A Double Blind Comparative Study between Intrathecal Bupivacaine and Intrathecal Fentanyl as the Initial Dose of Combined Spinal Epidural Technique for Labour Analgesia

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ABSTRACT

Introduction: Labour analgesia techniques is the most widely practised procedures of pain management performed by an anaesthesiologist and are requested by the obstetrician colleagues as well as the parturient mothers. Presently, Combined Spinal Epidural (CSE) is the most popular and effective technique of Labour Analgesia to render the mother pain free. This technique has two parts. Our study is primarily concerned with the first part of CSE for the comparison of drugs. The aim of the study was to compare the efficacy between a small and fixed doses Fentanyl (25µgm) and Hyperbaric 0.5% Bupivacaine (2.5mg) as the initial step of CSE technique for labour analgesia.

Material and methods: This double blind study aims to compare the efficacy between a intrathecal fixed dose of lipophilic opioid i.e, Fentanyl (25µgm) and a fixed dose of local anaesthetic hyperbaric 0.5% Bupivacaine (2.5mg) as the initial step to establish labour analgesia . 60 parturient will be divided into two group. Group I will receive intrathecal Fentanyl and Group II will receive intrathecal Bupivacaine. Onset, quality and quantity of pain relief achieved following intrathecal injection of drugs will be taken into account whereas incidence of side-effects like motor paralysis, hypotension, pruritus, foetal bradycardia & respiratory depression will be noted and compared. This will indicate which drug will be more preferable as a sole drug for the initial intrathecal component of CSE technique for labour analgesia.

Results: The shortest time of onset of analgesia in group I was 60sec and in group II was 40sec which was statistically significant ($p<0.05$). The average duration to reach maximum analgesia in Group I was 5.93 ± 1.68 min and in Group II was 5.30 ± 1.31 min.Whereas the duration of analgesia was found varying widely. It was 54±15.16 minutes in Group I whereas 73.5±14.74 minutes in Group II. The duration ranged from 25 minutes to 80 minutes in Group I and 35 minutes to 100 minutes in Group II. This difference was statistically significant ($p=0.000005$).The significant side effect noted was pruritus (56.67%) in Group I and motor paralysis (80%) and hypotension (6.67%) in Group II.

Conclusion: A small dose of Fentanyl is preferable to a similar small dose of Bupivacaine for the initial intrathecal administration as a part of Combined Spinal Epidural labour analgesia technique as muscle weakness prevents the mother from taking active part in second stage of labour and hypotension is non desirable.

Keywords : Analgesia, Fentanyl, Heavy bupivacaine, Labour, Motor Weakness

INTRODUCTION

Labour pain brings in a spectrum of adverse physical implications to the mother as well to the foetus. Apart from special situations, pain can complicate the delivery process to an otherwise healthy mother with normal foetus. Over the ages many techniques to relieve labour pain have been tried like physical, psychological and pharmacological means[1] but none has been so efficacious and successful than the present day's technique of Combined Spinal Epidural (CSE) Analgesia[2,3,4,5]. However, there is always a chance of further improvement. Combined Spinal Epidural technique provides effective and timely labour analgesia particularly for women in active labour. CSE technique consists of a spinal injection of a small dose of local anaesthetics and/or lipophilic opioids (usually Fentanyl or Sufentanil), followed by introduction of catheter into epidural space for maintaining of analgesia[2] by extradural drug administration.

Studies are available to use only a narcotic or a combination of a narcotic plus local anaesthetic for the initial intrathecal administration in the CSE technique of labour analgesia but few studies have compared the efficacy between a narcotic and a local anaesthetic alone for this purpose.This double blind study aims to compare the efficacy between a fixed dose of lipophilic opioid i.e, Fentanyl (25µgm) and local anaesthetic hyperbaric 0.5% Bupivacaine (2.5mg) as the initial step to establish analgesia given intrathecal and to compare which drug is more preferable as a sole drug for the initial intrathecal component of CSE technique for labour analgesia.

The aim of the study was to compare the efficacy between a small and fixed doses Fentanyl (25µgm) and Hyperbaric 0.5% Bupivacaine (2.5mg) being the sole drug for intrathecal injection as the initial step of CSE technique for

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labour analgesia with the following objectives to compare the onset, quality and duration of their analgesic action and to compare the incidence of unwanted effects like muscle weakness, hypotension, pruritus, nausea/vomiting and foetal bradycardia by the individual drugs.

MATERIAL AND METHODS

This double blind randomised controlled study was done in the command hospital (Eastern Command) Kolkata from December 2010 to December 2012 after obtaining approval from Institutional Ethical Committee. The sample size was calculated to be 60 on the basis of analgesia duration as the primary outcome measure from the literature search for the variation in the studied data. It was calculated that 23 subjects would be required per group in order to detect a difference of 30 min in analgesia duration with 90% power and 5% probability of Type I error. This calculation assumed a standard deviation of 30 minutes for analgesia duration. Rounding off, the recruitment target was kept at 30 subjects per group.

Inclusion criteria: ASA grade I and II Parturient undergoing delivery at CH (EC), aged between18 and 35 years.

Exclusion criteria: Patient refusal, Local infection of the back, Coagulopathy or anticoagulant therapy, Hypovolemia-haemorrhage or shock, Previous caesarean section for contracted pelvis and inadequate supervision. Other relative exclusion criteria are; pre-existing neurological disease & severe deformity of spine.

The design was a double blind study to avoid bias by the principal worker. A third party who was not directly connected to this study prepared two different intrathecal Injection, Groups of I & II. Injection of Group I contained 25µg of Fentanyl in 0.5ml of solution whereas Injection of Group II contained 2.5 mg of 0.5 ml of 0.5% hyperbaric Bupivacaine.

The patient were divided into two groups by allocating them a random number by a computer generated table.

Principal worker was handed over either of the drug groups each time at the beginning of each case without disclosing the identity of the drug. Results was compiled under each group of the drugs and analysed finally.

The mother was explained about the concept of painless delivery of the baby and the benefits of it. Obstetrician colleagues were discussed about the case and their concurrence was obtained. Informed-consent from the patient was obtained for labour analgesia.

Labour analgesia was made available to any women who requested for pain-relief and does not exhibit a specific contra-indication. Maternal BP, Pulse, $SpaO_2$, cervical dilatation and state of labour, fetal heart rate were recorded**.**

The mother was made comfortable in lateral position, preferable on left side. A good IV access was established and about 500ml of ringer lactate was transfused. Timing of the procedure depend on the request of the mother who was in labour. Generally, she was 3-4 cm dilated. It may be even earlier with specific indications like pre-eclampsia, in co-ordinate uterine action etc.

After taking proper aseptic precaution, 27G Quincke's spinal needle was inserted into subarachnoid space at L2-3/L3-4 intervertebral space. After return of clear CSF, patient received a single intrathecal injection(IT) of study drug. The time of the intrathecal injection was noted and the monitoring of clinical parameters for analgesia & side effects according to the study-protocol was initiated. As soon as the patient become comfortable and more co-operative, Tuohy needle was inserted into epidural space at either of the above spaces via midline approach using the loss of resistance technique and an epidural catheter was inserted 3-5 cm into the epidural space and was secured. If there was a failure to achieve desired analgesia following intrathecal injection or after getting a good relief following the injection, she again becomes uncomfortable of uterine contractions this study concludes there. She was given the epidural top up of 10-15 ml of 0.125% of Bupivacaine with 20µg of Fentanyl as standard institutional protocol and it was repeated sos till delivery of the baby. An observer (ie, principal worker) blinded to the treatment group, performed all post- intrathecal injection assessments. Onset of analgesia was enquired from the patient following the first few uterine contractions after the injection and time was recorded. She was also requested to tell when she became totally or maximum pain-free. This was also noted for comparison of the drug groups later. If she becomes totally pain-free, then duration of such period was noted. If she does not become pain-free or comfortable, then this study was terminated and first top up of conventional epidural dose of drug was administered and managed accordingly. For quantification of the pain, the conventional verbal rating scores (VRS) were employed. In VRS system of scoring; 0= No pain, 1= mild pain, 2= moderate pain, 3= severe pain, 4= intolerable pain. It was enquired verbally from the patient. VRS score 1 and anything more would merit for further supplementation of analgesia by epidural topping.

Maternal hemodynamic monitoring following the injection was continued. Onset of anaesthesia was noted on abdomen and lower limb by touching with cotton and hot/cold water. Parturient was examined at intervals for any motor paralysis by Modified Bromage scale and recorded. (Modified Bromage scale (0–3) 0- able to straight leg raise (SLR) and flex both feet and knees; 1- unable to SLR, able to flex knees and feet; 2- unable to SLR or flex knees, able to flex feet; and 3-unable to move legs or feet.)

Occurrence of maternal hypotension and bradycardia were noted and treated with IV fluids, vasopressors or vagolytic drugs. Fetal bradycardia was treated by giving oxygen to mother, avoiding aorto-caval compression and switching off oxytocin drip etc. Other common side effects like nausea and vomiting, were noted and treated with IV Ondansetron. Pruritus, if excessive was treated with Hydrocortisone 100 mg IV

Parameters Studied

1. Onset of action (sec).

2. Time to reach maximum analgesia (min)
3. Duration of analgesia
4. Systolic BP/ mean BP(mmHg).
5. Maternal and Fetal Heart Rate(/min).
6. Motor weakness.
7. Other complications (if any)

STATISTICAL ANALYSIS

Data from all 60 parturient were analysed. The statistical analysis was done by Software Statistica version 6 [Tulsa, Oklahoma: StatSoft Inc., 2001]. Non-parametric data were analysed using the chi-square or Mann-Whitney U tests, and parametric data were analysed with the Student's t test.

RESULTS

The table 1 shows the maternal demographic of parturient of both group. The parturient demographic were comparable in terms of Age, weight, parity and ASA grade.

The state of cervical dilatation (cm) at the time of intrathecal administration of the drug in both the groups was between 3-5cm (Table 2). No statistical difference was found between the two groups (p=0.26).

The VRS score at the time of intrathecal administration of the drug was found from verbal enquiry of patients. The average VRS score in group I was 3.3 ± 0.59 and in group II was 3.4 ± 0.57 (Table 3). There was no statistically significant difference between two group (p=0.33).

The speed of onset of analgesia (sec) in study groups was noted from lessening in howling of mother and from enquiring her regarding initiation of reduction in their perception of pre-existing pain using VRS, following administration of the study drug. The shortest time of onset found were 60 sec with Group I and 40 sec in group II (Table 4, Fig 1). The average speed of onset was early in group II. This difference was statistically significant (p = 0.000001) by Mann-Whitney U Test (p< 0.05).

The time to reach maximum analgesia (in minutes) was found from the maximum reduction in the pain score in individual patient after administration of intrathecal drug. This was observed between 4 to 10 minutes after administration of either drug in all patients (Table 5, Fig 2). The average duration was 5.93 ± 1.68 min in group I and 5.30 ± 1.31 min in group II. The difference between time to reach maximum analgesia between two groups was not statistically significant (p=0.12). Whereas the duration of analgesia was found varying widely. It was 54±15.16 minutes in Group I whereas 73.5±14.74 minutes in Group II (Table 6, Fig 3). The duration ranged from 25 minutes to 80 minutes in Group I and 35 minutes to 100 minutes in Group II. This difference of duration of analgesia between two groups was statistically significant (p=0.000005) by Student's unpaired t test (p< 0.05).

The side effects encountered were noted with either group of drugs and did not require any active management. The table 7 and Fig 4 summarises the side effects encountered in this study. The incidence of pruritus in group I was 17 (56.67%) whereas it is none in group II. There was significant statistical

Parameters	Group I	Group II	P value
Age (Years)	24.36±3.02	24.26±2.62	0.89
Body Weight (Kg)	60.16±5.37	61.73±6.06	0.29
Parity (Primi:Multi)	24:6	26:4	0.731
ASA GRADE (I:II)	28:2	28:2	1.00

Table-1: Demographic data

Group	n	Min	Max	Mean	Std Dev
I	30	3	5	3.6	0.72
II	30	3	5	3.33	0.54

Table-2: State of cervical dilatation (cm) at the time of intrathecal administration of drug

Group	n	Min	Max	Mean	Median	Std. Dev
I	30	2	4	3.3	3.0	0.59
II	30	2	4	3.4	3.5	0.57

Table-3: State of VRS score at the time of intrathecal administration of the drug

Group	n	Shortest (Minimum) time of onset	Delayed (maximum) time of onset	MeanTime of onset	Median	Std Dev
I	30	60	150	96.66	90.0	29.51
II	30	40	100	60.33	60.0	15.86

Table-4: The speed of onset of analgesia (in sec.) distribution in study groups

Group	n	Shortest time (minimum)	Longest time (Maximum)	Mean	Median	Std. Dev
I	30	4	10	5.93	5.00	1.68
II	30	4	10	5.30	5.00	1.31

Table-5: The time to reach maximum analgesia (in minutes): distribution in study groups

Group	n	Shortest (Minimum) Duration of analgesia	Longest (Maximum) Duration of analgesia	Mean	Std.Dev
I	30	25	80	54	15.16
II	30	35	100	73.5	14.74

Table-6: Duration of analgesia (minutes) in study groups

	Group I (N = 30)	Group II (N = 30)
*Pruritus	17 (56.67%)	0
**Nausea/vomiting	3(10%)	2(6.67%)
***Motor weakness	0	24(80%)
Shivering	0	0
Pdph	0	0
****Hypotension	0	2(6.67%)
*****Respiratory depression	0	0
Foetal bradycardia	0	0

Table-7: Comparision of foeto-maternal complications

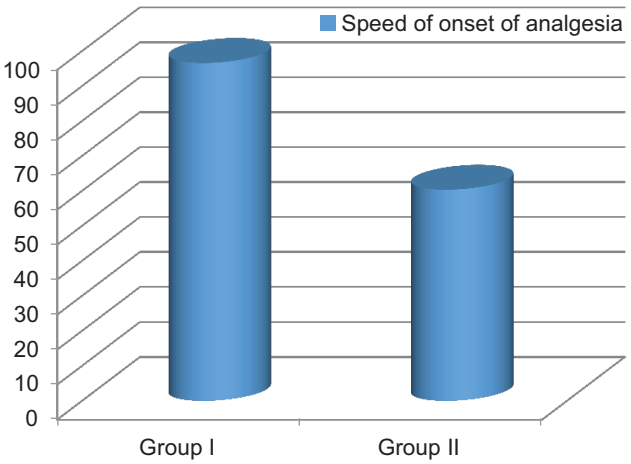

Figure-1: Speed of onset of analgesia (in seconds)

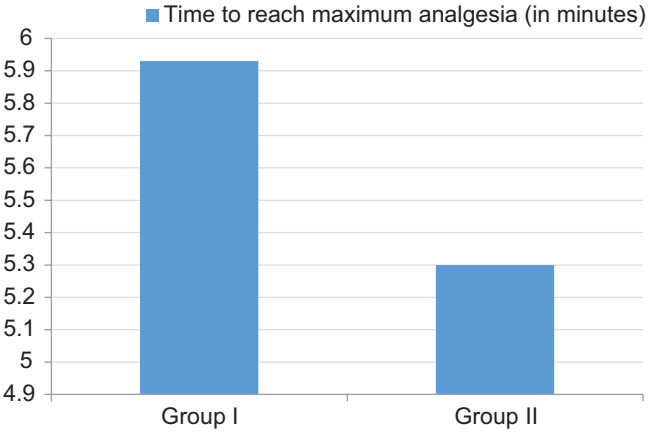

Figure-2: The time to reach maximum analgesia (in minutes)

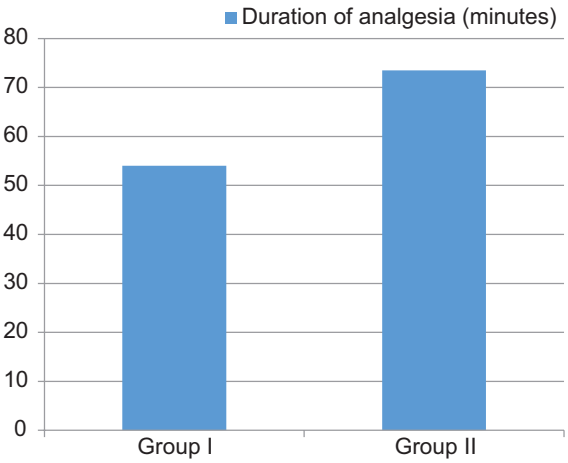

Figure-3: Duration of analgesia (minutes)

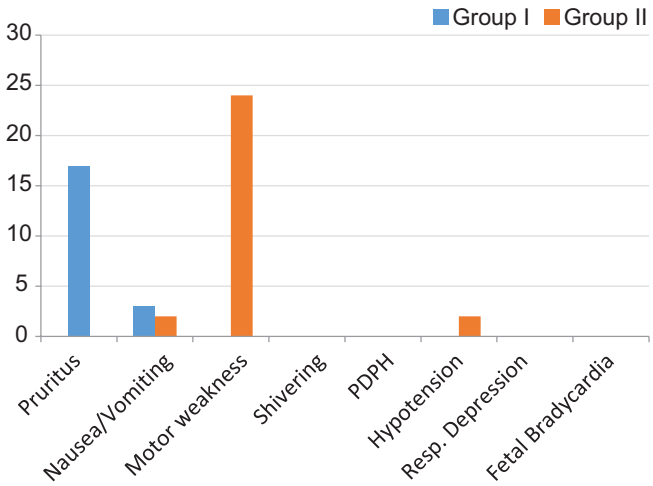

Figure-4: Comparision of Foeto –Maternal side effets

difference in pruritus between two groups ($p<0.001$) by Fisher's exact test 2-tailed. The incidence of motor weakness in group II was 24 (80%) whereas none in group I and was statistically significant ($p< 0.001$) by Chi square test 9 with yate's correction. Other side effects difference between two groups were not statistically significant.

DISCUSSION

Labour analgesia techniques, at the present time, are some of the most widely practised procedures performed by an anaesthesiologist and are requested by the obstetrician colleagues as well as the parturient mothers from the labour room. The newer methods of pain relief has not only brought joy and pleasure to the mother but also bring in a host of advantages and safety to her as well as to her offspring. This has become possible because of the most modern technique of Combined Spinal Epidural analgesia and using very minute dose of potent drugs by which some of the drawbacks are avoided while taking the advantages of their analgesic properties. The most popular among the drug groups used now a days for the purpose of labour analgesia are the potent lipophilic narcotics like Fentanyl / Sufentanyl and long-acting local anaesthetics like Bupivacaine / Ropivacaine. Both these group of drugs are known to produce rapid onset of analgesic action. But their inherent side effects are the matter of concern. This study is done to compare the onset, quality and duration of analgesic action between the initial intrathecal injection of Bupivacaine and Fentanyl during CSE labour analgesia. It also compares the incidence of unwanted effect.

Both the Groups had similar baseline pain scores i.e mean VRS before intrathecal administration of the drug and results are comparable to each other. All the mothers in each group experienced lessening of pain quickly as evidenced by decrease in the volume of their screams and admitted the relief of pain on enquiry. This beginning of the relief was recorded as onset of analgesia.

The average time of onset of analgesia was significantly early with Bupivacaine at 60.33 seconds compared to Fentanyl which was 96.66 seconds. This statistically significant difference was however not significant clinically because a

difference of about a half-a-minute was very short interval in a painful state.

The time of reaching maximum analgesia was considered when VRS attended '0' in each case. The mean time to reach maximum analgesia was 5.86 minute in Fentanyl Group compared to 5.30 minute in Bupivacaine and the difference was not very significant. Thus both the group provides good quality of analgesia as parturient was pain free. In the study done by Gary M stocks et al[6], onset time of '0'(VRS) analgesia was attended in 8.8 minute in parturient receiving 2.5 mg Bupivacaine IT and was 8.6 min in parturient receiving 2.5 mg Bupivacaine plus 25µgm Fentanyl. The study done by B.B. Lee et al[7] found onset was within 5-10 min in parturient receiving 2.5 mg Bupivacaine plus 25µgm Fentanyl and receiving 1.25 mg Bupivacaine plus 25µgm Fentanyl IT. The study done by Craig M. Palmer[8] found that pain score was significantly lower at 2.5 min in the different groups receiving different doses of fentanyl and bupivacaine IT. So, the present study result were also comparable to other studies.

Duration of analgesia was the time period from the onset of analgesia after intrathecal administration of the drug till the first epidural top-up required by the mother. This difference in duration found in present study was significant and in favour of Bupivacaine. The study done by Evangeline H.L.Lim et al[9] found duration of analgesia was 100.1 ± 57.2 minute in parturient receiving 25µg Fentanyl with normal saline, 129.5 ± 48.5 min in 25µg Fentanyl plus 1.25 mg heavy Bupivacaine and 100.4 ± 50.0 min in 25µg Fentanyl plus 1.25 mg plain Bupivacaine. In the study done by Buvanendran Asokumar et al[10] the duration after the IT dose was longer with the combination for 25µg of Fentanyl + 2.5 mg of Bupivacaine (94.5 min) Group than compared with groups of single dose of fentanyl and bupivacaine IT. The study done by Lt Daniel C. Celeski et al[11] found that duration was 95.62 ± 43.3 minute in group receiving 25µg Fentanyl, 105.78 ± 46.8 minute in group receiving 37.5µg Fentanyl and 99.24 ±42.6 min in group receiving 50µg Fentanyl. Another study done by Craig M. Palmer et al[8] found duration of analgesia in the 25µg Fentanyl- Bupivacaine 2.5mg group was 108 ± 20 min which was longer than the groups receiving 25µg Fentanyl-only (92 ± 23 min) and 25µg Fentanyl- Bupivacaine 1.25 (94 ± 25 min). Thus, in the present study difference in duration of analgesia between two groups were significant and similar differences were also found in other studies.

Both the drugs used in the present study were fast acting with onset of analgesia between 40 to 150 seconds after intrathecal administration but the onset of action of Bupivacaine was faster than Fentanyl. Their peak analgesic action attended between 4 to 10 minutes. Mean time to reach maximum analgesia was similar in both groups. Both the drugs provided excellent quality of analgesia. The difference in duration of analgesia was significant between the two groups statistically. Mean duration of analgesia lasted for 54 minutes in Fentanyl group whereas in Bupivacaine group it lasted for 73.5 minutes. But as the technique for labour analgesia was CSE, the subsequent Epidural top up was to cater for further analgesia. Intrathecal drugs were only meant to provide for faster and definite analgesia at the onset for a reasonable duration. The Fentanyl group provides about 54 minutes of quality analgesia and this duration serves the purpose adequately. So the difference is not very relevant clinically.

Various studies have been conducted have recorded the side effects of these potent drugs. Their incidences have been brought down by reducing the doses which are still capable of providing sufficient analgesic action to counter the labour pain. In present study, the incidence of side effects were noted in the form of pruritus, nausea/vomiting, motor weakness, shivering, hypotension, respiratory depression and foetal bradycardia.

The incidence of pruritus in the present study was 56.67% in Fentanyl group whereas nil in Bupivacaine group, which was significant. The pruritus lasted for a short period i.e., not more than 10 minutes in any case. The degree of pruritus was mild to moderate and needed no therapeutic intervention to control it and subsided itself. The study done by Buvanendran Asokumar et al[10] found that the overall incidence of pruritus was 95.0%, 36.4%, and 0% in the group receiving 25µg Fentanyl, 25µgm Fentanyl + 2.5 mg Bupivacaine and 2.5 mg Bupivacaine IT respectively. Lt Daniel C. Celeski and his colleague[11]in his study found 100% pruritus in group receiving different doses Fentanyl IT. Similar incidence of pruritus was found in the study done by Gary M. Stocks[6], Palmer et al.[12] and Ayman Rofaeel et al[13]. The occurrences of pruritus recorded by other workers were even higher and universal in some studies with IT Fentanyl.

In the present study, Nausea and vomiting was found both in Fentanyl and Bupivacaine group and were not severe enough to alter maternal haemodynamic. The study by Ayman Rofaeel et al[13] showed 3.3% incidence of nausea and vomiting in group receiving bupivacaine and fentanyl.

Although intrathecal opioids should have no effect on motor pathways or muscle strength, local anaesthetics can cause motor block. Unfortunately we were unable to test our patient's ability to walk in this study as ambulation during labour was not encouraged by our obstetricians. The incidence of motor weakness was 80% in Bupivacaine group where as it was nil in Fentanyl group. In study by Ayman Rofaeel et al[13] incidence of motor weakness of Grade 1 was 53%, Grade 2 was 7% and Grade 3 was 7% in group receiving 2.5 gm of hyperbaric Bupivacaine with Fentanyl IT. Incidence of grade 1 was 3% in group receiving 2.5 gm plain Bupivacaine with Fentanyl IT. In study by B. B. Lee et al[7] motor block was greater in group receiving 2.5 mg Bupivacaine and Fentanyl, with seven parturient compared with none in group receiving 1.25 mg Bupivacaine and Fentanyl and it was inferred that the ability of parturient to walk might be improved with the smaller dose. The study done by Gary M. Stock et al[6] the incidence of motor block was 4-5% in all four groups receiving Bupivacaine alone or with Fentanyl. The incidence of motor weakness found in present study was also found in other studies where intrathecal Bupivacaine was used.

The incidence of hypotension in the present study was seen

only with Bupivacaine which was significant. In study done by Aymann Rofaeel et al[13] incidence of hypotension was 10% in group receiving 2.5 mg hyperbaric Bupivacaine and 23.3% in group receiving 2.5 mg plain Bupivacaine both with 15µg of Fentanyl. In study of Craig Palmer et al[8] there were significant changes within groups only in maternal Diastolic blood pressure and was found only in the Fentanyl-Bupivacaine 1.25 group; a significant difference was found only between the baseline and 30-min post injection values. In the study done by Lt Daniel C. Celeski et al[11] found 1 parturient in group I (25µg Fentanyl), 3 parturient in group II (37.5µg Fentanyl) and one parturient in group III (50µg Fentanyl) decrease in systolic blood pressure of more than 20% after IT injection of drug and required treatment.

The other side effects like Shivering, PDPH, Respiratory Depression and Foetal Bradycardia were not noticed in our study in either of the group.

The possibility that intrathecal Fentanyl might be associated with foetal heart-rate abnormalities was initially raised by Clarke et al[14]. In study done by Aymann Rofaeel et al[13] showed 10% incidence of foetal bradycardia in group receiving hyperbaric Bupivacaine and 33.3% in group receiving plain Bupivacaine. In study done by Craig M Palmer et al,[8] found no differences in foetal heart rates variation between pre injection and post injection values. Though transient foetal heart rate changes were noted in eight parturient during the course of the study which resolved spontaneously and none required urgent or emergent obstetric intervention.

The incidence of shivering was nil in this study. In study done by Lim et al[9] the incidence of shivering was found in 6% parturient in group receiving Fentanyl alone, in 1% parturient in group receiving Fentanyl plus hyperbaric Bupivacaine and in 6% parturient receiving Fentanyl plus plain Bupivacaine.

Limitation of The Study: Some bias did occur as we did not explain the parturient about labour analgesia during antenatal visit made by them in the OPD but when they were in labour in the labour room and pain relief assessment was made by an anaesthetist though ideally it should have been done by someone who was not aware about the pain relief method.

CONCLUSION

Intrathecal drugs are meant to provide faster and definite labour analgesia at the onset for a reasonable duration. Both these drugs are fast acting and their duration of effective analgesia are very much assuring clinically. But the motor weakness and hypotension associated with Bupivacaine group are very significant and not desirable. Muscle weakness prevents the mother from taking active part in the second stage of labour and the concept of a "Walking Epidural" is defeated by this. Similarly, hypotension is also not desirable as it complicates the physiology of both mother and the foetus and risks their very viability when severe and prolonged.

To conclude, Fentanyl is preferable and recommended than Bupivacaine for the initial intrathecal administration as a part of Combined Spinal Epidural Labour Analgesia Technique.

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