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Research Paper

Epidural Analgesia for Labour and Delivery : Double Blind Comparison of Fentanyl and Bupivacaine with Sufentanil And Bupivacaine

Medical Science

KEYWORDS : Labour pain, fentanyl, sufentanil

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ABSTRACT

INTRODUCTION

The most popular method to control labour pain is epidural administration of opioids with local anesthetic agent .We have selected widely accepted option of epidural administration of Inj. Sufentanil 10µg and Inj. Fentanyl 100µg with 0.125% Inj. Bupivacaine for the labour pain.

AIMS AND OBJECTIVES

We compared the efficacy of epidural inj Bupivacaine with inj fentanyl and Bupivacaine with sufentanil with respect to their onset of action ,effectiveness , duration of analgesia & side effects of the drugs in mother and baby.

METHODS AND MATERIALS

Total fifty females of age group 18-30yrs, full term, primi or multigravida with vertex presentation, belonging to physical status ASA grade I or II were selected for randomised double blind study with local ethical committee approval. When patient had pain or VAS score >3, group F received 0.125% Bupivacaine + fentanyl100µg while group S received 0.125% Bupivacaine + sufentanil10µg as 10ml bolus dose through epidural route. All patients details were noted in preformed proforma with prior informed consent & Statistical analysis was done with student t test.

OBSERVATION AND RESULTS Duration of analgesia was significantly(p=0.035) prolonged in group S (338+/-177.4 min) as compared to group F (248.2+/-133.8 min) . In new born APGAR score noted at 1 min and 5 min were statistically significant (p=0.0006 &p=0.03 respectively).

CONCLUSION

We conclude that epidural administration of sufentanil with bupivacaine provides better analgesia.

INTRODUCTION

Attitude of society towards obstetrics patient and wrong beliefs about labour pain in earlier era was-

"Pain is for mother's safety, its absence her destruction".

The pain of childbirth is often rated by women as being most painful experience of their lives. It is estimated that about two third of normal healthy pregnant women, suffer severe intolerable pain during labour and only 2% describe it as little or no discomfort. There are several factors which influence parturition pain and its severity varies widely. It is influenced by parity, being primiparous women experiences more pain during early labour while multiparous women feel greater pain in the second stage. Occurrence of truly painless labour is rare. It is severe often but due to large emotional experiences of pain, each woman's experience of labour pain is unique. There is a need for the degree of flexibility to discuss options for pain relief before women experiences labour pain.

Labour pain represents the most common form of acute severe pain and lack of treatment results in severe psychological and systemic effects. To deprive mother from relief of labour pain is as good as giving a punishment.

In the recent era, there are many pharmacological and nonpharmacological methods available for labour analgesia but in the recent era, main focus is on the intrathecal and Epidural administration of opioids , with or without local anesthetics.

IDEAL METHOD OF LABOR ANALGESIA should provide sufficient pain relief, does not depress the uterine activity or foetal respiration. It should be safe for both mother and baby.

AIMS OF STUDY

- To study the effects of epidural analgesia on mother and fetus.
- To compare epidural Inj. Bupivacaine + Inj. Fentanyl and Inj. Bupivacaine + Inj. Sufentanil in low doses for following:
  1. Onset, effectiveness and duration of analgesia.
2. To study the side effects of the drugs & complications due to drugs & technique in mother and baby.
3. To study acceptability of technique by patient.

MATERIALS AND METHODS

Total 50 parturient belonging to age group 18-30 yrs , ASA I- II with full term pregnancy, primi or multigravida, with vertex presentation at cervical dilatation 4-5 cm were selected for this randomised double blind study with permission of ethical committee.

Parturients who refused for epidural analgesia, having abnormal spine, Parturients with Previous history of complicated labour, Lower segment ceaserean section , Contracted or inadequate pelvis ,Preterm labour , Abnormal presentation, Eclampsia and any other medical illness were excluded from our study.

All parturient were assessed for general and systemic examination for cervical dilatation 4-5 cm (by obstetrician), Pain score using Visual Analogue Scale(VAS). Each parturient were explained about the procedure. Written and informed consent of relative was taken

In all parturients iv infusion of crystalloid was started after securing 18 or 20G veinflow. Epidural catheter was inserted caudally or cephalic in all parturient in left lateral position, after local infiltration with Inj. Lignocaine 2% 2 cc using 23G hypodermic needle in L2-L3 or L3-L4 space, using epidural 18G toughy needle epidural space located with loss of resistance technique to 0.9% saline via midline approach, under all strict aseptic and antiseptic precautions, after negative aspiration epidural catheter was fixed. First dose of either Bupivacaine 0.125% + fentanyl100µg group F or Bupivacaine 0.125% + sufentanil 10µg group S administered through epidural catheter. Rescue analgesic was supplemented in form of 0.125% bupivacaine +50 microgram fentanyl in group F , 0.125% bupivacaine + 5 microgram sufentanyl in group S 10ml each as per requirement when Visual

Analogue Scale(VAS score ≥ 4) during the course of labour. Number of top up doses required or requirement of rescue analgesic was noted.

All parturients were monitored after epidural administration of epidural local anaesthetic which included patient pulse rate and systolic blood pressure, Mean arterial blood pressure, Diastolic blood pressure at 15 min in 1st hour and then every 30min till delivery of baby.

Quality of analgesia was judged by patient after delivery as Excellent(completely pain free after 1st or 2nd injection until delivery) , Satisfactory (satisfied but some pain for short period during labour), somewhat Satisfactory (some pain during most of time during labour), unsatisfactory (pain during most of time during labour and delivery, missing data (not possible to evaluate). Motor block was assessed using modified Bromage scale (0 = Able to raise the extended legs,1 = Unable to raise the extended legs, 2 = Unable to flex the knee, 3 = Unable to flex the ankle or complete motor block). Sensory level evaluated using alcohol swabs and pin prick. Sedation score[1] (0 = alert, 1 = Drowsy, aroused by verbally , 2 = Drowsy, not aroused by verbal but can be aroused by touch, 3 = Aroused by deep pain, 4 = Unarousable)

Mode of delivery was either normal vaginal delivery, normal vaginal delivery with episiotomy, Intrumental delivery (vacuum extraction , forceps application) or lower segment caesearean section.

Fetal outcome assessed using APGAR score at 1 min & 5 min after delivery and Fetal heart rate monitoring during labour. Side effects like nausea , vomiting , pruritis were noted. Pruritis score: none , minimal, (with minimal symptoms), moderate(bothersome, not requiring treatment), severe (requiring treatment)

stastistical analysis was done using Student t test-unpaired or paired.

OBSERVATIONS AND RESULTS

Total 50 full term pregnant women of ASA grade I or II all of age group 18 – 30 years randomly selected & divide in Group F (n= 25) & S (n = 25). Group-F(n=25) received 10ml Inj. bupivacaine 0.125%+Inj. Fentanyl 100 µg followed by top up dose with 10ml 0.125% bupivacaine + Inj. Fentanyl 50µg, while Group-S(n=25) received 10ml Inj bupivacaine 0.125% + Inj sufentanil 10µg followed by top up dose with 10ml 0.125% bupivacaine + Inj sufentanil 5µg .

Age, height, weight and parity , literacy & Anxiety score were statistically comparable between the groups and statistically not significant (p>0.05,NS)

Duration of analgesia with Group S (171.6 ± 70.17) was more as compared to Group F (132.2 ± 26.53), statistically significant (p = 0.006), after 1st dose . No patients in any group developed motor block. (Table no.I)

As shown in Figure I pain score were greatly reduced from 9.6 ± 0.76 to 2.04 ± 2.83 in Group F (statistically significant, p<0.001) while in Group S 9.2 ± 0.95 to 1.19 ± 1.34 (statistically significant , p<0.001) after 30 mins. Between the groups it was not statistically significant at 30 mins. VAS was statistically significant in both groups (p < 0.001) from 30 to 540 minutes as compared to baseline values. Between groups it was statistically significant at 360 (p= 0.03),390?(p=0.04), and 450 (p=0.02) minutes.

Incidences of instrumental deliveries were almost equal in both groups.(Table no. II)

Sedation score[3] between two groups was statistically not significant (p = 0.57).(Figure II)

In new born apgar score at 1 min (p = 0.0006) & at 5 mins (p= 0.03) noted and they were statistically significant.(Figure III & IV)

Fetal heart rates were statistically significant in Group F at 30 (p= 0.02), 360(p<0.001) , 390(p<0.001), 420(p<0.001),450(p<0.001) minutes. Group-S FHS were statistically significant at 30(p=0.01),60(p=0.005),90(p=0.004),120(p=0.003),300(p=0.01) minutes. Between the groups FHS were statistically significant at 60 (p=0.01), 90(p=0.03), 120 (p=0.008), 360(p<0.001), 390(p<0.001), 420(p<0.001), 450 (p<0.001) mins.(Figure V)

Side effects like pruritus were more in Group-F(9 patients) as compared to Group-S(6 patients) but statistically insignificant (p = 0.13,NS). Nausea/vomiting were comparable between 2 groups and statistically not significant (p = 0.34) .(Figure VI)

In our study no patient from any group required rescue analgesia in any form.

DISCUSSION

We carried out this study for comparison of potency and efficacy of sufentanil and fentanyl with 0.125% bupivacaine in women undergoing process of normal labour belonging to ASA 1 and II at the time of cervical dilatation of 3 to 5 cm. Both groups were comparable in the terms of age, weight, height , parity, mean duration of labour, mean duration of sensory analgesia, incidence of motor block and incidence of instrumental deliveries and LSCS.

The dose of bupivacaine used in the study is 0.125% 10ml below the central nervous system or cardiac toxic threshold. 0.125% bupivacaine provides satisfactory analgesia for labour. There are evidences that diluted large volume is more effective than concentrated small volume with less motor effects which reduce operative deliveries. There are evidences suggesting that low concentration of local anesthetics used alone may provide incomplete analgesia in 2nd stage of labour. Limited dose of diluted local anesthetics are sufficient to block the non – myelinated c fibres in the 1st stage of labour, but may be inadequate to block A-delta (δ) fibre in the 2nd stage . The combination of bupivacaine with fentanyl/sufentanil in varying doses, results in longer and more effective analgesia during labour .

Epidural infusion of 0.125% bupivacaine beyond a cervical dilatation of 8 cm prolongs the 2nd stage of labour and increases the frequency of instrumental delivery in nuliparous women.

Potency ratio of sufentanil to fentanyl is reported up to 8:1 – 9:1 with i.v.administration. It is reported that potency ratio for epidural sufentanil and fentanyl, when mixed with 0.125% bupivacaine to be approximately 5:1[2], sufentanil approximately 6 times more potent than fentanyl when given epiduraly for 1st stage of labour analgesia [3]. Intrathecal sufentanil is 4.4 times more potent than intrathecal fentanyl for labour analgesia, since sufentanil is more lipid soluble than fentanyl. (Lipid solubility is important when these drugs are administered epiduraly rather than subarachnoid space which explains different potency ratio) [3]. When Sufentanil is administered through epidural route, closer to the site of action, the greater lipid solubility of sufentanil , may result in longer uptake into epidural fat. Duration of analgesia was more with Group-S(171.6 ± 70.17 min) as compared to Group-F(132.2 ± 26.53 min,p = 0.006). In our study the effective potency ratio was 10:1for Sufentanil: Fentanyl.

As compare to the previous studies of various authors who used bupivacaine+fentanyl combination[4-19] our findings were almost

similar, for duration of analgesia (132.2 ± 26.53 mins), sedation score not significant, VAS score reduced from 9.6 ± 0.76 to 2.04 ± 2.83 in first 30 mins.,statistically significant (p< 0.05) from the baseline till the delivery of baby.

Anxiety score was not significant between the groups (p = NS). Pulse rate changes were statistically significant at 480(p=0.045) and 600mins (p =0.04) from baseline values. Systolic blood pressure was statistically significant at all the time from baseline value (p < 0.05).

As compare to the previous studies of various authors who used bupivacaine+sufentanil combination[2,3,8,11,12,14,15,17,18,20-29] our findings were almost similar, for duration of analgesia (171.6 ± 70.17mins), sedation score not significant, VAS score reduced from 9.2 ± to 0.95 to1.19 ± 1.34 in first 30 mins., statistically significant (p< 0.05) from the baseline till the delivery of baby.

Anxiety score was not significant between the groups (p = NS). Pulse rate changes were statistically significant at any time from baseline values. Systolic blood pressure was statistically significant at all times except 630mins.(p = 0.1) and 660mins.(p=0.1).

Apgar score reflects the obstetric management. Determinants of cesarean section rate maternal – fetal and obstetric factors. So it remains controversial whether epidural analgesia affects labour outcome because both groups received epidural analgesia. Rate of instrumental delivery were equal in both the groups. Most of the patients delivered normal or with normal episiotomy. Neurobehaviour scores were observed with maximal cumulative dose of 150 µg fentanyl over 3- 4 hours. Apgar score at 1 min and 5 min were comparable between both the groups in our study and 1 baby required. NICU care probably due to prolonged 2nd stage of labour. .

As compared with other studies, we also found pruritus more common with Group-F-(9 pts) as compared to Group-S-(6pts, p = 0.13). Intensity and incidences of pruritus after opioids administration is dose related and increases with increased concentration of opioids in cerebrospinal fluid. It may be decreased by more lipophilic drug e.g. sufentanil. No patient requested treatment. Urinary retention in the groups were not observed in any patient in our study but it can be due to epidural administration of fentanyl or indirectly from the longer 1st stage of labour. Nausea was found in Group-F(4 pts) as compared to Group-S(3 pts,p= NS). Both groups were also comparable for side effects like Nausea, vomiting, pruritus and dural puncture. Limited incidences of side effects noted in study are due to low concentration of sufentanil. Dose requirement may be more due to low concentration used.

In our study we had good to excellent quality of analgesia in both the groups in most of the patients. No patient had Incomplete or failure or not possible to evaluate. None of the cases had complete motor block. Intensity of pain was assessed VAS scale. It was better observed with Sufentanil group as compared to Fentanyl group.

We conclude from our study results and confirm the previous study results that epidural administration of 0.125% bupivacaine + 100µg fentanyl and 0.125% bupivacaine + 10µg sufentanil provides sufficient pain free period during the process of labour, requires less top ups, without much side effects and without affecting neonatal outcome.

We conclude from our study result and confirm that epidural administration of 0.125% bupivacaine +100microgram sufentanyl provides better VAS score and satisfactory score than 0.125% bupivacaine + fentanyl and requires less rescue analgesic.

Tables and Figures

TABLE I - DURATION OF ANALGESIA AFTER 1ST DOSE

	group F	GROUP S
Duration of analgesia after 1st dose (minutes) (Mean ± S.D)	132.2 ± 26.53	171.6 ± 70.17
p value between groups	p = 0.006 **(S)**	
p value< 0.05 **S** (significant) p > 0.05 **NS** (not significant)		

TABLE II - Mode of delivery

	Group F	GROUP S
Normal/episiotomy	15 (60%)	13(52%)
Normal	9(36%)	10(40%)
LSCS	1(4%)	1(4%)
Forcep outlet	0(0%)	1(4%)
Vacuum	0(0%)	0(0%)

FIGURE I - VAS SCORE

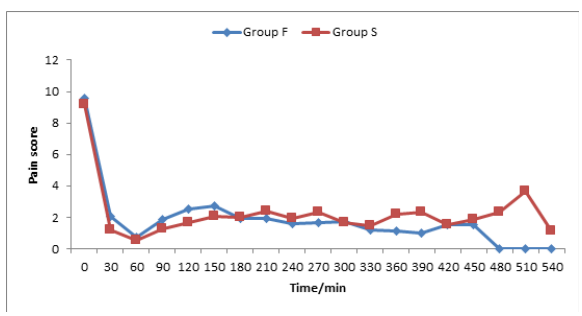

FIGURE II - SEDATION SCORE AFTER 45 MINS

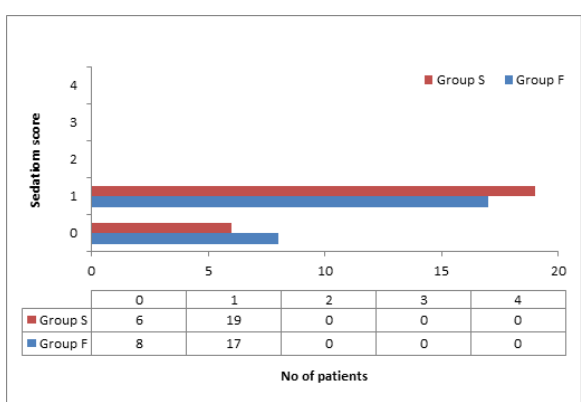

FIGURE III - APGAR SCORE AT 1 MIN

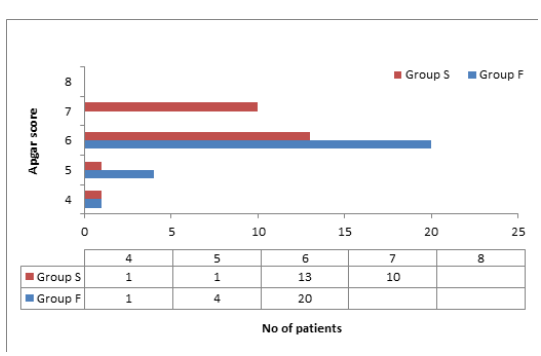

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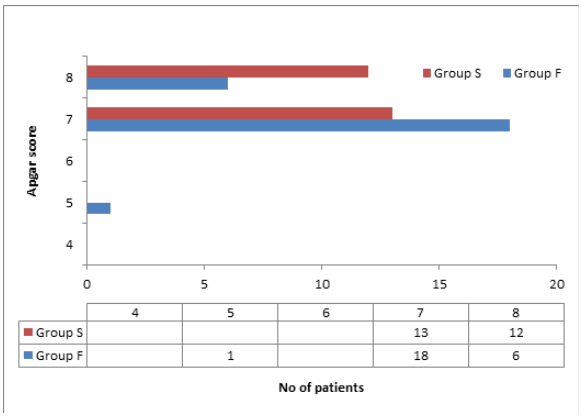
FIGURE IV - APGAR SCORE AT 5 MIN



	4	5	6	7	8
Group S				13	12
Group F		1		18	6

FIGURE V – FETAL HEART RATE CHANGES

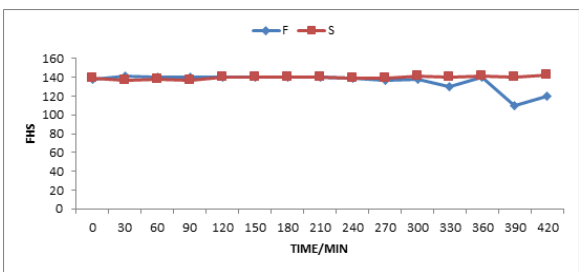
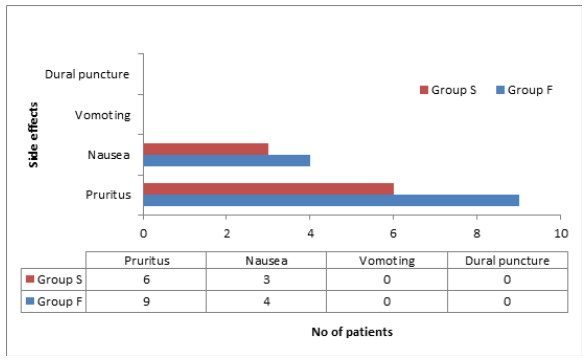


FIGURE VI - Side effects



	Pruritus	Nausea	Vomoting	Dural puncture
Group S	6	3	0	0
Group F	9	4	0	0

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