Original Article

Comparison of Bupivacaine Alone Versus Bupivacaine Plus Fentanyl During Labour in Terms of Mean Pain Score

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ABSTRACT

Objective: To compare bupivacaine alone versus bupivacaine plus fentanyl during labour in terms of mean pain score.

Study Design: Double Blind Randomized controlled trial study.

Place and Duration of Study: This study was conducted at the Department of Anesthesia, PIC, Lahore and GMC, Gujranwala from July 2018 to December 2018.

Materials and Methods: Before conduct of study informed consent from patient and permission from institutional ethical review committee was taken. On the basis of random numbers patients were divided into two different groups. The study group designated as group- A received bupivacaine 0.1%±2 mcg/ml fentanyl in 10 ml normal saline while the control group designated as Group-II received bupivacaine 0.125% alone. Visual Analogue Scale was used to assess the pain score during labour, where score of 10-30 was taken as mild whereas 30-60 and 60-100 were considered as moderate and severe pain respectively.

Results: A total of 80 patients divided into two equal groups were included in this study. The study results showed that in Group-I total of 31 patients (77.5%) were 20-28 years of age and 9 (22.5%) 29-35 years of age as compared to group B where 29 patients (72.5%) were 20-28 years of age and 11 patients (27.5%) of age 29-35 years. In Group-I mean ± standard deviation was 28.73±2.88 years whereas Group-II it was 29.35±3.00 years. Mean of gestational age in Group-I and mean parity was calculated as 39.48±1.09 weeks and 2.68±1.16 paras while in Group-II it was 39.18±1.08 weeks and 2.45±0.96 paras respectively. Comparison of bupivacaine alone versus bupivacaine plus fentanyl during labour in terms of mean pain score was recorded in Group-I as 1.32+0.47 and in Group-II as 18.22+2.32. A significant difference was shown by a P value of 0.00.

Conclusion: We concluded that mean pain score is significantly reduced in bupivacaine plus fentanyl when compared with bupivacaine alone during labour in terms of mean pain score.

Key Words: Labour pain, bupivacaine alone, bupivacaine plus fentanyl, mean pain score.

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INTRODUCTION

Majority of women experience the painful agonizing experience of labour which may be harmful to both mother and fetus[1-2]. This painful process results in an increased maternal stress, oxygen demand and mechanical workload which increases catecholamine release leading to fetal acidosis, fetal hypoxia, deceased placental perfusion and increased uterine contractility.[3]

Labour pain can be effectively treated by epidural analgesia.[4] Two third of American women receive epidural analgesia by epidural catheters which is the most effective method of pain relief during labour.[5]

Because of greater affinity for plasma proteins, bupivacaine is preferred agent for labour analgesia. Although it has cardiotoxic properties, bupivacaine is far from cardiotoxic effects in low concentration.[6] There is increased maternal satisfaction and less incidence of side effects like drug toxicity and hypotension when administering local anesthetic combined with opioids in low concentration. [7]

In a previous study Bupivacaine at 0.125% was administered and pain at 90 minutes pain on VAS was recorded as 1.0+0.5[6] while another study who added fentanyl adjunct to Bupivacaine recorded pain as 19.0+13.8, which shows no additional benefit for controlling the pain during labour.[7]

The rationale of the study is to analyze the effect of adding fentanyl in addition to bupivacaine low dose

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(0.1%) in terms of pain score during labour. If we find any significant difference of pain by adding fentanyl in low dose bupivacaine, then we may continue in future in our patients. According to best of our knowledge, no local study is done to compare these findings while international data is also scared. Our results will be primary and helpful for doctors dealing labour of the patients.

MATERIALS AND METHODS

This study was conducted at the Department of Anesthesia, PIC, Lahore and GMC, Gujranwala from July 2018 to December 2018. Patient of age 25-35 Years, all booked for active labor, ASA I-II and at term pregnant were included in this study. Exclusion group was of patients having history of stativity to amide local anesthetic, nulliparity, previous history of intravenous opioid agonist or antagonist and contraindication to regional anesthesia. A total of 80 patients were equally distributed in two groups. Sample size was calculated with confidence level of 95%, power of test 80%. Mean pain score was taken at 90 minutes as 1.0±0.5 in patients using bupivacaine alone and 19±13.8 in patients taking bupivacaine plus fentanyl undergoing active labour. Before conduct of study informed consent from patient and permission from institutional ethical review committee was taken. On the basis of random numbers patients were divided into two different groups. The study group designated as group-A received bupivacaine 0.1%±2 mcg/ml fentanyl in 10 ml normal saline while the control group designated as Group-II received bupivacaine 0.125% alone. Visual Analogue Scale was used to assess the pain score during labour, where score of 10-30 was taken as mild whereas 30-60 and 60-100 were considered as moderate and severe pain respectively.

The data was analyzed using SPSS version 10. Demographic information was recorded. Frequency and percentage were calculated as for ASA status. Mean and Standard Deviation was calculated for parity, gestational age and pain score at 90 minutes of administration of drugs. Pain score in both groups was compared using P test. Independent sample t-test was applied post stratification and P value less than 0.05 was considered significant.

RESULTS

A total of 80 cases (40 in each group) fulfilling the inclusion/exclusion criteria were enrolled to compare bupivacaine alone versus bupivacaine plus fentanyl during labour in terms of mean pain score.

Age distribution shows that 77.5%(n=31) in Group-I and 72.5%(n=29) in Group-II were between 20-28 years of age while 22.5%(n=9) in Group-I and 27.5%(n=11) in Group-II were between 29-35 years of age, mean+sd was calculated as 28.73+2.88 years in Group-I and 29.35+3.00 years in Group-II. (Table 1)

Gestational age distribution shows that 52.5%(n=21) in Group-I and 67.5%(n=27) in Group-II were between 37-39 weeks of gestational age while 47.5%(n=19) in Group-I and 32.5%(n=13) in Group-II were between 39-41 weeks of gestational age, mean+sd was calculated as 39.48+1.09 weeks in Group-I and 39.18+1.08 weeks in Group-II. (Table No. 2)

Distribution of parity shows that 72.5%(n=29) in Group-I and 85%(n=34) in Group-II were between 1-3 paras while 27.5%(n=11) in Group-I and 15%(n=6) in Group-II had >3 paras, mean+sd as 2.68+1.16 paras in Group-I and 2.45+0.96 paras in Group-II. (Table No. 3)

Frequency of ASA status shows that 37.5%(n=15) in Group-I and 42.5%(n=17) in Group-II had ASA status I while 62.5%(n=25) in Group-I and 57.5%(n=23) in Group-II had ASA status II. (Table No. 4)

Table No.1: Age Distribution (N=80)

Age (in yeas)	Group-I (No. of patients 40)		Group-II (No. of patients 40)	
	Total patients	%	Total patients	%
20-28	31	77.5	29	72.5
29-35	9	22.5	11	27.5
Total	40	100	40	100
Mean+SD	28.73+2.88		29.35+3.00	

Table No. 2: Gestational Age (n=80)

Gestational age (weeks)	Group-I (No. of patients 40)		Group-II (No. of patients 40)	
	Total patients	%	Total patients	%
37-39	21	52.5	27	67.5
39-41	19	47.5	13	32.5
Total	40	100	40	100
Mean+SD	39.48+1.09		39.18+1.08	

Table No. 3: Parity Distribution (n=80)

Parity	Group-I (No. of patients 40)		Group-II (No. of patients 40)	
	Total patients	%	Total patients	%
1-3	29	72.5	34	85
>3	11	27.5	6	15
Total	40	100	40	100
Mean+SD	2.68+1.16		2.45+0.96	

Comparison of bupivacaine alone versus bupivacaine plus fentanyl during labour in terms of mean pain score was recorded as 1.32+0.47 in Group-I and 18.22+2.32 in Group-II, p value was 0.000 showing a significant difference. (Table No. 5)

The data was stratified to control the effect modifiers i.e. age of the patients, ASA, gestational age and parity. P value <0.05 was taken as significant. (Table No. 6-9).

Table No.4: Frequency of ASA Status (N=80)

ASA status	Group-I (No. of patients 40)		Group-II (No. of patients 40)	
	Total patients	%	Total patients	%
I	15	37.5	17	42.5
II	25	62.5	23	57.5
Total	40	100	40	100

Table No.5: Bupivacaine alone versus Bupivacaine plus fentanyl during labour in terms of mean pain score (n=80)

Pain score	Group-I (No. of patients 40)		Group-II (No. of patients 40)	
	Mean	SD	Mean	SD
	1.32	0.47	18.22	2.32

P value=0.000

DISCUSSION

Although labour is a physiological process but labour pain is a severe type of pain. Providing adequate pain relief without fetal and maternal harm is the prime goal of labour analgesia. The most commonly used and effective method of pain relief is continuous epidural analgesia because of its effective pain relief during labour as well as analgesia and anesthesia for vaginal delivery and cesarean section if needed. Various Pharmacological and Non- Pharmacological methods have been used to provide labour analgesia. Another effective method of providing labour analgesia is the use of fentanyl and sufentanil in combination of local anesthetic.

In our study, we planned to analyze the effect of combining bupivacaine low dose (0.1%) with fentanyl in terms of pain score during labour. If we find any significant difference of pain by adding fentanyl in low dose bupivacaine then we may continue in future in our patients. According to best of our knowledge, no local study is done to compare these findings while international data is also scared. Our results are primary and helpful for doctors dealing labour of the patients.

In Previous study, Bupivacaine at 0.125% was administered and pain at 90 minutes pain on VAS was recorded as 1.0+0.5[6] while another study who added fentanyl adjunct to Bupivacaine recorded pain as 19.0+13.8, which shows no additional benefit for controlling the pain during labour.[7]

In another study[8] comparing the efficacy of fentanyl and sufentanil in combination of bupivacaine in low concentration (0.0625%) for labour analgesia, they concluded that there was no increase in chances of cesarean delivery in any group.

Although more patients in fentanyl group required supplementary boluses, the mean pain score was similar in both groups through out labour and delivery. They concluded that in terms of providing effective labour analgesia with hemodynamic stability, maternal satisfaction and no significant serious maternal or fetal side effects, both groups i.e. bupivacaine plus fentanyl (0.0625% + 2.5 mcg/ml) and bupivacaine plus sufentanil ((0.0625% + 0.25 mcg/ml) were equally effective by continuous epidural infusion.

Another study[9] comparing the efficacy of PCA administered bupivacaine plus fentanyl vs. low dose bupivacaine for labour analgesia, it was recorded that as compared to Group-II analgesia was more rapid in Group-IIF. There was higher sedation, less marked motor blockade and high sedation in Group-IIF than Group-II. In Group-IIF first phase of labour was shorter, volume of solution required by the pregnant women was lower and satisfaction level was higher. They concluded that there is better patient satisfaction and higher quality of analgesia with bupivacaine and fentanyl combination than bupivacaine alone.

A retrospective search was conducted by Wahlin et al[10] before the study on epidural analgesia for five-year period and on normal labour. Two groups were defined on the basis of presence or absence of opioid use, and the duration of hospital stay and type of labour were compared between two groups. The results showed that length of hospital stay, cesarean sections as well as number of assisted deliveries were reduced using combination of opioids with local anesthetics.[11]

A study conducted by Akkamahadevi et al comparing bupivacaine + fentanyl and bupivacaine + sufentanyl combinations found that there was an excellent labour analgesia and high patient satisfaction in both groups without serious neonatal and maternal side effects.[12]

CONCLUSION

We concluded that mean pain score is significantly reduced in bupivacaine plus fentanyl when compared with bupivacaine alone during labour in terms of mean pain score.

Author's Contribution:

Concept & Design of Study:	Syed Imran-ul-Hassan
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Conflict of Interest: The study has no conflict of interest to declare by any author.

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