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Single-Dose Intrathecal Fentanyl (25 Mgms) + 2.5 Mg of 0.5% Bupivacaine (Heavy) in Second Stage of Labour to Control Labour Pain in Normal Labour

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Abstract

Introduction: Bupivacaine is the first choice of local anaesthesia [LA] intrathecally for Caesarean Section or Labour analgesia. *Aim:* To assess intrathecal fentanyl (25 ugms)+2.5 mg of 0.5% bupivacaine effect during labour in second stage and its effect on mother & child. *Materials and methods:* This study was a prospective, observational study which was controlled and evaluated spinal analgesia efficacy in single dose in managing labour pain. 80 patients are taken for observation 40 controlled group, 40 study group. In study group intrathecal fentanyl 25 µg + hyper baric bupivacaine was given. *Results:* Duration of analgesia lasts up to 5 hours, patient's satisfaction levels were good with no side effects, C/S rate was 1 and it is statistically not significant. *Conclusion:* Administration of narcotics intrathecallyhas an analgesia effectand is the best option in women who have labour. ITN will have particular appeal for facilities that do not have readily available 24/7 epidural services. Fentanyl + LA in low doses is effective analgesia with no significant side effects.

Keywords: Bupivacaine; Labour analgesia; Intrathecal fentanyl.

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Introduction

Obstetrical anaesthesia shifting is reflected by modern labour analgesia neuraxially, which focuses on relief of pain and it also focuses on the analgesia quality. Pharmacotherapy and physiology knowledge of pain and the obstetric anaesthesia development has increased and has improved the training in obstetric anaesthesia, which further led to an overall improvement in the labour pain relief quality. Pain in labour is an extremely agonizing experience for most women. If not dealt properly, it can lead to unpleasant experiences and mental agony [1]. The ACOG summarises -"Labour causes severe pain for many women". During labour, for pain relief, in the absence of a medical contraindication, maternal request is a sufficient medical indication [2]. The dose of the drug influences the duration of sensory as well as motor blockade and has a significant effect on the hypotension degree. However, to provide complete analgesia despite high sensory block, intrathecal bupivacaine alone may not be sufficient [3]. Even after the intrathecal administration of 15 mg of bupivacaine, visceral pain was observed in 13% of the patients undergoing caesarean delivery. Many mothers need supplemental analgesics to relieve pain associated with exteriorization of the uterus, and the abdominal

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viscera traction. During spinal anaesthesia, larger doses are associated with higher block [4]. Similarly for labour analgesia adjuvants provide better analgesia. The quality of intra operative anaesthesia is improved by reducing the dose of LA, labour analgesia adjuvants like opiods (Morphine, Fentanyl, Sufentanyl) and non opioids such as α-2 adrenergic agonists, anticholinesterases, Midazolam, Steroids and Ketamine can be added to prolong the duration of post operative analgesia. Fentanyl, a lipophilic opiod, has rapid onset of action, as it does not tend to migrate to 4th ventricle in sufficient concentrations, after intrathecal administration, to cause delayed respiratory depression [5]. Fentanyl tends to diffuses into epidural space and further into the plasma, suggesting that it acts not only through spinal opioid receptors but also act systemically and it provides better intra operative analgesia. Intrathecally, 25 µg of fentanyl added to bupivacaine in low dose provided better surgical anaesthesia and enhanced block reliability than intrathecal bupivacaine alone or fentanyl 7.5 or 10 µg. Because of availability of minimal data on intrathecal LA combined with an opiod, the present study was planned with Single dose intrathecal Fentanyl (25 µg + 0.5% Bupivacaine (Heavy) 2.5 mg in second stage of Labour to control labour pain in normal labour and to evaluate the effect of intrathecal fentanyl (25 ugms) + 2.5 mg of 0.5% bupivacaine during second stage of labour and its effect on mother & child.

Materials and Methods

This study was a prospective, observational study which was controlled and evaluated spinal analgesia efficacy in single dose in managing labour pain. This study was approved by Institutional ethics committee and from all the patients, informed written consent was taken.

Inclusion criteria: Study includes 80 pregnant ladies between 18 to 35 yrs of age without any associated diseases. Control Group consisted of 40 patients; Study Group consisted of 40 patients, ASA grade 1 & 2.

Exclusion criteria: ASA grade 3 & 4, patients having any bleeding disorder and patients on anticoagulants, patients suffering from severe respiratory disease, Local infection at the injection site, any history of allergy to local anaesthetic & narcotics, Severe PIH & eclamsia and preeclamsia and patients on chronic steroid use. All necessary equipments and drugs needed for administration of general anaesthesia and for emergency resuscitation were kept ready. Monitors: Pulse oxymetry, NIBP, ECG Patients were given fentanyl 25 ugms + Inj.bupivacaine [0.5%] heavy 2.5 mg, intrathecally under aseptic precautions strictly. Patients were monitored and observed till their recovery. Pre-Anaesthetic Evaluation: BP, PR, Temp, CVS, RR, Airway, ASA grading. Pre-operative investigations: Hb%, CT, BT, Blood Urea, Serum Creatinine, Blood Grouping, & Rh Typing, Urine: Albumin & Sugar, CXR, ECG. After the request for analgesia, each patient to received spinal analgesia. As one patient among study group needed C/S for delivery, second spinal anaesthetic was given. At least 500 mL Ringer lactate solution, each patient received, upon patient request for labour analgesia. The blocks were carried out under complete aseptic conditions with the patient in sitting position. Using 25 gauge quincke needles, patients were given spinal block and these were directed to the middle line to reach the intrathecal space between L3-L4 or L4-L5 intervertebral space, 0.5 ml (2.5 mg) bupivacaine with 0.5 ml (25 µg fentanyl) was injected to improve intrathecal labour analgesia, after a successful dural puncture with acceptable cerebrospinal fluid flow.

Statistical analysis: Using the mean, standard error, by SPSS V17, statistical calculation and analysis of the present study were conducted.

Results

Table 1: Demographic distribution between control and study groups

Characteristics	Control Group (n=40)	Intrathecal Group (n=40)	p
Age (Years)	25.66 ± 3.98	25.87 ± 4.17	0.9NS
Weight (Kg)	85.89 ± 8.25	85.12 ± 5.22	0.904NS
Height (cm)	161.79 ± 3.97	162.84 ± 3.28	0.95NS
BMI (Kg/m^2)	33.67 ± 3.57	33.46 ± 3.74	0.9NS
Cervical dilatation (cm)	4.2 ± 0.6	4.1 ± 0.7	0.95NS
Oxytocin use	26 (53%)	17 (34%)	<0.001*
Fetal heart rate (beat /min)	140 ± 25	140 ± 28	0.97NS
Baby weight (grms)	3262 ± 355.6	3253 ± 228	0.96NS

Maternal age, weight, height, body mass index (BMI), cervical dilatation, fetal heart rate and baby weight were the demographics which were studied. All shows no significant difference, the p value is <0.001 (Table 1).

Table 2: Comparison between control and study groups regarding duration of labour

Time(Min)	Group Control	Intra thecal Group	P value
First Stage	243.5 ± 62.1	175.6 ± 55.5	<0.001*
Second Stage	34.4 ± 22.6	34.9 ± 24.7	0.904NS
Total Time	281.4 ± 77.7	209.6 ± 74.1	<0.001*

* Significant relation. NS not significant

There was significant difference in the first stage of labour duration among control and study groups. The p value was < 0.001. It was observed that no significant difference in the 2nd stage of labour duration among control and intrathecal group. The p value was 0.904 (Table 2).

Table 3: Shows the time duration of labour in primiparous and multiparous women in the control and study groups.

Time (Min)	Primiparous Women		Multiparus Women	
	Control group	Intrathecal group	Control group	Intrathecal group
First Stage	291 ± 35.7	222.3 ± 24.3	198.2 ± 51.2	128 ± 33.7
2nd Stage	54 ± 18.4	51 ± 22.3	84 ± 1	19 ± 7.6
Total Time	345.56 ± 41	273.0 ± 42.7	221.2 ± 56.5	146 ± 40.2

Significant difference in the duration of all stages of labour among intrathecal group was observed. The P value was (<0.001, 0.003) respectively (Table 3).

Table 4: Shows mode of delivery among control and study group.

Mode of Delivery	Intrathecal Group	Control Group
Assisted Vaginal delivery	0	1
Caesarian Section	1	0
Vaginal delivery	39	39

In the control group, one case delivered by assisted vaginal delivery (AVD) due to prolonged 2nd stage. In the intrathecal group, one case delivered by C/S (arrest of descend at 1 station at 2nd stage of labour). It was observed that no significant difference in incidence of number of delivery by a caesarean section among control and study groups (Table 4).

Table 5: APGAR Score

APGAR Score	No.of Patients	Percentages
APGAR - 4	0	0
APGAR - 6	1	3.33
APGAR - 7	1	3.33
APGAR - 8	1	3.33
APGAR - 9	2	6.7
APGAR - 10	25	83.33
Total	30	100

Table 5 shows APGAR score in 1 min of neonates delivered from women in the study groups. It was observed that no significant difference in APGAR score in 1 min. APGAR equal or more than 7 considered normal, and for discharged from neonatal care unit (NCU) the APGAR should be 10 at 10 min. according to visible beat. of neonates delivered from women in the study group. There is no significant difference in APGAR score in 10 min among all groups.

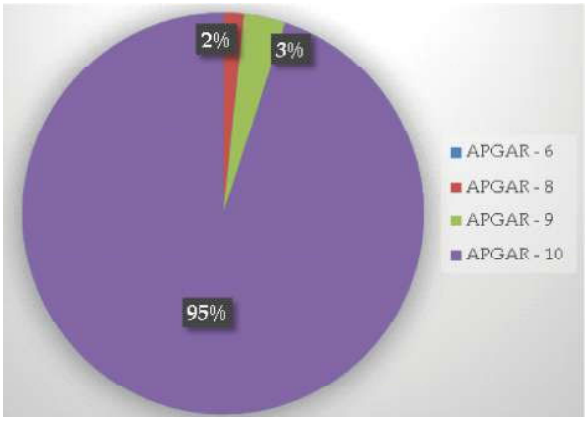

Fig. 1: APGARscore in 10 min.

Discussion

In providing labour analgesia,intrathecal narcotic (ITN) administration rivals epidural analgesia. ITN is faster in onset, safer, less technically demanding. Those women who choose to have it and has a high degree of patient satisfaction following its use receive ITN. ITN cannot and does have limitations and will not replace epidural analgesia/anesthesia. ITN is a technique that has its own merits and limitations, it has a significant potential for improving pain control.

In present study it was found that there was difference in level of satisfaction between the study groups regarding degree of pain control. Herpolsheimer et al. [5] and Zapp J et al. [6] said that ITA was preferred bysome multiparous patients to the EA during previous labours. ITA is associated with high Apgar scores and good neonatal outcomes when compared with intravenous analgesia, was observed by Wong et al. [7]. Throughout the different phases of labor while tailored to the specific needs of the individual parturient, the ideal labour analgesia should provide pain relief effectively. ITA will offer rapid and significant pain relief without affecting the course of labour, with good maternal and neonatal outcome in women in advanced labour, multiparous or women with suspected uncomplicated labour course. The technique is identical to a lumbar puncture and can be observed by obstetrician with minimal anesthetic involvement specially in area, where EA is not available. Arkoosh et al. [8] observed that

analgesia provided better maternal satisfaction in parturients who received continuous spinal analgesia compared with epidural analgesia and was superior. However, a higher failure rate was reported by investigators, in the spinal catheter group, that resulted in catheter dislodgement. A trend was observed towards more post-dural puncture headaches in parturients with continuous spinal analgesia [9]. In a controlled trial, Landau et al. [13], for labour analgesia between two groups of 224 healthy nulliparous women with uncomplicated pregnancycompared the ED50 of intrathecal fentanyl. Group A consisted of wild-type homozygote (304A) patients whereas group G included heterozygotes and homozygotes carrying the mutant 304G allele. The ED50 for fentanyl in group A, determined by an up-down sequential allocation method, was 26.8 μg (95% CI 22.7–30.9), compared to 17.7 μg (95% CI 13.4–21.9) in group G. Moreover, patients in group G (lower ED50) requested supplemental analgesia at a greater cervical dilation than patients in group A. This finding is a counterintuitive result because increasing cervical dilation has been demonstrated to correlate with greater epidural analgesic requirements. These results suggest that this 304A > G mutation in the OMPR1 gene may not only affect the potency of intrathecal fentanyl for labour analgesia, but also modulate pain tolerance. In a comparable population, Wong et al. [7] investigated the effect of this same mutation on the duration of analgesia following a 25-μg intrathecal dose of fentanyl for labour.

Several episodes of hyperactivity of uterine associated with fetal bradycardia following intrathecal administration of 50 μg of fentanyl was observed. In 7 of 30 consecutive patients, a decrease in fetal heart rate to 80 - 100 beats/min was noted. In two other patients the fetal heart rate decreased below 70 beats/min. On several occasions, this uterine hyperactivity following intrathecal fentanyl has since been confirmed. More recently Abrao and co-workers [11] performed a randomized controlled trial on 77 parturients to estimate the effects of combined spinal-epidural and traditional epidural analgesia on uterine basal tone and its association with the occurrence of FHR abnormalities. This is the only study in which intrauterine pressure was directly prospectively measured. Patients in the CSE group received bupivacaine 2.5 mg plus sufentanil 2.5 μg. In the epidural group patients received bupivacaine 12.5 mg of a 0.125% solution plus of sufentanil 10 μg. The type of analgesia was shown to be the only independent predictor of uterine hyper tonus. The authors concluded that CSE is associated with a significantly greater incidence of FHR abnormalities related to uterine hyper tonus compared with epidural analgesia, but this did not lead to a higher incidence in caesarean section. In comment of this study by Abrao and co-workers [10], Landau et al. [11]. state that the two analgesic regimens used in this study may not be equipotent as shown by the higher pain scores in the epidural group compared to the CSE group. Also the slower onset of pain relief with epidural analgesia makes it likely that FHR and intrauterine tone changes only become apparent after the study period of fifteen minutes. This may have exaggerated the differences reported between study groups. Landau et al. [11]. Also comment on the late initiation of labour analgesia in this study (6 cm cervical dilation) as it is known that neuraxial analgesia in this stage of labour is more commonly associated with FHR abnormalities than when it is initiated earlier. FHR changes and abnormalities may also be influenced by parity and use of oxytocin which are not adequately detailed in the study by Abrao and co-workers [10]. The 2.5 μg of sufentanil for intrathecal analgesia in the study by Abrao et al. is also substantially higher than the dose in group 2 used earlier by Van de Velde and co-workers [12] in a double-blind, double placebo-controlled trial comparing two forms of CSE with epidural analgesia. In this study a comparison was made between epidural bupivacaine 12.5 mg plus 7.5 μg sufentanil 7.5 μg with epinephrine 12.5 μg, intrathecal bupivacaine 2.5 mg plus sufentanil 1.5 μg with epinephrine 2.5 μg, and a third group with sufentanil 7.5 μg intrathecally. Twenty four % of the patients in the high dose intrathecal sufentanil group developed FHR abnormalities compared to 11% in the lower dose intrathecal sufentanil and 12% in the epidural group. Uterine hyperactivity occurred in 12% of the high dose intrathecal sufentanil group compared to 2% in the other two groups, but tocolytic therapy was rarely needed. The data from these recent studies warrant caution in the use of higher doses of opioids intrathecally because of the risk of uterine hyperactivity and FHR abnormalities, without however increasing the risk for caesarean delivery or detrimental effects on neonatal out come. One study has been done with addition of intrathecal tramadol to CSE analgesia. Since there is no human toxicology available for intrathecal administration of tramadol, such studies ethically need to be conducted under specific approval from the appropriate government source. Frikha et al. [13] conducted a randomized prospective study comparing bupivacaine 2.5 mg with sufentanil 2.5 μg to bupivacaine 2.5 mg with

tramadol 25 mg intrathecally. The purpose of this study was to compare tramadol and sufentanil in terms of duration of analgesia and frequency of adverse maternal or fetal effects. FHR tracings of all patients were done from one hour before analgesia to one hour after initiation of analgesia. All FHR tracings were normal before initiation of CSE. FHR tracings after initiation of analgesia were comparable between the sufentanil and tramadol groups. No patient in this study had a non-reassuring FHR tracing. The group of patients receiving tramadol had significantly longer-lasting analgesia. Five of the 20 patients receiving tramadol also presented with vomiting, which is the only major side effect noted with tramadol in this study. In present as low dose (25 µg) of fentanyl was added no fetalbradycardia was observed.

Conclusion

Intrathecal narcotic administration is an effective analgesia option to consider for women in labour. ITN will have particular appeal for facilities that do not have readily available 24/7 epidural services. Fentanyl + LA in low doses is effective analgesia with no significant side effects. Implementing ITN in a facility would require that the facility also provide staffing levels to ensure that monitoring of the patient, intra and postpartum, is adequate to recognize complications in a timely fashion should they arise.

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