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A DOUBLE BLIND COMPARATIVE STUDY BETWEEN INTRATHECAL BUPIVACAINE AND INTRATHECAL FENTANYL AS THE INITIAL DOSE OF COMBINED SPINAL EPIDURAL TECHNIQUE FOR LABOUR ANALGESIA

Anaesthesiology

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ABSTRACT

Introduction: Labour pain is among the most severe pain a woman can experience in her lifetime. Painful labour has decrimental effects on both mother and fetus leads to severe physical and psychological stress. Maternal hyperventilation in response to pain reduces fetal oxygenation and hypoventilation between contractions combined with decreased blood flow worsens fetal hypoxemia. It has been suggested that confining women to bed during labour may cause the labour to be longer and more painful with increase in abnormal presentation, instrumental deliveries and fetal distress.

Aims And Objectives: The onset, quality and duration of their analgesic action. Incidence of unwanted effects like muscle weakness, hypotension, pruritus, nausea/vomiting, fetal bradycardia by the individual drugs.

Materials And Methods: The study was conducted in the department of anesthesia, Darbhanga Medical College & Hospital, Laheriasarai, Bihar. Methods of collection of data (including sampling procedure if any) : After institutional committee approval and written informed consent from parturients and their relatives for the procedure the study was conducted and data were collected.

Results: Duration of analgesia was found varying widely. It was 55±12.34 minutes in Group I whereas 75 ±14.36 minutes in Group II. The incidence of pruritus almost mild or negligible in both groups. The incidence of motor weakness in group II was 24 (80%) whereas in group I it was 10(33%). There was significant statistics difference in motor weakness between two groups ($p< 0.001$) by Chi square test 9 with yate's correction. Other side effects differences between two groups were not statistically significant.

Summary And Conclusion: Both the drugs provided excellent quality of analgesia to the parturient in pain. The difference in duration of analgesia was significant between the two groups statistically. Mean duration of analgesia lasted for 55 minutes in group I whereas in group II, it lasted for 75 minutes. Main side effects encountered in this study were motor weakness of longer duration in group II than in group I. Other side effects like nausea-vomiting were comparable to each other and were minimal in nature.

KEYWORDS

INTRATHECAL BUPIVACAINE , INTRATHECAL FENTANYL , SPINAL EPIDURAL , LABOUR ANALGESIA

INTRODUCTION

Labour pain is among the most severe pain a woman can experience in her lifetime. Painful labour has decrimental effects on both mother and fetus leads to severe physical and psychological stress. Maternal hyperventilation in response to pain reduces fetal oxygenation and hypoventilation between contractions combined with decreased blood flow worsens fetal hypoxemia.

It has been suggested that confining women to bed during labour may cause the labour to be longer and more painful with increase in abnormal presentation, instrumental deliveries and fetal distress. [1]

The approach to labour analgesia with low dose local anesthetics and opioids by combined spinal–epidural (CSE) technique has gained widespread acceptance. The rapid onset of analgesia is one of the major advantages of combined spinal-epidural analgesia with its increased association with maternal satisfaction.

There are special situations where relief of labour pain has paramount importance as in pre-eclampsia, incordinate uterine function, premature labour, maternal cardiovascular or respiratory disease and diabetes mellitus.[2]

Combined spinal epidural (CSE) technique provides effective and timely labour analgesia particularly for women in active labour. CSE technique consist of a spinal injection of small dose of local anesthetics (Bupivacaine) and/or lipophilic opioids (usually Fentanyl or Sufentanil), followed by introduction of catheter into epidural space for maintaining of analgesia by extradural route.[3]

- The aim of the study is to compare the efficacy between a small and fixed doses of lipophilic opioid i.e, Fentanyl (25µgm) and a local anaesthetic i.e, Hyperbaric 0.5% Bupivacaine (2.5mg) as the sole drug, for intrathecal injection as the initial step of CSE technique for labour analgesia with the following objectives:-
- To compare the onset, quality and duration of their analgesic action.
- To compare the incidence of unwanted effects like muscle weakness, hypotension, pruritus, nausea/vomiting, fetal bradycardia by the individual drugs.

MATERIALS AND METHODS

Source Of Data :

The study was conducted in the department of anesthesia, Darbhanga Medical College & Hospital, Laheriasarai, Bihar.

Study period: March 2019 – February 2020.

Methods Of Collection Of Data (Including Sampling Procedure If Any) :

After institutional committee approval and written informed consent from parturients and their relatives for the procedure the study was conducted and data were collected.

Inclusion Criteria:

a) Healthy gravida 1and Gravida 2 parturients at term.
b) ASA 1 and ASA II.
c) Maternal request for Epidural analgesia.
d) Age group 18-30 yrs.
e) Women in active labour with cervical dilatation in primi about 4 -5 cm and Gravida 2 with cervical dilation of 2-3 cm.

Exclusion Criteria :

a) parturient unwilling for procedure.
b) Parturient with gravida 3 or more.
c) Parturient with multiple pregnancy.
d) Pregnancy induced hypertension.
e) Severe anaemia.
f) Cephalopelvic disproportion.
g) Previous LSCS.
h) History of antepartum hemorrhage.
i) History of allergy to local anaesthetic.
j) History of CVS disease.
k) History of bleeding disorders.
l) Diabetes mellitus
m) History of psychiatric / neurologic disease.

RESULTS

Our study showed that represent maternal age in years. The youngest parturient was 18 year old and the oldest parturient was 30 year old. The average age of the patient in group I was 24.80 ± 3.3years and in group II was 24.60 ± 2.4 year. Represents Body weight of groups. The

average weight of the parturient in group I was 59.33 ± 5.054 kg and in group II was 62.27± 4.756 kg. Shows status of parity in two study group. Shows cervical dilatation(cm) at the time of intrathecal administration of drug in both groups. In our study VRS score at the time of intrathecal administration of the drug and was found from verbal enquiry of patients. The shortest time of onset found in group I was 60 sec and group II was 40 sec. The average speed of onset was fast in group II.

We found that the time to reach maximum analgesia (in minutes). This was observed between 10 to 20 minutes after administration of either drug in all patients. The average duration was 14.90 ± 2.734 min in group I and 12.13 ± 2.776 min in group II. The difference between time to reach maximum analgesia between two groups was not statistically different (p=0.12) by Mann –Whitney U test (p> 0.05). Shows duration analgesia. Duration of analgesia was found varying widely. It was 55±12.34 minutes in Group I whereas 75 ±14.36 minutes in Group II.

The incidence of pruritus almost mild or negligible in both groups. The incidence of motor weakness in group II was 24 (80%) whereas in group I it was 10(33%). There was significant statistics difference in motor weakness between two groups (p< 0.001) by Chi square test 9 with yate's correction. Other side effects differences between two groups were not statistically significant.

Table: The Speed Of Onset Of Analgesia (in Sec.) Distribution In Study Groups

Group	n	Shortest (Minimum) time of onset	Delayed (maximum) time of onset	MeanTime of onset	Median	StdDev
I	30	60	180	111.7	100	32.91
II	30	40	100	72.67	65.00	14.37

Table: The Time To Reach Maximum Analgesia (in Minutes): Distribution In Study Groups

Group	n	Shortest time (minimum)	Longest time (Maximum)	Mean	Median	Std.Dev
I	30	10	20	14.90	15.00	2.734
II	30	8	16	12.13	12.00	2.776

Table: Duration Of Analgesia (minutes) In Study Groups

Group	N	Shortest (Minimum) Duration of analgesia	Longest (Maximum) Duration of analgesia	Mean	Std.Dev
I	30	40	80	55	12.34
II	30	60	120	75	14.36

Table: Comparison Of Foeto-maternal Complications

	GROUP I (n = 30)	GROUP II (n = 30)
*PRURITUS	0	0
**NAUSEA/VOMITING	3(10%)	2(6.67%)
***MOTOR WEAKNESS	10(33%)	24(80%)
SHIVERING	0	0
PDPH	0	0
****HYPOTENSION	0	2(6.67%)
*****RESPIRATORY DEPRESSION	0	0
FOETAL BRADYCARDIA	0	0

DISCUSSION

Labour analgesia techniques, at the present time, are some of the most widely practiced procedures performed by an anaesthesiologist and are requested by the obstetrician colleagues as well as the parturient mothers from the labour room. The newer methods of pain relief have not only brought joy and pleasure to the mother but also bring in a host of advantages and safety to her as well as to her offspring.

The environment inside the labour rooms is no longer a place of agony and apprehension but a place full of assurances and co-operation between the mother and the assisting persons during the delivery process.

This has become possible because of the most modern technique of Combined Spinal Epidural analgesia and using very minute dose of potent drugs by which some of the drawbacks are avoided while taking the advantages of their analgesic properties appropriate to the duration and the situation for the delivery process to complete.

The average time of onset of analgesia was signicantly early with group II at 72.67 seconds compared to group I which was 111.7 seconds. This statistically significant difference of time of onset is however not significant clinically because a difference of about a half-a-minute is very short an interval in a painful state. The shortest time of onset of analgesia found in group II was 40 seconds whereas it was 60 seconds with group I.

The **Time Of Reaching Maximum Analgesia** was considered when VRS attended '0' in each case. The mean time to reach maximum analgesia was 14.90 minutes in group I, compared to 12.13 minutes in group II, the time to reach maximum analgesia between two groups was not statistically different. In studydone by **Gary M stocks et al [4],** onset time of '0'(VRS) analgesia was attended in8.8 minute in patient receiving 2.5 mg Bupivacaine IT and was 8.6 min in patient receiving 2.5 mg Bupivacaine plus 25µgm Fentanyl IT. The study done by **B.B. Lee et al**[5] found onset of peak analgesia was achieved within 5-10 min in parturient receiving 2.5 mg Bupivacaine plus 25µgm Fentanyl IT and in parturient receiving 1.25 mg Bupivacaine plus 25µgm Fentanyl IT. The study done by **Craig M. Palmer** [6] found that pain score was significantly lower at 2.5 min in the 25µgm Fentanyl- Bupivacaine 2.5mg group and 25µgm Fentanyl- Bupivacaine 1.25 groups than in the 25µgm Fentanyl-only.

So, in the present study, both the sole drugs were comparable to each other in respect of achieving peak analgesia and result of this study were also comparable to other studies.

Duration of analgesia was the time period from the onset of analgesia after intrathecal administration of the drug till the first top-up (Epidural) dose was administered as and when required by the mother. Duration of analgesia in Group I was 55 minutes whereas 75 in group II. This difference in duration of analgesia was significant and in favour of group II.

The study done by **Evangeline H.L.Lim et al** [7] found duration of analgesia was 100.1 ± 57.2 minute in parturient receiving 25µg Fentanyl plus 0.25 ml of normal saline , 129.5 ± 48.5 min in 25µg Fentanyl plus 1.25 mg heavy Bupivacaine and 100.4 ± 50.0 min in parturient receiving 25µg Fentanyl plus 1.25 mg plain Bupivacaine. The median duration of analgesia after the intrathecal dose was significantly longer for25µg of Fentanyl + 2.5 mg of Bupivacaine (1 mL of 0.25%) + 0.5mL of NS (94.5 [35-2001 min) Group compared with the25 µg of Fentanyl (0.5 mL)+1.5mL of preservative-free isotonic sodium chloride solution (NS); (62.5 [30-1461 min) and2.5 mg of Bupivacaine (1 mL of 0.25%) + 1 mL of NS (55 [20-931 min) Group. The study done by **Lt Daniel C. Celeski and his colleague** [8] found that mean ± SD duration of analgesia was 95.62 ± 43.3 minute in group receiving 25µg Fentanyl, 105.78 ± 46.8 minute in group receiving 37.5µg Fentanyl and 99.24 ±42.6 min in group receiving 50µg Fentanyl. Another study done by **Craig M. Palmer et al**[6] found durationof analgesia in the 25µg Fentanyl- Bupivacaine 2.5mg group was 108 ± 20 min was longer than in the 25µg Fentanyl-only was 92 ± 23 min and 25µg Fentanyl- Bupivacaine 1.25 groups 94 ± 25 min. In another study done by **Gary M. Stocks et al** [4] found duration of analgesia in group receiving Bupivacaine alone was 43.1 minute and in group receiving Bupivacaine plus 25µgm Fentanyl was 77.2 minute.

The incidence of pruritus found in present study was only with Fentanyl and none with Bupivacaine. Percentage of occurrence was high at 56.67%. Occurrences of pruritus recorded by other workers were even higher and universal in some studies with intrathecal Fentanyl. However, only a few cases were severe where as none was in this study.

In the present study, **Nausea and vomiting** was found 33% in group I and 80% in group II showing almost significant difference in incidence between both group but not severe enough to alter maternal hemodynamic.

In study by **Ayman Rofaeel et al** [9] showed 3.3% incidence of nausea and vomiting in group receiving 2.5mg hyperbaric Bupivacaine and 2.5 mg plain Bupivacaine both with 15µg Fentanyl IT.In study by **Lim et al** [7] incidence of vomiting was nil in group receiving 25µg Fentanyl IT alone, also in group receiving 25µg Fentanyl with 1.25mg plain

Bupivacaine IT and in 2 parturient out of 16 was found in group receiving 25µg Fentanyl with 1.25 mg hyperbaric Bupivacaine IT.

Although intrathecal opioids should have no effect on motor pathways or **muscle strength,** local anaesthetics can cause motor block. Traditional tests to assess motor strength (Bromage scale, straight leg raising) may not be well suited to assessing minimal degrees of motor block; this has led to the description of a modified Bromage scale, which is more sensitive[74]. Unfortunately we were unable to test our patient's ability to walk in this study as ambulation during labour is not encouraged by our obstetricians. The incidence of motor weakness was 80 % in Bupivacaine group where as it was nil in Fentanyl Group. In study by Ayman Rofaeel et al incidence of grade 1 was 53%, in grade 2 was 7% and in grade 3 was 7% in group recieving 2.5 gm of hyperbaric Bupivacaine with 15µg FentanylIT. Incidence of grade 0 was 97%, grade 1 was 3% and nil incidence in grade 2 and grade 3 in group recieving 2.5 gm plain Bupivacaine with 15µg Fentanyl IT. In study by **B. B. Lee et al** [5] motor block was greater in group Brecieving2.5 mg Bupivacaine and Fentanyl 25µg at 15 min, with seven patients having a Bromage score of 1 or greater compared with none in group A receiving Bupivacaine 1.25 mg and Fentanyl 25µg. At 30 min, more patients in group B had evidence of motor block compared with group A but the difference was not significant. A lower incidence of motor block with Bupivacaine 1.25 mg compared with Bupivacaine 2.5 mg, and it was inferred that the ability of parturients to walk might be improved with the smaller dose. The study done by **Gary M. Stock et al** [4] incidence of motor block was 4-5% in all 4 groups of Bupivacaine alone or with 5, 15 or 25µgFentanyl. The incidence of motor weakness found in present study was also found in other studies where intrathecal Bupivacaine was used.

The incidence of **hypotension** in the present study was 6.67 % with group II and none with group I, which is significant.

In study done by **Aymann Rofaeel et al** [9] incidence of hypotension was 10 % in group receiving 2.5 mg hyperbaric Bupivacaine and 23.3 % in group receiving 2.5 mg plain Bupivacaine both with 15µg of Fentanyl.In study of **Craig Palmer et al** [6] baseline maternal blood pressures did not differ among the three groups, group I receiving 25µm Fentanyl, group II 1.25 mg Bupivacaine with 25µg Fentanyl and group III receiving 2.5 mg Bupivacaine with 25µg Fentanyl. There were no significant changes within groups in maternal systolic blood pressure. Diastolic blood pressure change occurred only in the Fentanyl- Bupivacaine 1.25 group; a significant difference was found only between the baseline and 30-minpostinjectionvalues. In the study done by **Lt Daniel C. Celeskiand his colleague** [8] they found 1 parturient in group I who received 25µg Fentanyl intrathecally, 3 parturients in group II who received 37.5µg Fentanyl intrathecally and one parturient in group III who received 50µg Fentanyl intrarhecally decrease in systolic blood pressure of more than 20 % after injection of drug and required treatment consisting of 5 – 10 mg ephedrine and repeated fluid bolus.

SUMMARY AND CONCLUSION

In this double blind study for labour analgesia provided by combined Spinal Epidural (CSE) technique, intrathecal Bupivacaine heavy with different doses+ Fentanyl with same dose administered were compared for onset, quality and quantity of pain relief achieved and the incidence of their side effects. The summary of the study is as follows:-

1. Both the different doses drugs were fast acting with onset of analgesia between 40 to 180 seconds after administration. Onset of action of group II was faster than group I.
2. Their peak analgesic action attended between 8 to 20 minutes. Mean time to reach maximum analgesia was similar in both groups.
3. Both the drugs provided excellent quality of analgesia to the parturient in pain.
4. The difference in duration of analgesia was significant between the two groups statistically. Mean duration of analgesia lasted for 55 minutes in group I whereas in group II, it lasted for 75 minutes.
5. Main side effects encountered in this study were motor weakness of longer duration in group II than in group I.
6. Other side effects like nausea-vomiting were comparable to each other and were minimal in nature.

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