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EPIDURAL FENTANYL VERSUS SUFENTANIL FOR ANALGESIA IN AMBULATORY PATIENTS IN EARLY LABOR- COMPARATIVE STUDY

Anaesthesiology

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ABSTRACT

A prospective, observer blinded comparative study was done on 60 nulliparous women at >37 weeks of gestation and 18-35 years age group, requested for epidural labor analgesia, In Group BS Sufentanil 12.5 mcg (0.25 ml) + 2.5 ml Bupivacaine (0.5%) + 7.25 ml normal saline was given and in Group BF Fentanyl 25mcg (0.5 ml) + 2.5 ml Bupivacaine (0.5%) + 7 ml normal saline given.It was observed that epidural Fentanyl and Sufentanil with low dosage of Bupivacaine improved the quality of analgesia in regarding their onset and duration, in early labour in both the groups. There were no significant adverse effects like maternal hypotension, sedation, respiratory depression, nausea/ vomiting, pruritus, shivering in both the groups. Instrumental delivery did not increase and maternal satisfaction was excellent. Neonatal Apgar score in one and five minutes in both the groups was also 9-10.

KEYWORDS

Epidural analgesia,Fentanyl,Sufentanil

Introduction: The spinal cord extends from the foramen magnum to the level of L1 in adult and L3 in children. The meninges covering spinal cord are of three layers; the pia, arachnoid, and the dura matter. The epidural space is defined potential space within the spinal canal that surrounds the dural sac and is bounded by the posterior longitudinal ligament anteriorly, the ligamentam flavam and the periosteum of the laminae posteriorly, and the pedicles of the spinal column and the intervertebral foramina containing their neural elements laterally Epidural anesthesia is one of the most commonly employed technique of providing pain relief during labor. The goal of maternal labor analgesia is relief of pain without compromising progress of labor and fetal wellbeing. Epidural analgesia is the most effective and least depressant method of intrapartum pain relief in current practice[1].Low concentration of bupivacaine combined with fentanyl or sufentanil result superior analgesia with minimum side effect[2]. Bupivacaine is an amino amide derivative of local anesthetic agent with molecular formula C19H28N2O. HCL.H2O. Bupivacaine is long acting local anesthetic with duration of action up to 10 hours due to binding to nerve tissue. It prevents the transmission of nerve impulses by inhibiting passage of sodium ions through ion-selective sodium channels in nerve membrane (Butterworth and Strichartz, 1990). Alteration in protein binding characteristics of bupivacaine may be result in increased concentration of pharmacologically active unbound drug in the parturients' plasma (Denson et al 1984).

Fentanyl is a phenylpiperidine-derivative synthetic opioid agonist that structurally related to meperidine. As an analgesic, it is 75 to 125 times more potent than morphine and available as fentanyl citrate solution in 2 ml, 10ml ampoules. The formula is C22H28N20.C6H8O7.It acts primarily as mu (μ) receptor agonist.and also acts on kappa (K) and delta (δ) receptors producing spinal analgesia. It also antagonizes 5HT in the brain, thereby potentiating the analgesic activity of the opioids. Sufentanil is a thienyl analogue with analgesic potency 5 to 10 times that of fentanyl, and has a greater affinity for opioids receptors compared with that of fentanyl. It is available as a sufentanil citrate in 1 ml vial. Each vial contains 50 mcg of drug.The contraindications of epidural analgesia are severe maternal hemorrhage, coagulopathy and local or generalized sepsis. Many physicians induce as soon as the diagnosis of true labor pain established and patient request pain relief while others follow the practice of inducing labor when particular cervical dilation reached. The most common complication occurring during epidural anesthesia is maternal hypotension. Retrospective studies have demonstrated association between epidural anesthesia and increase in duration of labor, instrumental vaginal delivery and cesarean section. However recent prospective studies concluded that epidural anesthesia does not adversely affect the progress of labor or increases the rate of cesarean section[3] The study was done to compare epidural fentanyl and sufentanil regarding their onset and duration of action, their adverse effects if any, upon the foetus and mother.

Material and Methods

The prospective, observer blinded comparative study was done after getting consent from the mother and her spouse. It was conducted on 60 nulliparous women at >37 weeks of gestation who requested for labor analgesia, at any time during labor. Pregnant woman between the age group 18-35 years were chosen .

Exclusion criteria:

1. Refusal to give consent for regional anesthesia.
2. Allergy to local anaesthetic agent
3. Contraindication to fentanyl and sufentanil
4. Active maternal hemorrhage/hypovolemia
5. Presence of any coagulopathy
6. Maternal septicemia or untreated febrile illness
7. Infection at or near the proposed needle insertion site
8. Cervical dilation more than 6 cm
9. Patient receiving any other analgesics concurrently or within last four hours
10. Severe medical disorders of mother and or foetus
11. Foetal distress
12. Bad obstetric history/ valuable baby
13. Neurological / psychiatric problem of mother.
14. Non-vertex presentation
15. Multiple foetus

Before the procedure was begin, the patients' base line vital signs (blood pressure, heart rate, and respiratory rate, SPO2) and fetal heart rate was documented. The patients were asked to relate any symptoms of pruritus, nausea, or vomiting. After proper assessment from history,and physical examination women in spontaneous or induced labor consenting for labour analgesia was allocated into two groups with 30 women in each group, GroupBF and Group BS respectively.

Patients were requested to evacuate the bladder before the procedure. Pulse oxi-metry for SPO_2 [NIBP], ECG and were attached before giving the epidural. Each patient was preloaded with15 - 20 mL/ kg of lactated Ringers solution IV over a period of 15 minutes.

Anesthetic drugs and equipments for resuscitation and general anesthesia were kept ready at hand before starting the procedure

Epidural technique was performed in sitting position by using a Tuohy-Schiff needle (16G) under full asepsis at L3-4 or L4-5 interspace and advanced 3 to 5 cm for achieving a T10-S5 neural blockade. The patients received a test dose of 3 mL of 1.5% lidocaine with 1: 200,000 epinephrine. If the test dose became negative for intravascular injection (20% increased in maternal heart rate within 20 seconds of

test dose) and intrathecal injection (no signs of motor block after 3 minutes of monitoring), preservative free isobaric bupivacaine 0.125 % was used for labour analgesia with either sufentanil or fentanyl as follows by random allocation into two groups using sealed envelope technique:

Group BS (n = 30): sufentanil 12.5 mcg (0.25 ml) + 2.5 ml bupivacaine (0.5%) + 7.25 ml normal saline to a total volume of 10 ml

Group BF (n =30): fentanyl 25mcg (0.5 ml) + 2.5 ml bupivacaine (0.5%) + 7 ml normal saline to a total volume10 ml

After performing the block patients were placed in the recumbent position, with left uterine displacement. VAS scores, were recorded in every minutes for 10 minutes, motor block for every 5 minutes for 30 minutes .And haemodynamic status , any adverse effects were recorded at 5, 10, 15, 20, and 30 minutes after the administration of the study drugs and every 30 minutes, thereafter, upto 3 hours. Observations continued at 1 hour interval after 3 hours. Observations were performed by anaesthesiologist blinded to the study drugs administered. After performing the procedure the onset of sensory and motor block were assessed by using alcohols swab test and modified Bromage score (Bromage PR) respectively.

Episodes of side effects such as hypotension (SBP <20%) of base line or SBP <90 mmhg, bradycardia (<50/min, respiratory depression RR < 10/min and hypoxia spo2 <90%) were recorded.

The fetal heart rate pattern was evaluated by using continuous cardio. After the first 30 minutes, patients were allowed to ambulate, provided there was no detectable motor block and the foetal heart rate pattern was normal. Women were asked to report immediately when pain relief started. The onset of analgesia is defined as the time between each injection and the first notion of pain relief by the patient.

Duration of analgesia was defined as the time from onset of block till the time when the patient first requested additional analgesics. The study concludes whenever the patient asked for rescue analgesic or baby was delivered.

. The duration of labor, mode of delivery and neonatal Apgar scores at one and five minutes were recorded. After removal of catheter, the tip of catheter was also checked and the needle puncture site was sealed with antiseptic solution.

RESULT ANALYSIS

Table 1 : Table comparing Mean Duration of Onset of Motor Block and Duration of Motor Block, Onset of Sensory Block, Duration of Analgesia and Duration of Second Stage of Labor between the groups under study. Applying the two tail unpaired t-test, p > 0.05, there was no statistical significance difference between the groups under study

	Statistical Analysis						
	Two tail unpaired t-test						
	BF			BS			
Category	Number	Mean	SD	Number	Mean	SD	Two - tailed - p - Value
Onset of motor block	30	8.300	1.622	7	7.143	0.690	0.075
Duration of motor block	30	14.567	2.223	7	12.857	1.069	0.057
Duration of 2nd stage of labour	30	109.200	11.987	28	108.893	16.945	0.936
Onset of sensory block	30	3.567	0.858	28	3.321	0.548	0.204
Duration of analgesia	30	106.033	8.795	28	104.536	10.171	0.550

Table 2: Chart showing distribution of Cervical Dilatation in cms when a epidural catheter was placed in two groups under study

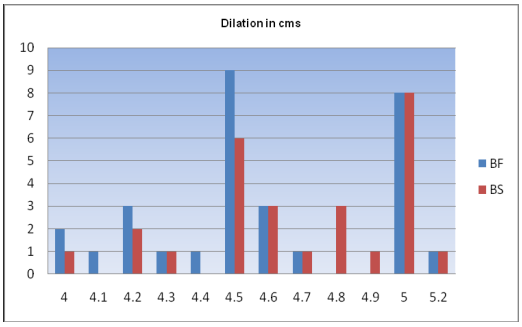

Table 3 : Chart comparing Mean Arterial Pressure (MAP) between the groups under study, at given time intervals

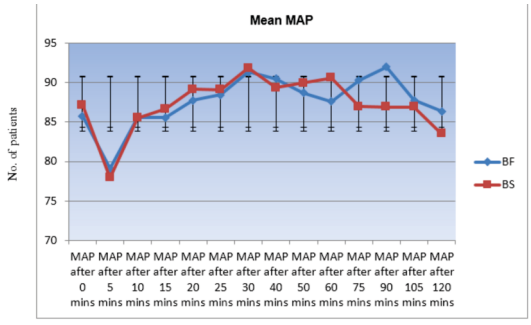

Table 4 comparing maternal complicationsafter epidural analgesia between the groups under study

Nausea	BF	BS	Total
Yes	2 (6%)	0	2
No	**28**	**28**	**56**
Total	30	28	58
Vomiting	**BF**	**BS**	**Total**
No	30	28	58
Total	**30**	**28**	**58**
Shivering	**BF**	**BS**	**Total**
No	30	28	58
Total	30	28	58
Pruitus	**BF**	**BS**	**Total**
Yes	3	2	5
No	37	26	53
Total	30	28	58
Sedation Scale	**BF**	**BS**	**Total**
Sedated	0	0	0
No Sedation	30	28	58
Total	30	28	58

Table 5 : Table comparing Mode of Delivery of Babies and Apgar Score between the groups under study. Applying chi-square test in mode of delivery p-value >0.05, there was no significance difference between the groups.In Apgar score applying chi-square test p-value >0.05, there was no significance difference between the groups.

Mode of Delivery	BF	BS	Total	Chi-Square Test P value
Normal	24 (80%)	20 (71%)	**44**	0.796
CS	3 (10%)	5 (17%)	**8**	0.672
Forceps	3 (10%)	3 (10%)	**6**	
Total	**30**	**28**	**58**	
Apgar score in 1 minute	**BF**	**BS**	**Total**	
8	0	1	1	
9	6	3	9	
10	24	23	47	
Total	**30**	**27**	**57**	

DISCUSION:

Comparative statistical analysis was done in between the groups regarding the time of onset of T10-L1 sensory block, duration of

analgesia, adverse action upon the mother and the fetus. Fifty eight patients were requested for labor analgesia and randomly allocated in to two group(BF and BS) The groups were similar in respect to demographic parameters.Connelly et all found that duration of labour,incidence of cesarean section,and Apgar score were comparable in both groups[4] The onset of sensory block was similar in the two groups (BF=3.5+0.8 vs BS 3.32+ 0.2 minutes; P=0.204, not significant).

Patients in both the groups had mean VAS score <3 in 3-5 minutes. These were also comparable in both the groups.

There was no significance difference in the pulse rates, systolic blood pressures, mean arterial pressures, respiratory rates, SPO2, fetal heart rates between the groups (p> 0.05, not significant , in each case).In a study it was observed that much lower pain score with least adverse effects on maternal cardiovascular or pulmonary functions and fetal physiology with higher maternal satisfaction are reported with the use of neuraxial analgesic techniques during labor and delivery[5].

Also there was no significant difference in the incidence of hypotension (fall of systolic blood pressure >20 % from base line) between the groups. None of patients any groups had bradycardia of <50/ minute, or respiratory depression (respiratory rate <10/ minute) or hypoxia (SPO2<90%). No patients in any groups had sedation or developed shivering and vomiting in any point of time. Only 2 patients in group BF had nausea and 3 patients in group BF &, 2 patients in group BS had pruritus. These were statistically not significant (p=>0.05).The incidence of pruritus wasobserved as 36% in Bupivacaine-Fentanyl and 40% in Bupivacaine-Sufentanyl group in a meta-analytical review which attempted to study the efficacy and safety of this combination.[6] The mean duration of analgesia in group BF&BS were 106+ 8.7 minutes and 104+10.1 minutes respectively (p=0.550, not significant). The duration of second stage of labor in group BF&BS was 109 + 11.9 minutes and 108+16.9 minutes respectively, (p=0.936, not significant).P Akkamahadevi,HT Srinivas in 2012 observed that combined spinal epidural analgesia using Sufentanyl will produce longer duration of labour analgesiacompared with Fentanyl.[7]Regarding delivery of babies by vaginal vs caesarean section, in two groups(p=0.672, not significant). Apgar score in both groups in 1 minute & 5 minutes were also similar (p=0.380, not significant).Maternal satisfaction score was also comparable in both groups. There was no significance difference in maternal satisfaction score in both the groups

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