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Original Research Article

Effect of single low dose intrathecal labor analgesia on maternal and fetal outcome

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ABSTRACT

Background: Labour is one of the most painful experiences women encounter during their lifetime and the experience is different for each women. Aim of the study was to evaluate the effect of low dose intrathecal labour analgesia using fentanyl, bupivacaine and morphine on maternal and fetal outcome.
Methods: 100 parturients with uncomplicated pregnancy in spontaneous or induced labor at cervical dilatation 4-6cm were enrolled for the study. They were randomized into two groups of 50 each, using computer based block randomization. Group 1 (N=50) received intrathecal labor analgesia using. Fentanyl (25µg), bupivacaine (2.5mg) and morphine (250µg) and Group 2 (N=50) received programmed labor. The two groups were well matched in terms of age, weight, height, parity, baseline vitals and mean cervical dilatation at the time of administration of labor analgesia . Progress of labor, duration of analgesia, and neonatal APGAR score were recorded. Feto-maternal and neonatal outcomes were studied and compared between the two groups.
Results: The mean duration of analgesia in group1 was 238.96±21.888 min whereas the mean duration of analgesia in group 2 was 98.4±23.505 min. The difference was significant P value 0.00. One out of 50 (2%) of the parturients required rescue analgesia in Group 1. On the contrary all 44 parturients in Group 2 required rescue analgesia. Difference was significant (p value=0.00) However duration of the stages of labor, operative and instrumental deliveries and APGAR score did not differ in the two groups.
Conclusions: Single shot intrathecal labor analgesia is a safe, effective, reliable, cheap and satisfactory method of pain relief for labor and delivery. Moreover, it is devoid of major side effects.

Keywords: APGAR score, Intrathecal labor analgesia, Local anesthesia, Neonatal resuscitation, Programmed labor, Rescue analgesia

INTRODUCTION

Labour is one of the most painful experiences women encounter during their lifetime and the experience is different for each woman. Most women experience moderate to severe pain during labour and delivery, often requiring some form of pharmacological analgesia.[1,2] Maternal pain and stress have adverse effects on fetus. Maternal anxiety is associated with an increase in plasma catecholamines and prolonged sympathomimetic activity, may lead to incoordinate uterine contractions and reduced uteroplacental perfusion.[3] Effective labour analgesia is known to decrease inhibitory effect of endogenous maternal catecholamines on uterine contractility thus improves utero-placental flow, attenuates maternal

acidosis and improves maternal well being.[1,3] There are many different techniques, both regional and non-regional to provide labor analgesia. Currently, the proven obstetric analgesia is epidural anesthesia. But programmed labour and Intrathecal labor analgesia are simple, easy and effective methods for painless and safe delivery. They can be used effectively as well as economically in low resource set up for intrapartum pain relief. Authors therefore conducted the study to evaluate the effect of low dose Intrathecal labour analgesia on maternal and fetal outcome.

Aims of this study were to study the effect of single low dose intrathecal labor analgesia on maternal and fetal outcome. To study the effect of programmed labor on maternal and fetal outcome.

METHODS

A study was conducted at Kamla Nehru State Hospital for mother and child, Indira Gandhi Medical College, Shimla to study the effect of single low dose intrathecal labor analgesia on maternal and fetal outcome for a period of one year with effect from 1st August 2017 to 31st July 2018.

100 laboring parturients without pregnancy complications, scheduled for normal vaginal delivery, fitting into the inclusion criteria and requesting for labor analgesia, were recruited for this prospective randomized study after obtaining informed written co.

Inclusion criteria

- Parturients requesting for labor analgesia
- Age 18-40 years
- Booked patients at gestation 37-42weeks with Singleton uncomplicated pregnancies with cephalic presentation with spontaneous or induced labor
- Cervical dilatation 4-6cm.

Exclusion criteria

- Refusal and contraindication for labor analgesia
- Pregnancy complications and medical disorders
- Sensitive or allergic to local anesthesia and opiods
- BMI >30
- Prelabour rupture of membrane (PROM)
- Intra uterine death (IUD), Intra uterine growth restriction (IUGR) and fetal distress
- Malpresentations
- Previous uterine surgeries including lower segment cesarean section (LSCS)
- Neuromuscular disorders.

The two groups were well matched in terms of age, weight, height, parity, baseline vitals and mean cervical dilatation rate at the time of administration of labor analgesia.

A thorough general physical examination was done. After thorough GPE per abdominal examination was done to note height of uterus, lie, presentation, frequency, intensity and duration of uterine contractions. Fetal heart was auscultated and noted. Per vaginum examination was done and cervical dilation, effacement, position and station of presenting part was noted and artificial rupture of membrane (ARM) was done. Parturients with meconium stained liqor were excluded from the study.

IV line was secured using 18G cannula and 500 ml of ringer lactate was infused. In case parturient failed to have adequate uterine contraction (3-4 contractions in 10 minutes each lasting for 40-45 seconds) oxytocin augmentation was after 1 hour of ARM. Oxytocin administered as per the hospital protocol. Maternal pulse rate, basal noninvasive blood pressure and oxygen saturation (SpO_2) were recorded.

Group 1: (Intrathecal analgesia). Parturient in group 1 was positioned in left lateral position, L3-L4 interspace was identified and intrathecal injection comprising of total 2ml [0.5 ml of fentanyl (i.e. 25µg), 0.5ml of 0.5% bupivacaine heavy (2.5mg) and 1ml of morphine (250 µg/ml diluted] was administered under all aseptic precaution using 26G spinal needle by median/paramedian approach. The time of injection was noted and patient kept in supine position for subsequent 10min.

Group 2: (Programmed labor). Parturient received programmed labor comprising of 6mg of pentazocine and 2 mg of diazepam after dilution as a bolus through the infusion line. Thereafter inj. Tramadol in the dose of 1mg/kg body weight deep intramuscularly (IM), along with antispasmodic inj. Drotaverine 40mg intravenously (IV) was administered. Inj. Drotaverine was repeated half hourly total three doses.

Rescue analgesia for both groups: Single shot of inj ketamine 0.5mg/kg of body weight in 10 ml normal saline was given intravenously slowly over 10 min at 7-8 cm cervical dilatation as rescue analgesia in both the groups.

In both the groups the following data was obtained every 5 min for first 20 min, then every 30 min until delivery: maternal vitals and side effects (nausea, vomiting, drowsiness, palpitations, hypotension and pruritis). Fetal heart rate was recorded. The labour was monitored partographically. The third stage of labor was managed actively to shorten its duration, minimize blood loss and to ensure that the uterus remained retracted along with early placental delivery. The indication for instrumental delivery (ventouse/forceps) or caesarean section if any were noted. Neonatal assessment was done by assessing APGAR score at 1 and 5 min and need for resuscitation and NICU admissions.

Statistical analysis

Data collected was transformed into MS excel sheet for further processing and analysis. Appropriate statistical software and tools were used for analyzing the data. Parametric and non-parametric test of significance were used accordingly to find the association between different quantitative and qualitative variable of interest P-value < 0.05 was considered as statistically significant.

RESULTS

T100 parturients with uncomplicated pregnancy in spontaneous or induced labor at cervical dilatation 4-6cm were enrolled for the study. They were randomized into two groups of 50 each, using computer based block randomization. Group 1 (N=50) received intrathecal labor analgesia and Group 2 (N=50) received programmed labor. The two groups were well matched in terms of age, weight, height, period of gestation, mean cervical dilatation at the time of administration of labor analgesia, parity and onset of labor shown in following Tables 1, 2, and 3.

Feto-maternal and neonatal outcome was observed and compared between the two groups.

Table 1: Parameters.

Parameters	Group 1	Group 2	SD
Age (in years)	26.24±3.783	26.62±4.075	0.630
Height (cm)	157.32±3.950	157.46±3.995	0.861
Weight (kg)	74.36±6.133	73.60±6.141	0.537
Period of gestation	38.10±0.863	38.18±1.004	0.670
Mean cervical dilatation at time of labor analgesia administration (cm)	4.86±0.808	4.92±0.804	0.711

Table 2: Gravidity.

Gravidity	Group 1 (N=50)	Percentage	Group 2 (N=50)	Percentage
Primigravida	30	60%	31	62%
Multigravida	20	40%	19	38%

Table 3: Onset of labor.

Onset of labor	Group 1 (N=50)	Percentage	Group 2 (N=50)	Percentage
Spontaneous	29	58%	26	52%
Induced	21	42%	24	48%

Table 4: Maternal outcomes.

Parameters	Group 1	Group 2	P value
Mean cervical dilatation rate cm/hour	1.472±0.4305	1.488±0.4614	0.858
Mean duration of active phase of first stage of labor (min)	193.821±25.300	191.061±37.612	0.668
Mean duration of second stage (min)	50.93±16.851	50.64±22.923	50.64
Third stage of labor	4.77±1.2	4.88±1.6	0.818
Mean duration of labor analgesia (min)	238.96±21.88	98.40±23.505	0.00
Need for rescue analgesia	1 (2%)	100% (44)	0.00*
Need for local anesthesia for episiotomy	8 (17.7%)	44 (100)	0.00*

The mean rate of cervical dilatation were comparable in the two groups (Table 4) i.e. 1.472±0.4305cm/hour in Group 1 and 1.488±0.4614cm/hour in Group 2. P value 0.858 (not significant). Similar to programmed labor, the single shot intrathecal labor analgesia was found to shorten labor and lead to more rapid cervical dilatation.

No significant difference was observed in duration of labor in the two groups including the mean duration of active phase of first stage of labor (193.82±25.300min) in Group 1 and in Group 2 (191.06±37.612min). (P value 0.668 not significant). Similarly the duration of second stage in Group1 (50.93±16.851min) did not differ from Group 2 (250.64±22.923min) with P value 0.944.

Duration of third stage of labor in Group 1 (4.77±1.23min) and in group 2 (4.88±1.62min) was also comparable (P value 0.818). Same shown in Table 4.

The mean time to delivery since administration of analgesia did not differ in Group 1 (240.08±21.809min) and Group 2 (241.70±25.687min). Table 4 shows the same. P value 0.735 (not significant).

Table 5: Type of delivery.

Type of delivery	Group1 (N=50)	Percentage	Group 2 (N=50)	Percentage	P value
NVD	35	70%	36	72%	0.826
IVD	10	20%	8	16%	0.603
NRFHR with poor maternal efforts	8	16%	5	10%	
Prolonged second stage	2	4%	3	6%	
Abdominal delivery	5	10%	6	12%	0.749
Fetal tachycardia	1	2%	0	0	
Fetal bradycardia	2	4%	4	8%	
Non progress of labor	2	4%	2	4%	

The mean time to delivery from the time of administration of labor analgesia in group 1 (240.08±21.809min) was comparable to group 2 (241.70±25.687min). Therefore Labor analgesia administration to delivery interval did not differ between the two groups, P value 0.735 (Table 4).

In Group 1 (N=50) 70% had NVD, 20% had IVD and only 10% had abdominal delivery. Similarly in Group 2 (N=50), 72% had NVD, 16% had IVD and 12% had abdominal delivery. P value 0.826, 0.603 and 0.749 for NVD, IVD and abdominal delivery respectively (Table 5). Therefore the mode of delivery did not differ in the two groups.

Table 6: Analgesic efficacy of the two groups.

Group	1	2	P value
Mean duration of labor analgesia (min)	238.96±21.88	98.40±23.505	0.00*
Need for Rescue analgesia	1(2%)	100% (44)	0.00*
Need for local anesthesia for episiotomy	8(17.7%)	44(100)	0.00*

Table 7: Side effects.

Side effects	Group 1 (N=50)	Percentage	Group 2 (N=50)	Percentage
Pruritis	4	8%	0	0
Nausea vomiting	2	4%	2	4%
Hypotention	1	2%	0	0
Paresis	0	0	0	0
Urine retention	1	2%	0	0
Total	**8**	**16%**	**2**	**4%**

The mean duration of analgesia in Group 1 was 238.96±21.888min whereas the mean duration of analgesia in Group 2 was 98.4±23.505 min. The difference was significant P value 0.00 (Table 6).

Majority of the parturients (98%) did not require rescue analgesia in Group 1. On the contrary 88% parturients (excluding 6 abdominal deliveries) in Group 2 required rescue analgesia P value 0.00 (Table 6).

Single shot intrathecal labor analgesia succeeded in providing a 4 hours window of analgesia. All parturients delivered within 3½ to 4½ hours of administration of intrathecal labor analgesia and it was not found to prolong labor and also devoid of any serious complications.

16% parturients in Group 1 had side effects, among them four (8%) had pruritis, two (4%) had nausea and vomiting, one (2%) had hypotension and one (2%) had

urinary retention requiring catheterization. Only few (2/50 i.e. 4%) parturients in Group 2 reported side effects (Table 7). P value 0.003 significant. However no serious side effect related to labor analgesia was observed in the two groups as depicted in the following Table 7.

Table 8: Fetal outcome.

Neonatal parameter	Group 1 (N=50)	Group 2 (N=50)	P value
APGAR score at 1min	7.08±0.665	7.00±0.571	0.520
APGAR score at 5min	8.42±0.499	8.46±0.503	0.691
Neonatal resuscitation	No	No	-
NICU admissions	No	No	-

The mean APGAR score in Group 1 at 1min and 5min were 7.08±.665 and 8.42±.571 respectively and the mean APGAR score in Group 2 at 1min and 5min were 7.00±0.499 and 8.46±0.503 respectively (Table 8). Therefore the mean APGAR score at 1min and at 5min did not differ in relation to the type of labor analgesia with P value 0.520 and 0.691 respectively (Table 8).

Study results showed that the intrathecal labor analgesia using fentanyl (25µg), bupivacaine (2.5mg) and morphine (250µg) is safe and provides adequate analgesia during labor and delivery. Intrathecal labor analgesia is easy to perform, provide effective labor analgesia. It can be used as a good alternative to epidural analgesia which is costly and more time consuming procedure. Programmed labor protocol is less efficient in pain relief with all parturients requiring rescue analgesia. However duration of the stages of labor, operative and instrumental deliveries did not differ in the two groups.

DISCUSSION

There is a paucity of literature on the studies comparing intrathecal labor analgesia and programmed labor. Few authors have studied the maternal and fetal outcome of intrathecal labor analgesia. The mean cervical dilatation at the time of administration (4.86±0.808cm) in the present study was comparable to the cervical dilatation in a study conducted by Viitanen H et al (5±0.9).[4] On the contrary the mean cervical dilatation at the time of administration of intrathecal analgesia in the study conducted by Tshibuyi PN et al (7.6±0.71) was higher and the mean cervical dilatation at the time of administration of intrathecal analgesia was lower in the study conducted by Nelson KE et al (4±1cm) and Mathur P et al (4.17±0.808cm).[6,7] This difference was due to the fact that intrathecal labor analgesia was administered at ≥5cm cervical dilatation in the study conducted by Tshibuyi PN et al.[5] The mean rate of cervical dilatation in the present study was 1.472±0.4305cm/hour which was relatively less as compared to the study conducted by Mathur P et al, (3.02±0.584cm/hour) P value <0.001 however the mean cervical dilation in the present study was comparable to the cervical dilatation in Viitanen H et al study.[7] The mean duration of first stage of labor in the present study (193.82±25.300min) was relatively longer as compared to the study conducted by Owen MD et al (171±172min) and Mathur P et al (115.50±27.33min).[7,8] Difference could be because the study conducted by Mathur P et al had enrolled all the parturient in active phase of labor which is characterized by rapid cervical dilatation. Duration of second stage of labor in the study conducted by Viitanen H et al was significantly less (9.6±10.7min) as compared to present study (50.93±16.85min).[4] Difference is significant (P value 0.002) and it could be attributed to difference in parity i.e. all parturient receiving intrathecal labor analgesia in the study by Viitanen H et al were multigravidae and in the present study only 40% of parturients were multigravidae and 60% primigravidae.[4] Moreover the baseline parturient characteristics and the neonatal birth weight details are likely to effect the duration of labor and such data was not provided by Viitanen H et al study. Mean duration of analgesia in the present study (238.96±21.888min) was longer as compared to the studies conducted by Owen MD et a, Kenneth E et al, Viitanen H et al, and Mathur P et al.[4,6,8,9] The difference can be attributed to the administration of morphine in addition to bupivicaine and fentanyl in the present study whereas the intrathecal labour analgesia comprised of bupivacaine and fentanyl in the rest of the studies. Yeh et al, found that the addition of 150µg of morphine sulphate to a combination of bupivacaine 2.5mg and fentanyl 25µg prolonged the request for analgesia from 146min to 252 min.[10] Viitanen H et al, concluded that the majority of multiparous parturients found intrathecal analgesia (ITL) adequate for pain relief during delivery. However Hess et al, demonstrated that the addition of morphine 150µg to a mixture of intrathecal bupivacaine 2.0mg and fentanyl 25µg failed to prolong spinal analgesia significantly beyond 80 minutes when administered as a part of combined spinal-epidural technique.[11] 16% present subjects reported side effects in the study in contrast to 58.1% conducted by Anabah T et al.[12] The difference could be due to the administration of multiple doses of opioids administered 4 hourly by Anabah T et al, whereas authors administered single shot of opioids.[12] All the parturients had normal vaginal delivery in the study conducted by Mathur P et al as the FHR abnormalities were transient and all caesareans were also excluded from the study whereas in the present study the subjects who delivered by caesarean section were not

excluded from the study.[7] Overall caesarean rate was 10% among the parturients receiving single shot intrathecal labor analgesia and indications were fetal tachycardia (2%), fetal bradycardia (4%) and non progress of labor (4%). In the study conducted by Nelson KE et al, 55% delivered vaginally, 21% had IVD and the remaining 24% underwent caesarean section.[6] The number of parturients having instrumental vaginal delivery in the present study (20%) was comparable to the study conducted by Nelson KE et al (21%) and the indications for instrumental delivery in the present study were NRFHR with poor maternal efforts (16%) and Prolonged second stage (4%). The mean APGAR score (8.08±0.665 at 1min and 8.42±0.499 at 5min) in present study and in the study conducted by Tshibuyi PN et al (6.88±0.937 at 1min and 8.0±0.869 at 5min), and Bilge A et al13 (7.88±0.64 at 1min and 9.85±0.56 at 5min) were comparable.[5] Intrathecal labor analgesia seemingly did not appear to affect the neonatal mean APGAR score at 1min and 5min. Dani C et al, also observed that the administration of labor analgesia in form of epidural and spinal analgesia did not affect the neonatal outcome.[14] Therefore combination of fentanyl, bupivacaine and morphine gives safe analgesia during labor and delivery.

CONCLUSION

The single shot intrathecal labor analgesia using a combination of bupivacaine (2.5mg), fentanyl (25µg) and morphine (250µg) is a viable method of pain relief during labor and delivery. The reliability of spinal block, in terms of achieving satisfactory analgesia within a reasonable time limit and providing adequate analgesia till the end of delivery may make it a favourable option in low resource settings. Single shot intrathecal labor analgesia is a safe, effective, reliable, cheap and satisfactory method of pain relief for labor and delivery.

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