IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 23, Issue 11 Ser. 9 (November. 2024), PP 40-45
www.iosrjournals.org

Comparative Study Of Fentanyl Versus Tramadol As Adjuvant With Low Dose Local Anaesthetic Ropivacaine (0.1%) For Epidural Labour Analgesia

Dr Satyam[1], Dr Ekramuddin[2], Dr Ashutosh Jha[3], Dr Arshad Imam[4]
[1-4](Anesthesia, Katihar Medical College, India)

Abstract:
Background: *Epidural nerve block is widely used for labor analgesia because of its effective pain relief, reduced maternal stress response, improved parturient satisfaction, and potential ability to provide anesthesia. The quality of analgesiais improved with the combined use of a local anesthetic and an opioid when combined with the use of either agent alone. An example of avcombination epidural therapy that provides excellent sensory block with relatively little motor block includes a co-administration of ropivacaine and fentanyl or tramadol.*
Materials and Methods*: The study was carried out at the Department of Anaesthesiology, Katihar Medical College & Hospital, Katihar, Bihar, study was done for 1 Year, 100 individuals were enrolled, Group F (Fentanyl Group) with 50 patients received Ropivacaine and Fentanyl and Group T (Tramadol Group) with 50 patients received a Ropivacaine and Tramadol. Every variable was subjected to statistical analysis within the same individual and between 2 treatment categories using a suitable biostatistical methodology.*
Results*: In the present study, mean age in group F (ropivacaine with fentanyl) was 23.54±2.5, mean age in group T*
(ropivacaine with tramadol) was 23.86±2.17, and weight in group F was 56.78±2.75 and group T was 56.68±2.58.
Duration of labour in group F was 3.39±1.01 hrs and in group T was 3.42±0.70 hrs. There was no significant difference between the two groups at any time points for mean VAS score. There was no significant difference in the mean heart rate and arterial blood pressure among both the groups statistically (p>0.05). More side effects were seen in group F.
Conclusions*: Both fentanyl and tramadol in combination with ropivacaine provide similar analgesia with minimal*
motor block. Both have no adverse effects on cardiotocographic parameters. However side effects were relatively more common in fentanyl group. Thus tramadol is a safer alternative to fentanyl as an adjunct to epidural labour analgesia.
Key Word: *Tramdol, Fentanyl, Epidural analgesia, Ropivacaine, Labour analgesia*

Date of Submission: 29-11-2024 Date of Acceptance: 09-12-2024

I. Introduction

Epidural nerve block is widely used for labor analgesia because of its effective pain relief, reduced maternal stress response, improved parturient satisfaction, and potential ability to provide anesthesia (1). Severe labour pain can have neuropsychological consequences, postnatal depression and it has also been correlated with the development of post-traumatic stress disorder (2,3). The quality of analgesiais improved with the combined use of a local anesthetic and an opioid when combined with the use of either agent alone. Bupivacaine and ropivacaine are widely used to provide efficient epidural analgesia in labour. Ropivacaine, an amide local anaesthetic is less cardiotoxic as well as it may also be more selective for sensory fibers when compared to other local anaesthetics, producing less motor block. An example of a combination epidural therapy that provides excellent sensory block with relatively little motor block includes a co-administration of ropivacaine and fentanyl (4). However, the side-effects of fentanyl are still of concern during its use in perioperative period (5). Tramadol not only binds to opioid m-receptors but also interacts with the central nervous system by inhibiting the withdrawal of noradrenaline and serotonin (6). The unique pharmacological profile of tramadol makes it an attractive drug for postoperative pain management. In several preliminary clinical trials, tramadol has been proved to be a safe and effective drug for epidural analgesia (7,8). When the two drugs are combined, both the local anaesthetic and opioids can be administered at low concentrations, resulting in increased maternal satisfaction and most importantly, a decrease in the incidence of adverse effects such as hypotension and drug toxicity (9). The absence of the neuronal toxicity of tramadol and fentanyl allowed its use in neuraxial analgesia.

Hence, the purpose of the present study was to compare the analgesic and side-effects of two solutions that combined 0.125% ropivacaine with either tramadol 5 mg/mL or fentanyl 2 mg/mL in parturients undergoing labor during epidural analgesia.

II. Material And Methods

This prospective randomized controlled double blind study was carried out on patients of Department of epidural anesthesia undergoing labour at Katihar Medical College, Katihar, Bihar for 1 year after the approval from ethical committee. A total 100 adult subjects of aged ≥ 18, years were enrolled for in this study.

Study Design: Prospective randomized controlled study

Study Location: This was a tertiary care teaching hospital based study done in Department of general anesthesia at Katihar Medical College, Katihar, Bihar.

Study Duration: 12 Months, March 2023- February 2024.

Sample size: 100 patients.

Subjects & selection method: The study population was drawn from patients who presented in labour at Katihar Medical College, Katihar, Bihar between from March 2023- February 2024. Patients were divided into two groups (each group had 50 patients).

- Group F (Fentanyl Group): 50 patients received 10 ml epidural bolus dose was administered according to the group selected viz group F- ropivacaine 0.1% and 2 mcg/ml of fentanyl
- Group T (Tramadol Group): 50 patients received T- ropivacaine 0.1% and 5 mg/ml of tramadol After the administration of bolus dose, an epidural infusion of ropivacaine/fentanyl (0.1%/2 mcg/ml) was started at the rate of 5 ml/hr by syringe pump in group F. Similarly, group T received a 5 ml/hr continuous infusion of ropivacaine/tramadol (0.1%/5 ml). Supplemental doses of 5 ml ropivacaine (0.1%) were administered on demand in each group. Epidural infusion was continued till the completion of second stage of labour.

Inclusion criteria:

The following criteria were included in the study:
1.Patients undergoing epidural anaesthesia during labour
2.Age >18years
3.Those who gave informed and written consent to be part of the study
4.ASA Grade I, II
5. Height more than 150 cm
6. Weight less than 110 kg

Exclusion criteria:

The following criteria were excluded from the study:
1.Those who refused consent
2.Age <18years
3.ASA Grade II or above
4.Patients allergic to any of the drug used.
5. Individuals with high risk pregnancy

Procedure methodology

A detailed history was taken and a complete general physical examination including airway assessment, spine and systemic examination was done to confirm the inclusion and exclusion criteria. The parturients were evaluated by the obstetrician for cervical dilatation, effacement, position, station, integrity of membranes and adequacy of pelvis.

Baseline recording of heart rate, blood pressure and oxygen saturation and fetal heart rate (FHR) were noted. An intravenous (IV) line was accessed and maintenance fluid started. The patient was positioned in a sitting position. Under aseptic conditions the back was prepared was 5% povidone iodine solution and spirit. The L2-L3/L3-L4 interspace was identified by palpation and overlying skin was infiltrated with 2-3 ml of xylocaine (1%). Epidural space was identified with the help of 18 G tuohy needle using loss of resistance (LOR) to air technique and then 20 G epidural catheter was threaded through the epidural needle into the epidural space in cephalic direction, the catheter about 3 to 5 cm was left in epidural space. 10 ml epidural bolus dose was administered according to the group selected viz group F- ropivacaine 0.1% and 2 mcg/ml of fentanyl and group T- ropivacaine

0.1% and 5 mg/ml of tramadol. After the administration of bolus dose, an epidural infusion of ropivacaine/fentanyl (0.1%/2 mcg/ml) was started at the rate of 5 ml/hr by syringe pump in group F. Similarly, group T received a 5 ml/hr continuous infusion of ropivacaine/tramadol (0.1%/5 ml). Supplemental doses of 5 ml ropivacaine (0.1%) were administered on demand in each group. Epidural infusion was continued till the completion of second stage of labour.

Statistical analysis

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Student's *t*-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test. Chi-square and Fisher exact tests were performed to test for differences in proportions of categorical variables between two or more groups. The level $P < 0.05$ was considered as the cut off value or significance.

III. Result

Mean age, height, weight, cervical dilatation during epidural placement and gestational age in both the group were similar and non-significant. Group F and group T were similar with respect with to age of the parturient. (p>0.05) The mean age in group F was 23.54±2.5 years and group T was 23.86±2.17 years (Table 1).

Height of parturient in this study ranged from 153 cm to 164 cm in both the groups. The mean height in group F was 154.22±2.63 cm and 157.76±3.05 cm in group T. The p value was >0.05. The results were not statistically significant. Most of the parturient weighed between 50-60 kgs in the two groups. The P value was >0.05 which was not significant.

Around half (49%) of parturient in group F and 39% of parturient in group T had cervical dilatation of 5 cm while 36% in group F and 42% in group T had cervical dilatation of 4 cm. P value was >0.05 and was not statistically significant.

Table no 1: Demographic profile of both the groups.

	Group F	Group T	P value
Age (years)	23.54±2.5	23.86±2.17	>0.05
Height (cms)	158.22±2.63	157.76±3.05	>0.05
Weight (kg)	56.78±2.75	56.68±2.58	>0.05
Cervical dilatation during epidural placement (cms)	4.32±0.74	4.18±0.74	>0.05
Gestational age (weeks)	38.4±0.93	38.38±0.94	>0.05

Table no 2: Duration of labour and requirement of ropivacaine in both the groups.

Duration	Group F	Group T	P value
First stage (hours)	2.60±0.87	2.67±0.56	>0.05
Second stage (min)	47.08±17.0	45.34±14.01	>0.05
Total (hours)	3.39±1.01	3.42±0.70	>0.05
Total dose of ropivacaine (mg)	40.05±8.47	42.07±7.77	>0.05

Duration of labour in group F the mean duration of first stage of labour was 2.65±0.87 hours while in group T the mean was 2.68±0.56 hours. The difference between the two groups was not statistically insignificant (Table 2).

Figure 1: Line diagram showing trend of heart rate among study participants

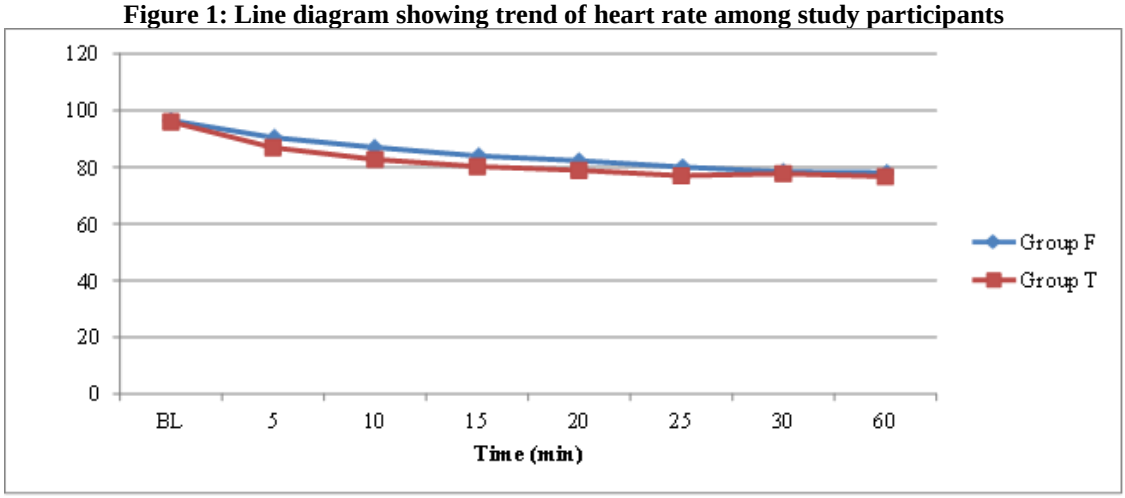
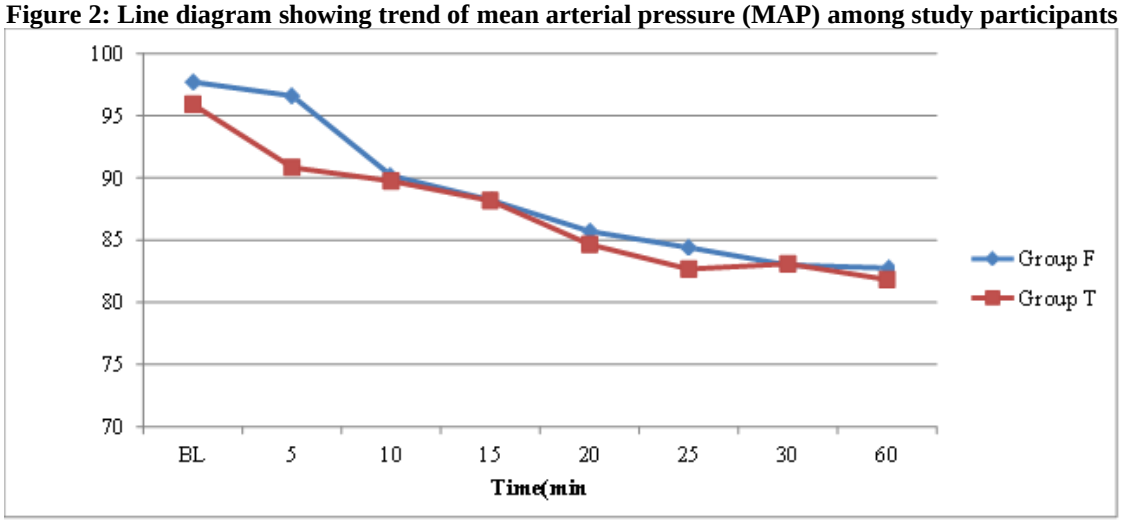


Figure 2: Line diagram showing trend of mean arterial pressure (MAP) among study participants



There was no significant difference in the mean heart rate and mean arterial blood pressure at any time interval among both the groups (p>0.05) (Figure 1 and 2).

Table no 3: Distribution of VAS score in both the groups.

Time interval (min)	Group F	Group T	P value
Basal	9.78±0.67	9.46±1.17	>0.05
5	6.58±1.70	5.92±1.73	>0.05
10	3.7±1.23	3.26±1.29	>0.05
15	2.66±1.08	2.4±0.83	>0.05
20	1.88±0.98	2±0.80	>0.05
25	1.54±1.05	1.66±0.79	>0.05
30	1.08±0.94	1.14±0.8	>0.05
60	1.06±0.89	1.36±0.87	>0.05

Basal visual analogue scale (VAS) of parturient was comparable in the two groups with p value >0.05 which was statistically not significant. There was no significant difference between the two groups at any time points (Table 3).

Table no 4: Distribution of side effects in both the groups

Side effects	Group F	Group T
Nausea	2	5
Vomiting	1	-
Pruritus	1	-
Urinary retention	2	-
Shivering	4	-
Hypotension	-	-
Respiratory depression	-	-

Side effects between the two groups showed that more side effects were seen in group F i.e. fentanyl along with ropivacaine (Table 4).

IV. Discussion

Epidural analgesia for painless labour was given to 100 parturient belonging to ASA grade I and II admitted to hospital. The parturient were randomly allocated by computer generated system into 2 groups. Group F (n=50) received ropivacaine (0.1%) with fentanyl (2 mcg/ml) and group T (n=50) received ropivacaine (0.1%) with tramadol (5 mg/ml) given as an initial bolus of 10 ml followed by continuous epidural infusion of 5 ml/hour continued until the delivery. Extra top ups of 5 ml ropivacaine (0.1%) were given on patient demand (VAS>3).

Finegold et al also conducted a similar type of randomized double blind study comparing ropivacaine (0.1%) fentanyl and bupivacaine (0.125%) fentanyl infusions for epidural labour analgesia (10). Rao et al also carried out a similar study on walking epidural with low dose bupivacaine plus tramadol on normal labour in primipara patients (11). Gupta et al conducted a study on painless labour by epidural analgesia and its effects on cardiotocographic parameters and labour (12). Dostbil et al compared maternal and neonatal effects of adding morphine with fentanyl to low dose bupivacaine for epidural labour analgesia (9).

In our study after giving a bolus dose we used the same drug concentration as a continuous epidural infusion till the completion of second stage of labour, top-up doses were given in supine position. The dose used for subsequent top-ups was 5 ml ropivacaine (0.1%) in both the groups.

Demographic variables and obstetric characteristics were similar between the two groups. There was no statistically significant difference between the two groups. Demographic and obstetric data were similar with the Indian studies by Kalra et al and Tomar et al (13,14). The baseline mean arterial blood pressure (MAP) and maternal heart rate (HR), VAS score were comparable in both the groups. For study purpose data were recorded for the first 60 minutes. These parameters were in accordance with the study carried out by Fan et al (15).

Many studies have reported sensory loss up-to T10 to cold, pain and warmth sensation. Tomar et al and Fan et al studied the analgesic effects of fentanyl and tramadol in combination with bupivacaine and ropivacaine for extradural labour analgesia and found that the height level of sensory block was T8 in 16 and T10 level in 10 parturient (14,15). In our study we used pinprick method to test the level of sensory blockade 54% in group F versus 56% in group T achieved the sensory level up to T10 which was comparable between the two groups. Motor block was assessed using a modified Bromage scale. All the parturient in both groups had grade 0 score. Most patients usually walked around the room, where they voided spending approximately 10-15 minutes out of bed on each occasion with accompanying person. Kalra et al, Fan et al, and James et al found that in both ropivacaine/fentanyl group and ropivacaine/tramadol group, modified bromage scale was 0 or 1 with most of the patients scoring in both groups (13,15,16).

James et al and Saunders et al reported attenuation of endogenous oxytocin during second stage by epidural block which reduced the uterine contractility (16,17). They recommended the use of oxytocin during second stage of labour to improve outcome in nulliparous women receiving epidural analgesia.

In our study the mean duration of first stage of labour was 2.60 hours in group F and 2.67 hours in group T. As far as the duration of labour was considered, there was no statistically significant difference between the two groups. Tomar et al in a study using fentanyl 2 mcg/ml with bupivacaine 0.125% for epidural labour analgesia found the mean duration of first stage of labour to be 2.87 hours.12 The mean duration of second stage of labour was 47.08 min in group F and 45.34 min in group T in this study. There was no statistically significant difference between the two groups. Rao et al also found similar results in a study using tramadol 5 mg/ml with 0.1% bupivacaine (11).

Total amount of drug used from bolus till the completion of second stage was calculated. Total average dose of ropivacaine used was 40.05±8.47 mg and 42.07±7.77 mg in group F and T respectively. Total average dose of fentanyl used in group F was 53.77±10.08 mcg. Total average dose of tramadol used in group T was 135.96±17.67 mg.

In our study no significant difference in maternal men arterial pressure (MAP), heart rate (HR) and visual analogue scale (VAS) score seen in both groups at any time points. Similar finding were seen in a study conducted by Fan et al (15).

In our study, spontaneous vaginal delivery occurred in 94% of the parturient in group F and 96% in group T. Three patients in group F and 2 patients in group T underwent caesarean. There was no statistically significant difference between the two groups. Fan et al in a comparative study of epidural tramadol/ropivacaine and fentanyl/ropivacaine for labour analgesia found that caesarean was done in 2 patients in both groups (15). Kalra et al in a study comparing efficacy of bupivacaine/fentanyl with bupivacaine/sufentanyl for epidural labour analgesia found the similar results where one patients in each group had undergone caesarean (14).

In our study FHR were comparable in both the groups throughout the study. Gupta et al found no significant effect on cardiotocographic parameters in epidural and control group (12). Fan et al found neonatal HR comparable between both groups at any time points (15). Reynold et al in their study did not report any change in the neurobehavioural or appearance, pulse, grimace, activity, and respiration (APGAR) score when up to 80 mcg fentanyl was given for first stage of labour for pain relief (18).

In our study APGAR score was employed to assess the newborns. At 1-minute interval only 10% of the newborns in group F, 4% in group T had an APGAR score of less than 7. Although no significant difference was seen, there was a tendency that the incidence of side-effects (pruritus, shivering and urinary retention) was higher in group F. No significant difference was observed in other side effects such as nausea, vomiting, motor block, respiratory depression and hypotension between the two groups. Furthermore, none of the parturient in any group required specific treatment during labour. Chestnut et al found pruritus (7%), nausea (14%), emesis (14%) and urinary retention (41%) when bupivacaine (0.0625%)/fentanyl (0.0002%) was used as continuous infusion (19). Cohen et al reported pruritus in 26%, drowsiness in 11% and urinary retention 21% of the patients when bupivacaine (0.068%) with fentanyl 10 mcg was used (20). Fan et al in a comparative study of tramadol/ropivacaine and fentanyl/ropivacaine for epidural labour analgesia found the similar results (15).

In our study 40 in group F and 38 patients in group T had good satisfaction score while 7 patients in group F and 10 patients in group T had excellent satisfaction scores. There was no statistically significant difference between the two groups. Tomar et al in a study using fentanyl 2 mcg/ml with bupivacaine 0.125% for

epidural labour analgesia found 7 patients reporting good satisfaction level and 20 reporting excellent satisfaction levels (14).

V. Conclusion

Epidural analgesia is a safe and excellent method of relieving pain in labour with excellent satisfaction in parturient. Both fentanyl and tramadol in combination with ropivacaine provide similar analgesia with minimal motor block. Both have no adverse effects on cardiotocographic parameters. However side effects were relatively more common in fentanyl group. Thus tramadol is a safer alternative to fentanyl as an adjunct to epidural labour analgesia.

References

[1] Hawkins JL. Epidural Analgesia For Labor And Delivery. N Engl J Med. 2010;362:1503–10. Doi: 10.1056/Nejmct0909254.
[2] Hiltunen P, Raudaskoski T, Ebeling H, Moilanen I. Does Pain Relief During Delivery Decrease The Risk Of Postnatal Depression?. Acta Obstet Gynecol Scand. 2004;83:257-61.
[3] Soet JE, Brack GA, Dilorio C. Prevalence And Predictors Of Women Experience Of Psychological Trauma During Childbirth. Birth. 2003;30:36-46.
[4] Halpern SH, Breen TW, Campbell DC, Muir HA, Kronberg J, Nunn R, Et Al. A Multicenter, Randomized, Controlled Trial Comparing Bupivacaine With Ropivacaine For Labor Analgesia. Anesthesiology. 2003;98:1431–5. Doi: 10.1097/00000542-200306000-00020.
[5] Cashman JN, Dolin SJ. Respiratory And Haemodynamic Effects Of Acute Postoperative Pain Management: Evidence From Published Data. Br J Anaesth. 2004;93:212–23. Doi: 10.1093/Bja/Aeh180.
[6] Lehmann KA. Tramadol In Acute Pain. Drugs. 1997;53:25–33. Doi: 10.2165/00003495-199700532-00007.
[7] Yildiz TS, Ozdamar D, Bagus F, Solak M, Toker K. Levobupivacaine-Tramadol Combination For Caudal Block In Children: A Randomized, Double-Blinded, Prospective Study. Paediatr Anaesth. 2010;20:524–9. Doi: 10.1111/J.1460-9592.2010.03296.X.
[8] Siddik-Sayyid S, Aouad-Maroun M, Sleiman D, Sfeir M, Baraka A. Epidural Tramadol For Postoperative Pain After Cesarean Section. Can J Anaesth. 1999;46:731–5. Doi: 10.1007/BF03013907.
[9] Dostbil A, Celik M, Alici HA, Erdem AF, Aksoy M, Ahiskalioglu A. Maternal And Neonatal Effects Of Adding Morphine To Low Dose Bupivacaine For Epidural Labour Analgesia: Niger J Clin Prac. 2014;17(2):205-11.
[10] Finegold, Mandell G, Ramanathan S. Comparison Of Ropivacaine 0.1% Fentanyl And Bupivacaine 0.125% Fentanyl Infusions For Epidural Labour Analgesia. Can J Anaesth. 2000;47(8):740-5.
[11] Rao ZA, Choudhri A, Naqvi S, Haq EU. Walking Epidural With Low Dose Bupivacaine Plus Tramadol On Normal Labour In Primipara. J Coll Phys Surg Pak. 2010;20(5):295-8.
[12] Gupta N, Gupta S, Agarwal A, Agarwal S, Dwivedi S, Singh A. To Study The Painless Labour By Epidural Analgesia And Its Effects On Cardiotocographic Parameters And Labour. Int J Reprod Contracept Obstet Gynecol. 2013;2(4):666-7.
[13] Kalra S, Saraswat N, Agnihotri GS. Comparison Of Efficacy Of Bupivacaine And Fentanyl With Bupivacaine And Sufentanil For Epidural Labour Analgesia Saudi J Anaesth. 2010;4(3):178-81.
[14] Tomar GS, Godwin RB, Gaur N, Sethi A, Narang N. A Double Blind Study On Analgesic Effects Of Fentanyl Combined With Bupivacaine For Extradural Labour Analgesia. Anaesthesia: Essays And Researches. 2011;5(2):147-52.
[15] Fan Y, Ji M, Zang L, Wang W, Yin Q, Xu J, Yang J. Comparison Of Epidural Tramadol Ropivacaine And Fentanyl Ropivacaine For Labour Analgesia: A Prospective Randomized Study. Upsala J Med Sci. 2011;116:252-7.
[16] James KS, Mcgrady, Quasim J, Patrick. A Comparison Of Epidural Bolus Administration Of 0.25% Bupivacaine And 0.1% Bupivacaine With 0.0002% Fentanyl For Analgesia During Labour. Br J Anaesth. 1998;81:501-10.
[17] Saunders NJ, Spiby H, Gilbert L, Fraser RB. Oxytocin Infusion During Second Stage Of Labour In Primiparous Women Using Epidural Analgesia. BMJ. 1989;299(6713):1423-6.
[18] Reynolds F, Sullivan GO. Epidural Fentanyl And Perineal Pain In Labour. Anaesth. 1989;44:341-4
[19] Chestnut DS, Laszewski LJ Pollack K, Bates JN, Manage NK, Choi DW. Continuous Epidural Infusion Of 0.0625% Bupivacaine+0.0002% Fentanyl During Second Stage Labour. Anaesthesiol. 1990;72:613-8.
[20] Cohen SE, Tan S, Albright GA, Halpern J. Epidural Fentanyl/Bupivacaine Mixture For Obstetric Analgesia. Anesth. 1987;67:403-7.