EPIDURAL LABOUR ANALGESIA WITH LOW DOSE OF BUPIVACAINE WITH LOW DOSE OF FENTANYL VS BUTORPHANOL

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ABSTRACT

BACKGROUND
Epidural analgesia is the most commonly accepted and used technique for painless labour. Local anaesthetic bupivacaine when combined with low dose of opioid analgesics gives excellent results.

The aim of this study is to evaluate and compare the efficacy and safety of epidural fentanyl vs butorphanol for painless labour and effect on newborn (Apgar score).

Settings and Design - Randomised double-blind trial.

MATERIALS AND METHODS
50 parturients were randomly allocated in two groups. Group I: receive epidurally 15 mL bupivacaine 0.0625% + fentanyl 130 mcg and Group II: receive epidurally 15 mL bupivacaine 0.0625% + butorphanol 1 mg.

RESULTS
The mean onset of analgesia was faster in Group I, whereas duration of analgesia was longer in Group II. There was no incidence of motor block, high rate of Normal Vaginal Delivery and very low incidence of forceps application or LSCS in both the groups. Somnolence was the main side effect in Group II and other side effects were seen equally in both groups.

CONCLUSION
The addition of low dose of opioids has greatly improved the quality of labour analgesia and at the same time reduced the incidence of instrumental deliveries and LSCS without depressing the neurobehavioral status of the newborn.

KEYWORDS
Fentanyl, Butorphanol, Epidural, Bupivacaine.

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BACKGROUND
Experience of pain during childbirth is a natural phenomenon. Epidural analgesia is the most commonly accepted and used technique for painless labour. Using this technique, good analgesia may be achieved at any stage of labour without incurring undue maternal or foetal depression.(1) With the advent of new, acting local anaesthetic bupivacaine, this technique has become more popular. This local anaesthetic when combined with low dose of epidural opioid analgesics gives excellent results. The current use of fentanyl with local anaesthetic gives safe analgesia, while motor block is avoided. Fentanyl acts as agonist at opioid receptors at presynaptic and postsynaptic sites in CNS, principally the brainstem and spinal cord and 3 cause decrease in neurotransmission. Butorphanol, a lipid narcotic with weak µ receptor agonist and antagonist activity and strong kappa receptor agonist has been proved to be a useful and safe adjunct to bupivacaine used for epidural analgesia during labour.(2)

MATERIALS AND METHODS
After Institutional Ethical approval and written informed consent, 50 full-term parturient of ASA Grade I and II with spontaneous onset of labour were included in this prospective, randomised, double-blind trial. Parturient with cephalopelvic disproportion (CPD), contracted pelvis, pregnancy-induced hypertension (PIH), active phase of labour, foetal distress, coagulopathy, hypersensitivity to local anaesthetics or studied drugs and any contraindication to epidural anaesthesia were excluded from the study. In sitting position after all aseptic precautions, 18-G Epidural needle was introduced in L3-L4 interspace. After confirmation of correct position of needle by loss of resistance technique, epidural catheter was advanced into epidural space and secured at desired length. When labour was well established, allocated drugs were given to respective groups. On patient demand, top-up was given. All patients were randomised (computer generated randomisation and concealment via sealed opaque envelope technique) into two equal groups (n=25): Group I: To receive 15 mL of bupivacaine .0625% + fentanyl 30 mcg through epidural catheter and top up doses of 10 mL .0625% + fentanyl 10 mcg was given as and when
required Group II: To receive 15 mL of bupivacaine 0.625% + butorphanol 1 mg through epidural catheter and Top up doses of 10 mL 0.625% + butorphanol 0.6 mg was given as and when required. Haemodynamic parameters (BP, PR) were recorded every 5 mins. for 30 minutes after first injection and then every 30 mins. Foetal heart rate was also monitored at every 30 mins. interval during first stage and every 5 mins. during second stage. Analgesia was measured with VAS. Pain was assessed by VAS (0 - 10) on which 0 indicates “no pain” and 10 indicates “maximum pain.” Time of onset of analgesia (time from the injection of drugs into epidural space up to the time when desired level of analgesia is achieved or diminished sensation to pin prick in any of required dermatomes), level of analgesia (highest level of dermatome up to which no pinprick sensation was appreciated was labelled as upper level of analgesia) and duration of analgesia (Time from onset of analgesia to return of pain of uterine contraction felt by parturients) were recorded. Motor block was assessed using Bromage scale 30 mins. after injection of drug in epidural space and in 1st and 2nd stage of labour.

- **Grade 0**: No motor block.
- **Grade 1**: Impaired hip flexion, normal knee and ankle movement.
- **Grade 2**: Impaired hip and knee movements, normal ankle movements.
- **Grade 3**: Impaired hip, knee and ankle joint movements.

Any maternal side effects like motor block, bradycardia, hypotension (Fall in BP more than 30 mmHg of pre-epidural BP or fall of BP below 100 mmHg) were recorded. Systemic side effects like light headedness, anxiety, restlessness, circumoral numbness, nausea, somnolence were also observed and recorded if present.

**RESULTS**

Descriptive statistics was done for all data and were reported in terms of mean values and percentages. Continuous variables were analysed with unpaired ‘t’ test. Categorical variables were analysed with chi-square test and Fischer Exact test. Statistical significance was taken as \( p < 0.05 \).

| Group | No. of Cases | Range | Mean ± SD | \( p \) value |
|-------|--------------|-------|-----------|--------------|
| I     | 25           | 20-25 | 22.56 ± 1.63 | > 0.05       |
| II    | 25           | 19-32 | 22.76 ± 3.05 | > 0.05       |

**Table 1. Age Incidence**

Mean age was similar in two groups. The values were statistically insignificant.

Mean time of onset of analgesia was 11.60 ± 1.87 min in Group I and 15.6±2.16 min in Group II. The difference in mean of onset of analgesia was statistically highly significant. Mean duration of analgesia was 71.40 ± 9.30 min in Group I and 116 ± 13.22 min in Group II. The difference in Mean duration of analgesia was (Table 2) statistically significant. Mean requirement of top-ups was 3.0 ± 1.17 in Group I and 2.30 ± 1.01 in Group II. Statistically, this difference between two groups is significant. Injection delivery interval, assessment of neonates using Appgar score at 1 min and 5 mins. was comparable in both groups. Statistically, these results were not significant.

| Time of onset of analgesia (mins.) Mean±SD | Group I | Group II | \( p \) value |
|-------------------------------------------|---------|---------|--------------|
|                                            | 11.60±1.87 | 15.60±2.16 | < 0.01       |
| Duration of analgesia (mins) Mean±SD      | 71.40±9.30 | 116.0±13.22 | < 0.01       |

**Table 2**

As shown in Table 3, 4, 5 there was no statistically significant difference of pulse rate and SBP between two groups before injection and after injection. However, the difference in PR and SBP in both groups before and after injection was statistically significant. Motor blockade was assessed using Bromage scale and Grade 0 was seen 30 mins. after injection in all patients of both groups.

No case of somnolence was observed in Group I and 10 cases in Group II. This difference is statistically significant.

| PR | Group I | Group II | \( p \) value | Significance |
|----|---------|---------|--------------|--------------|
| PR before injection | 92.96±8.10 | 88.88±7.35 | > 0.05 | NS |
| PR after injection | 83.76±6.74 | 80.72±6.34 | > 0.05 | NS |
| SBP before injection | 125.92±11.11 | 128.96±9.14 | > 0.05 | NS |
| SBP after injection | 118.08±10.17 | 120.64±8.99 | > 0.05 | NS |

**Table 3**

| SBP | Group I | Group II | \( p \) value | Significance |
|-----|---------|---------|--------------|--------------|
| SBP before injection | 125.92±11.11 | 118.08±10.17 | < 0.05 | S |
| SBP after injection | 128.96±9.14 | 120.64±8.99 | < 0.05 | S |

**Table 4**

| SBP | Group I | Group II | \( p \) value | Significance |
|-----|---------|---------|--------------|--------------|
| SBP before injection | 125.92±11.11 | 118.08±10.17 | < 0.05 | S |
| SBP after injection | 128.96±9.14 | 120.64±8.99 | < 0.05 | S |

**Table 5**
DISCUSSION

Labour analgesia is often provided by epidural administration of local anaesthetic and opioid solutions. An opioid is combined with local anaesthetic to reduce local anaesthetic requirements and side effects including systemic toxicity, hypotension and motor blockade.

In the present study, mean time taken for onset of analgesia was 11.60 ± 1.87 mins. in Group I which was significantly less than when compared to Group II which was 15.60 ± 2.16 mins. Our results are in concordance with Campbell et al.[3](5) and Hunt et al.[12]

Mean duration of analgesia was 71.40 ± 9.30 mins. In Group I which was significantly shorter than Group II which was 116 ± 13.22 mins. Our results are in concordance with Breen et al.[9] James et al.[10] and Kizilarslan et al.[6]

Maternal SBP and PR decreased following analgesia in both groups, but with no difference between the groups. No patient in any of the groups had hypotension or bradycardia. Our results are in concordance with Casio et al.[7] and Deschamps et al.[9]

All the patients in both groups had no motor block. So all the patients had walking epidural. Our results are in concordance with Chestnut et al.[9] Rodriguez et al.[10] James et al.[5] and Campbell et al.[3]

The major side effects encountered were somnolence, nausea, emesis and retention urine. Somnolence was the main side effect in Group II. None of the patients in Group I had somnolence. Nausea, emesis and retention urine were seen in both groups. Our results are in concordance with Crawford et al.[11] Justin et al.[12] and Campbell et al.[3]

24 parturients in Group I had spontaneous VND, while 22 parturients in Group II had NVD. The incidence of forceps delivery and LSCS was greatly reduced in both groups. Our results are in concordance with Chestnut et al.[9] Rodriguez et al.[10] James et al.[5] and Justin et al.[12]

In Group I, new borns with Apgar score ≥ 7 at 1 min were 84%, while with Apgar score ≥ 7 at 5 mins. were 100%. In Group II, new borns with Apgar score ≥ 7 at 1 min were 88%, while with Apgar score ≥ 7 at 5 mins. were 92%. Assessment of neonates using Apgar score at 1 min and 5 mins. was comparable in both groups. Our results are in concordance with Chestnut et al.[9] and Murphy et al.[13]

CONCLUSION

The combination of low dose of local anaesthetic with low-dose opioids have provided consistent, effective and safe labour analgesia without causing clinically significant adverse maternal or foetal side effects. Time taken for onset of analgesia was shorter with fentanyl than butorphanol and duration of analgesia was longer with butorphanol than fentanyl. The addition of low dose of opioids has greatly improved the quality of labour analgesia at the same time reduced the incidence of instrumental deliveries and LSCS without depressing the neurobehavioural status of the new born.

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