- Labour may be prolonged.
- Catheterization of the bladder may be required
- Increased need for instrumental delivery
- Extremely rare, but life threatening risk exists, about which the mother and the partner must be aware

TIMING

Appropriate to induce epidural after diagnosis of active labour is established and the patient has begun to request pain relief. However, women receiving oxytocin augmentation may request analgesia at minimal cervical dilatation.

COMPLICATIONS

- Hypotension
- Perforation of duramater
- Total spinal blockade
- High epidural block
- Epidural hematoma
- Toxic reactions [0.2%] in the form of generalized fits

- Breakage of catheter or needle
- Late neurological sequel : rare

SIDE EFFECTS

- Nausea and vomiting
- Post spinal headache
- Chills & shivering
- Pruritus
- Disturbance in micturition.
- Low backache

MATERIAL & METHODS

STUDY DESIGN

Experimental study

SETTING

Govt. R.S.R.M Lying in Hospital, Chennai.

PERIOD OF STUDY

July 2007 to September 2007

PARTICIPANTS

80 Primi in labour assigned to

GROUP A

40 Parturients who were administered epidural analgesia for

pain relief.

GROUP B

40 Parturients who received no form of pain relief.

INCLUSION CRITERIA

- Spontaneously labouring mothers
- Single term cephalic foetus.
- Cervix 3 to 4 cm dilated.
- Normal obstetric and medical history.
- No contraindication for epidural analgesia.

EXCLUSION CRITERIA

- If they have received an opiod drug preceding epidural analgesia.
- Malpresentation and multiple pregnancies.
- Previous history of miscarriages.
- Major degree of CPD.

TECHNIQUE

All women fulfilling the inclusion criteria were identified, and the study was explained. If they agreed, they were allotted to group A. If they refused, they were allotted to group B. A written consent duly signed by the patient was obtained.

BASELINE PARAMETERS such as

- Pulse rate
- Blood pressure
- Respiratory rate
- Visual analogue pain scale
- O2 saturation
- Foetal heart rate were assessed.

After the baseline assessments, the parturient was wheeled into the operation theatre. The pulse oximetry, the boyle's apparatus, and emergency drugs were checked and kept ready.

Within 30 mins of recruitment, determination of cervical dilatation was done and the patient prepared for study. Intravenous line was secured and maternal circulation was preloaded with 500ml of Ringers lactate solution.

Under strict aseptic precautions with the patient in right lateral position, 17G Tuohy needle was introduced through the L2 – L3 interspace. The epidural space was identified, and the catheter was then introduced for a distance of 5 cm into the epidural space and aspirated gently for blood or cerebrospinal fluid. After the catheter's position was checked, a test dose of 3ml of 1.5% lignocaine with 15mcg of adrenaline was injected via the catheter. The catheter was then secured and the patient shifted to labour room. In the labour room the parturient was placed in supine position with a left tilt (by using a wedge) and head end elevation of 15– 20 degrees. An initial bolus of 10ml of the study solution containing 0.1% bupivacaine with 2mcg per ml of fentanyl was administered.

The maternal heart rate, blood pressure, respiratory rate, SpO2, foetal heart rate, VAS, sensory level and motor level were assessed every 2 minutes for the first ten minutes and thereafter every 5 minutes till 30 minutes and then every 30 minutes till next topup. The time of onset of painless contraction was noted. The establishment of epidural blockade was identified by loss of pinprick sensation. VAS scoring was performed every 30 mins after each topup till the end of delivery. Hypotension (defined as a decrease of 20% from the baseline blood pressure) was treated with ephedrine. Motor block assessed by Bromage scale.

BROMAGE SCALE

Grade	Level of motor block	Clinical assessment
0	Nil	Free movement of legs and feet
1	Partial	Just able to flex the knees, free movement of feet
2	Almost complete	Unable to flex the knees, free movement of feet
3	Complete	Unable to move both legs and feet.

The motor block was tested after 30 min of initiating the block to assess the adequacy of motor function to permit ambulation. The parturient was asked to perform the following tests sequentially.

- Straight leg raising
- To sit at the edge of cot
- Stand for a min without support
- Perform a deep knee bend test

• Three unassisted steps

Only if the parturient was able to perform all these tests she was allowed to ambulation with the help of a companion.

- Ability to micturate or the need for catheterization was assessed.
- Foetal heart rate was monitored using foetoscope and cardiotocograph.
- Progress of labour was assessed by per abdomen and per vaginal examination.
- The occurrence of side effects or complication was noted.

Topup doses of 7ml of the study solution were given on an hourly basis irrespective of the pain status. If the second stage commenced after 30 min of the preceding dose then 7ml was injected in sitting position. If it was less than 30 min then topup was not given and the VAS score was assessed after 10 min. If the patient did not receive adequate pain relief within 30 min then an additional 5ml of the study solution was given and the topup doses were administered from then.

In the second stage, labour was accelerated with oxytocin 5u in 500 ml of ringers lactate solution.

- Duration of 1st stage and 2nd stage of labour was noted
- Mode of delivery noted and if other than normal the reason for the intervention was noted.
- The response to episiotomy was noted and if inadequate local infiltration was given

Grade 0	No pain
Grade 1	Tolerable pain
Grade 2	Intolerable pain

• Foetal outcome (by APGAR scoring at 1min and 5mins) was noted.

REVIEW OF LITERATURE

"When a thing ceases to be a subject of controversy, it ceases to be a subject of interest".

-William Hazlitt.

In spite of the widespread acceptance that epidural analgesia has achieved among many patients and physicians, disagreement remains regarding the effect of intrapartum epidural analgesia on the subsequent progress of labour and mode of delivery.

Although a cause and effect relationship has not been proven, this form of analgesia has been blamed for a host of adverse maternal and foetal events, namely prolonged 1st and 2nd stages of labour, dystocia, malrotation of foetal head, and a increased risk of operative delivery.

This review highlights some controversies in this regard.

CONTROVERSIAL ISSUES

 Primigravida can be reassured that epidural analgesia does not increase the incidence of forceps delivery.
1. (a) ARGUMENTS FOR : J.A.STORRS(8)

Despite the long standing controversy, the assumption that a correlation between the forceps rate and epidural analgesia in any particular obstetric unit represents cause and effect is incorrect.

Forceps delivery rates are specific to that particular obstetric unit and are demonstrably independent of the application of epidural analgesia.

DATA SUPPORT

- The obstetric activities in the Princess Mary maternity hospital from 1969 – 1985 were examined. Despite the introduction and establishment of the epidural services, there had been a stable rate of forceps intervention in the range of 18% to 24%
- Bailey et al., 1983 (3) reported that, the patterns of obstetric interventions 'before' and 'after' the establishment of epidural services were similar.
- Doughty et al ., 1969(10) had shown that , as the epidural services moved from start up stage to a steady state level there was a fall in the epidural / forceps ratio.

4. WHY THEN DOES THE MYTH EXIST THAT AN EPIDURAL MEANS THAT A FORCEPS DELIVERY WILL INEVITABLY RESULT?

- This is probably the result of statistics derived from the early application of the method in restricted population. The extrapolation of these findings to unbiased, unrestricted patient population is invalid (8).
- A primigravida may therefore be reassured that epidural analgesia, does not per se increase the incidence of forceps delivery.

1(b) ARGUMENTS AGAINST: R.P.HUSEMEYER (8)

Why would any woman having a baby need reassurance about a possible increased incidence of forceps delivery?

"The simple answer is that women obtain an enormous sense of achievement from delivering babies exclusively by their own effort".

There are several, clear, logical reasons, why we should expect an epidural block to increase the need for assisted delivery:

- Epidural block interferes with the primary forces of labour, that is force of uterine contraction by obtunding the fergusson's reflex.
- 2. There is interference with the secondary forces of labour, both voluntary and semi-voluntary.
- 3. Pressure exerted, by the presenting part, initiates the bearing down effect which leads to an irresistible urge to respond with strongest expulsive forces. It is difficult to generate the same effort simply by verbal encouragement to push harder.
- 4. Epidural causes relaxation of the pelvic diaphragm and interferes with the rotation of the foetal head.

DATA SUPPORT

- 1. On Oxford, Hoult et al., 1997 (11) concluded in his study that instrumental delivery was 5 times more common in women with epidural.
- 2. In 1980, a report from Birmingham (23) found the epidural were associated with a 20 fold increase in rotational deliveries.

3. Sir, John Stallworthy, 1969 (22) Professor of OBG at Oxford, recognized the increased need for assisted delivery in epidural analgesia and said that:

"The increase in the incidence of assisted delivery is a small price to pay for the benefit received"

2. EPIDURAL ANALGESIA NEED NOT INCREASE OPERATIVE DELIVERY RATES

IMPEY L, MAC QUILLAN, ROBSON.M 2000 (13)

This is a retrospective analysis of the first 1000 nulliparous pregnancies in woman at term in each of 3 different years, over which epidural rate increased from 10% to 57%.

RESULTS

Caesarean and forceps delivery rates were similar in all 3 years, though oxytocin use in the second stage increased considerably.

CONCLUSION

Increased use of epidural analgesia had no effect on operative delivery rates. Although early randomized trials have suggested an increase in forceps delivery rate, this might be overcome by active management of labour or judicious of oxytocin in second stage of labour.

3. OBSERVATIONS ON LABOUR EPIDURAL ANALGESIA AND OPERATIVE DELIVERY RATES :

YANCEY MK, PIERCE B, SCHEWEITZER D, DANIEL D. 1999 (2)

A total of 4859 women gave birth during the study period (20 months) when on demand epidural analgesia was available, and 4778 woman gave birth in the study period before the availability of epidural analgesia.

RESULTS

Comparisons demonstrated no statistically significant differences in the rate of spontaneous vaginal delivery, overall caesarean delivery or the operative vaginal delivery rate, between the two periods.

CONCLUSION

The introduction of an on demand epidural analgesia services does not increase the rate of caesarean or forceps rates.

4. HOWEL C.J; EPIDURAL VS. NON EPIDURAL FOR PAIN RELIEF IN LABOUR – COCHRANE REVIEW, 1999 (12)

Both a Cochrane library review and a meta-analysis published in the Journal of American Medical Association concluded that epidural analgesia is associated with longer labours, greater use of oxytocin, and an increase in the rate of operative vaginal deliveries.

5. EPIDURAL ANALGESIA AND CAESEREAN DELIVERY RATES

This controversial issue is illustrated by the opposing conclusions of two studies originating from the same institution.

Ramin and Colleagues, 1995 (19) reported that the risk of operative delivery for dystocia was increased nearly two fold among women who were given epidural rather than intravenous meperidine analgesia.

In the same institution two years later, Sharma et al., 1997(26) observed identical caesarean rates among women randomized to receive either epidural or intravenous meperidine analgesia.

6. RESULTS OF META ANALYSIS

SALLY C.MORTON, MARK.S. WILLIAMS, KEELER, 1994 (21)

A 1994 Meta analysis of pooled data from six studies determined that the caesarean delivery rates were 10% higher in women with epidural.

But two years later, another Meta analysis by Howel C.J. et al., 1999 (12) did not find statistically significant association between the use of epidural and caesarean sections.

7. DOES THE EPIDURAL ANALGESIA INCREASE THE SECOND STAGE OF LABOUR?

JOHNSON'S, ROSENFELD JA, MARCH 1995 (31).

The study included all women in Bristol Residency delivering over one year period, from July 1, 1993 to July 30, 1994. The average length of second stage of labour was increased to 84 minutes in the epidural group compared to 46 minutes in the control group. The differences in the number of caesareans were not statistically significant, while the difference in the number of forceps deliveries was significant.

SHARMA et al., 2007 (27) demonstrated that the second stage was not prolonged markedly (30 to 90 min.) with Bupivacaine 0.1% and opiod.

8. STUDIES OF CHESTNUT et al., 1990 (6) & C.BAWFORD et al., 1972 (9)

In general, there appears to be no clear effect on the duration of first stage of labour. The second stage is more consistently prolonged in both primi and multiparous women, but this prolongation is less marked , when dilute concentrations are used.

9. LOW DOSE EPIDURAL AND SECOND STAGE

Hart Em et al., 2003 (29) and Sharma et al., 2007 (27) have demonstrated that low dose epidural (0.1% Bupivacaine and 2mcg/ ml Fentanyl) did not prolong the second stage markedly.

10. EPIDURAL ANALGESIA AND LABOUR OUTCOME

Lieberman E, et al.,1996 (20, 30) demonstrated that Epidural analgesia is associated with prolonged duration of labour and increased forceps deliveries .

The controversy especially between the anesthetist and obstetricians, is whether this is a cause and effect relationship, or, if a woman at risk of dysfunctional labour and operative delivery is more likely to ask for epidural analgesia.

PALMER AND COLLEAGUES 1996(17) demonstrated that patients at risk for prolonged labours are more likely to request epidural analgesia than women with uncomplicated labours.

11. REDEFINING THE MANAGEMENT OF SECOND STAGE OF LABOUR WITH EPIDURAL ANALGESIA

Some physicians have developed specific innovations in the management of second stage with epidural in an effort to reduce complications and increase the rate of normal vaginal deliveries.

- Early aggressive use of oxytocin to prevent dystocia (32)
- Increasing the acceptable limits for second stage of labour (1, 7, 15)
- Delayed pushing, until the baby's head is crowning(16).

12. N.J.SAUNDERS et al., 1989 (32) demonstrated that oxytocin acceleration was associated with shorter second stage and a reduction in non- rotational forceps delivery and less perineal trauma.

13. KADAR AND ROMERO et al., 1983 (15)

According to their data, 97% of the primigravida, delivered spontaneously, with a second stage lasting for two hours.

Prolongation of the second stage is not itself, harmful to the foetus. If there is no evidence of foetal distress and if the mother displays no sign of undue fatigue, there is no recognizable limit to time which can be invested in delivery process.

A retrospective study by Cohen W.R et al., 1977(7) on 4403 primipara found, "No relationship between apgar and the duration of second stage of labour" **14. THE ACOG COMMITTEE IN FEB. 1988** (1) pointed out that with the use of electronic foetal monitoring, a prolongation of second stage, need no longer be a reason for instrumental delivery.

15. THOBRURN AND MOIR, 1981(24) reported a significant decrease in the forceps rate using epidural with more dilute solutions of Bupivacaine and addition of opiods further reduces the forceps rate. (CHESTNUT DH et al.,(6)).

MCQUEEN et al., 1977 (16) observed that rotational forceps could be reduced by delayed pushing, until the head has rotated and descended.
 (The mean duration of 2nd stage being, 2.5 hours)

17. TURNER M.J. et al., 1987 (25) pointed out that an infusion of oxytocin in the second stage restores uterine action, causes the baby's head to descend to the pelvic floor and rotate at this level, thereby causing a reduction in the rate of forceps delivery.

18. DICKERSON 1981, suggests the use of a more liberal approach to the length of second stage of labour, provided that the foetal condition is not compromised and carefully monitored.

19. CATBUSH et al., 1998 (33) accordingly intrathecal opiod for labour analgesia shortened the duration of labour.

20. TIMING OF EPIDURAL BLOCK

The timing may be important as increase in the operative delivery rates in the trials were found in women who had epidural block in early labour. There are no randomized trials as yet to answer this important question.

STATISTICAL ANALYSIS

- By Students 't' test and Fishers 'z' test
- P > 0.05 Statistically not significant.
- $P \leq 0.05$ Statistically significant.
- $P \le 0.01$ Highly significant.
- $P \le 0.001$ Very highly significant.

GROUP A - CASE
$$(n = 40)$$

GROUP B - CONTROL (n = 40)

Observations and results 1) MATERNAL CHARACTERISTICS

	Mean \pm sd (A)	Mean ±sd (B)	P (students
			't' test)
Age	22.33±1.86	22.05±1.77	0.500
Height	151.48 ± 4.27	151.78 ± 4.15	0.751
Weight	55.88 ± 5.36	54.83 ± 6.02	0.413
Gestational age	38.53 ± 0.88	38.42±0.78	0.592
Cervical dilatation	3.25 ± 0.44	3.23 ± 0.42	0.796
Base line VAS	7.95 ± 1.01	7.80 ± 1.5	0.754

Both the groups were comparable with respect to age, height, weight, gestational age, cervical dilatation and VAS base line.

RESULTS

2) EFFECT OF ANALGESIA

 $(MEAN \pm SD)$

Time of onset of 1^{st} painless contraction - 9.38 ± 1.72

Time of loss of sensation of pin prick - 10.81 ± 2.1

3) MAXIMUM HEIGHT OF SENSORY BLOCK.

n = 38	(exclud	ing 2 I	LSCS)
--------	---------	---------	-------

	Sensory level	A group	%
1.	<t6< td=""><td>0</td><td>0%</td></t6<>	0	0%
2.	T6-T10	38	100%
3.	>T10	0	0%

Maximal height of sensory block was confined to T6 to T10.

3) AMBULATION / MOTOR BLOCK

	Bromage scale	Group A	%
	8_	r	
1.	0	33	87%
2.	1	5	13%
3.	2	0	0%
4.	3	0	0%.

n = 38.

Only 5 patients (13%) developed motor block of grade 1 Bromage scale. 87% were successfully allowed to ambulate during their labour.

4) VAS.

$$n = 40.$$

	VAS (A)	VAS (B)	(P)
	Mean ± SD	Mean ± SD	Students
			't'test.
1 st stage	2.4 ± 0.47	8.3 ± 0.46	0.000
2 nd stage	4.3 ± 0.49	9.3 ± 0.46	0.000

There was highly significant pain relief in the group with epidural analgesia. Pain relief in the 1^{st} stage was better than the 2^{nd} stage of labour.

6) EPISIOTOMY PAIN RELIEF

n = 38.

Grade	Group A	%
0	25	66
1	10	26
2	3	8

In group A 66% had no episiotomy pain. 3 patients had intolerable pain.

7) VITAL SIGNS

n = 40

Vitals	(A) Mean \pm SD	(B) Mean± SD	(P) Students 't'test
Pulse rate	92.9 ± 0.32	104.6 ± 1.36	0.00
Systolic B.P	120.6 ± 11.86	131.1 ± 2.62	0.00
Diastolic B.P	74.2 ± 3.21	79.2 ± 2.51	0.00

Hemodynamic stability was significantly better in group A.

8) FOETAL HEART RATE

$$n = 40$$

	(A) Mean ±SD	(B) Mean± SD	(P) Students 't'test
FHR	140.1 ± 0.76	140.9± 0.80	0.5267

No significant difference was noted between the two groups.

9) MODE OF DELIVERY

n = 40

Mode of delivery	(A) Mean ±SD	(B) Mean± SD	(P)
			Fishers
			'z'test.
Labour natural / labour natural	36	36	1.0000
with episiotomy			
Forceps	2	2	1.0000
Caesarean section	2	2	1.0000

There was no statistically significant difference with respect to the mode of delivery between the two groups.

Cases taken up for caesarean section in group A (epidural group),

-One case for foetal distress with cord once around the neck and the other for failure to progress.

Two cases of outlet forceps were for failure of secondary powers.

10) DURATION OF LABOUR

$$n = 40$$

	(A) Mean \pm SD	(B) Mean ± SD	(P) Students 't'test.
1 st stage	227.9 ± 25.31	226.1 ± 27.17	0.6231
2 nd stage	51.7 ±5.21	32.6 ± 4.21	0.0000

Compared to the control group, second stage was prolonged significantly in the epidural group.

11) APGAR SCORE

n = 40

Min .	Apgar score(/ 10)	A	В
1′	<7	0	1
	7 - 10	40	39
5'	<7	0	0
	7 - 10	40	40

Only one baby in control group had APGAR score less than 7 at 1 minute.

12) MATERNAL SIDE EFFECTS & COMPLICATIONS.

n = 40

a.	Dural puncture	- 0
b.	Venous puncture	- 2
c.	Nausea & vomiting	- 2
d.	Shivering	- 3
e.	Pruritis	- 1
f.	Urinary retention	- 26
g.	Hypotension	- 0
h.	Sedation	- 0
i.	Respiratory depression	- 0

- 65% of the epidural group needed catheterization, for urinary retention.
- In venous puncture both catheter and needle were removed enbloc and was inserted one space below L3 – L4 level.

• Itching was controlled with antihistamines.

DISCUSSION

Labour pain is a normal physiological event which indicates the beginning of the labour process.

The main issue that is to be noted while considering pain relief is to minimize its effects on the maternal powers (uterine activity and the progress of labour), the passage (birth canal), and the passenger (foetus).

DOSE – CONCENTRATION & SCHEDULE

Bupivacaine 0.1% was used for the study. The rationale behind using this concentration was based on the following studies:

Hart Em et al.,2003 (29) reported in their study that using a concentration of 0.1 % of Bupivacaine with fentanyl, maternal satisfaction was high and reduces the incidence of instrumental deliveries when compared to patients who were administered 0.25% Bupivacaine.

Sharma et al., 2007 (27) reported that 0.1% Bupivacaine with fentanyl 2 mcg / ml proved to be effective in labour pain relief.

QUALITY OF ANALGESIA ONSET OF ANALGESIA

With regard to the onset of analgesia, the mean time of onset of painless contractions was 9.38 ± 1.72 min, and the loss of pin prick sensation was 10.81 ± 2.1 min.

These findings correlate with the study of Cohen et al., 1987. He found that the onset of analgesia was 7.0 ± 1 min in patients receiving 0.25% Bupivacaine as initial bolus with addition of 50 mcg fentanyl.(Higher concentration hastened the onset).

MAXIMAL SENSORY BLOCK

All the parturients had a sensory level between T6 - T = 10. In none of them did the level ascend beyond T6.

Bellini et al., reported that 81% of the patients who were administered 0.125% Bupivacaine demonstrated a block of T6 – T10.

LEVEL OF MOTOR BLOCK

In the epidural group, 87% of the parturients were allowed to ambulate. Only 5 parturients developed motor block.

Bleyart et al., 1979 demonstrated that 96 % were able to ambulate in their study using 0.125% Bupivacaine.

VISUAL ANALOG SCALE

The pain relief was good in the epidural group (mean VAS score in the 1^{st} stage was 2.4 and the 2^{nd} stage was 4.3). They correlate well with the studies of:

Sharma et al., 2007 reported that 0.1% Bupivacaine with fentanyl produced a VAS of 1-3 in the first stage and 4-6 in the second stage in labouring women.

Vella LM et al., 1985 reported that addition of fentanyl to 0.125% of Bupivacaine relieved the perineal pain better.

EPISIOTOMY PAIN RELIEF

In the epidural group 66% had no pain during episiotomy and only 8% had intolerable pain.

Smith et al., 2002 (28) in her study demonstrated that only 22 - 30 % of the patients needed an additional local infiltration for relief of pain during an episiotomy while receiving 0.125% Bupivacaine with fentanyl.

MATERNAL VITAL PARAMETERS

Hemodynamic stability was definitely better in epidural group.

The increased pulse rate and blood pressure found in the control group was due to the sympathetic activity, provoked by pain, anxiety and apprehension. Epidural analgesia by producing complete block of nociceptive pathways obviates the pain induced sympathetic activity and this eliminates alterations in cardiac output and blood pressure. This is an advantage in patients with pregnancy induced hypertension.

<u>FOETAL HEART RATE</u>

No significant difference was noted between the two groups.

This was achieved by ensuring avoidance of maternal complications like hypotension or aortocaval compression by use of a wedge and cardiotocogragh monitoring.

DURATION OF LABOUR

The duration of first stage of labour was not significantly different in both groups, whereas the second stage was prolonged in epidural group from about 33 min. (group B) to about 52 mins. (group A) compared to the control group. Although the duration of second stage is longer than the control, it is not prolonged markedly (52mins.), and well within the normal limits. Low dose epidural and acceleration of labour with oytocin does not prolong the second stage. Although one may see an increase in the duration of labour with epidural analgesia the risk of this to the parturient and foetus is negligible.

The present study reinforces the conclusion of several authors :

a) Johnson S.Rosenfeld, JA, 1995(31) in a study over one year period reported that the length of the second stage was increased to 86 mins.

in the epidural group compared to 46 mins. in the non epidural group.

b) Chestnut et al., 1990 (6) and Craw-ford et al., 1972 (9)have also concluded that, though there was no clear effect on 1st stage, epidural analgesia is consistently associated with prolonged 2nd stage.

Prolongation of 2nd stage is not in itself harmful to the foetus as long as the maternal and foetal well-being is preserved.

- c) Cohenet al., 1977 (7) in a retrospective study found no relationship between apgar and duration of second stage.
- Rusell R and Reynold et al in 1996 observed that the administration of a dilute solution of local anaesthetic is less likely to result in prolonged labour.
- e) Sharma et al., 2007 (27) reported that low dose epidural analgesia does not prolong the second stage markedly (30-90 mins.).
- f) Saunders et al., 1989 (32) reported shorter second stage in epidural analgesia with oxytocin acceleration.

<u>MODE OF DELIVERY</u>

The results of this study suggests that use of epidural analgesia, per se, does not increase the incidence of instrumental and caesarean deliveries.

DATA SUPPORT

- 1. Bailey et al., 1983 (3) and Doughty had earlier reported that the patterns of obstetric interventions both before and after the establishment of epidural service were similar.
- 2. The myth that exists, is a consequence of the very early (restricted) use of this technique. As such it is of historical interest now, and inappropriate to contemporary practices.(J.A.Storrs (8)).
- Impey L.et al., 2000 (13) in a retrospective analysis of thousand pregnancies, found that the increased use of epidural analgesia had no effect on the operative deliveries.
- 4. Sharma et al., 2007 (27) reported that epidural analgesia had no effect on the operative deliveries.

On the contrary to the above studies,

- The Cochrane Review, 1999 (12) published a meta analysis, which concluded that epidural analgesia is associated with longer labours and an increase in the rate of operative deliveries.
- 2. Ramin and colleagues, 1995 (19) reported a two fold increase in the operative delivery rates. Sharma et al., from the same institution, two years later observed identical caesarean rates among the epidural and non epidural groups.

Sally C.Morton et al., in 1994 (21) meta analysis reported a 10% increase in caesarean rates in epidural group.

There was no significant increase in the forceps deliveries in the epidural group compared to other group. The possible reasons would be :

- 1. Use of oxytocin to prevent dystocia.
- 2. Increasing the time limit of 2^{nd} stage of labour.
- 3. Delayed pushing of head.
- 4. Use of low concentrations of Bupivacaine with opiod.

This active management of 2^{nd} stage of labour has been widely mentioned in literature.

- Kadar et al., 1983 (15) reported 97% of spontaneous delivery rate with a second stage lasting for two hours.
- The ACOG committee (1) pointed out that with continuous foetal monitoring prolonged second stage is no longer an indication for forceps delivery.
- Thorburn et al., 1981 (24) suggested that use of low concentration of Bupivacaine with opiods would reduce the instrumental delivery rate.

- Turner et al ., 1987 (25) pointed out the use of oxytocin, whereas Macqueen suggested that delayed till head is visible at the perineum, as means to increase spontaneous delivery rates.
- Dickerson et al., 1981 suggests that a more liberal approach to length of 2nd stage, would help in reducing the instrumental delivery rate.
- 6. Saunders et al., 1989 (32) reported oxytocin acceleration reduced the rate of operative deliveries.

NEONATAL OUTOME

Except for the new born in group B which had a Apgar of 6, all the others had Apgar of greater than 7. This is consistent with the finding of many authors, who have argued that a prolonged second stage is not associated with low Apgar, low cord blood pH, as long as the electronic foetal monitoring is employed, maternal analgesia and hydration are maintained. This was comparable with the study of Chestnut et al., 1990 (6).

DISCUSSION OF SIDE EFFECTS

The commonest side effect reported in our epidural group is urinary retention (65%). In 1988, Chestnut et al., also reported an incidence of 63% of urinary retention in mother in epidural group.

Pruritus was seen in one case only. Variable incidence of pruritus have been reported by many authors like Chestnut et al., and Cohen et al.,

None of the cases had Respiratory depression. Even in U.K where epidural is widely used, so far, there has been only one case report of Respiratory depression with use of opiates in epidural analgesia.

SUMMARY

- The mean time of onset of painless contraction after administration of epidural analgesia was 9.38 ± 1.72 mins.
- The meantime of onset of loss of sensation to pin prick was 10.81±
 2.1 mins.
- Maximal upper level sensory block was confined to T6- T10 in 100% of the patients.
- No detectable motor block occurred in 87% of the patients, whereas 13% of the patient had Grade 1 motor block.
- 66% of the patients had no pain at all during episiotomy.
- The overall VAS for the labouring women was 2.4.
- Hemodynamic stability was significantly better in the epidural group.
- No significant variation in the foetal heart rate was seen.
- No significant variation in the length of 1st stage of labour.
- The length of the second stage was longer in epidural group from about 33 min. (group B) to about 52 mins. (group A) compared to the control group.
- Although the duration of the second stage is longer than the control, it is not prolonged markedly (52mins.), and well within the normal limits.
- The incidence of caesarean section in the epidural group was 5 %.
- The incidence of forceps delivery in the epidural group was 5%.
- There was no significant differences in the incidence of operative delivery rates between the two groups.
- The commonest side effect observed was urinary retention (65%).
CONCLUSION

From this study, it is concluded that,

- 1) Low dose epidural analgesia provides effective pain relief during labour with ambulation.
- 2) Active management of labour with oxytocin acceleration in the second stage and administering low dose epidural analgesia do not prolong the second stage markedly and decrease the rate of operative deliveries.
- 3) Though there may be increase in the duration of labour with epidural analgesia, the risk of this to the parturient and the foetus is negligible.
- 4) Epidural analgesia does not result in an increase in the instrumental delivery rate or caesarean section rate.

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PROFORMA

NAME:	AGE:	IP. NO.:								
WEIGHT:	HEIGHT:	GEST. AGE :								
CLINICAL ASSESSMEN	Г: P.R - B.P - HB - URINE	CVS RS ALB. SUGAR								
PHYSICAL STATUS :										
BASE LINE PARAMETER	RS :									
PR BP RR SPO2 CERVICAL DILATATION VAS		FHR. :								
TIME TO ONSET OF SENSORY LOSS :										
TIME TO ONSET PAINLESS CONTRACTION :										

MAXIMAL HEIGHT OF SENSORY LEVEL :

VAS SCORE AFTER EPIDURAL :

DURATION OF LABOUR :

 1^{ST} STAGE : 2^{ND} STAGE :

EPISIOTOMY PAIN GRADE :

TOTAL VOLUME OF DRUG USED :

MODE OF DELIVERY :

NATURAL :

INSTRUMENTAL :

CAESEREAN :

APGAR SCORE AT :

1 MIN. : 5 MIN. : BABY WEIGHT:

DEGREE OF MOTOR BLOCK :

PATIENT COMFORT :

SIDE EFFECTS :

FOLLOW UP :

LABOUR ANALGESIA CHARACTERISTICS / VARIABLES

VARIABLE	0	2	5	10	15	30	45	60	120	180	240	300
	min											
PR												
RR												
Syst. BP												
Dias. BP												
FHR												
VAS												
Sensory												
level												
Motor level												