International Journal of Science and Research (IJSR)
ISSN (Online): 2319-7064
Index Copernicus Value (2015): 78.96 | Impact Factor (2015): 6.391

Comparative Study of Dexmedetomidine and Fentanyl for Epidural Analgesia for Lower Limb Orthopaedic Surgeries

Dr. Reshma Korat[1], Dr. Malti Pandya[2], Dr. Pinal Patel[3], Dr. Pragna Vachharajani[4]

Department of Anaesthesiology, Surat Municipal Institute of Medical Education and Research (SMIMER), Surat, Gujarat, India

Abstract: ***Context: comparison of two drugs for analgesia in lower limb orthopaedic surgeries along with ropivacaine. Aim: This study was carried out to evaluate and compare the effect of dexmedetomidine and fentanyl when combined with ropivacaine administered via epidural route for lower limb orthopaedic surgeries. Method: A hospital based, randomised and comparative study was performed in total 60 patients divided into 2 groups of 30 each. Thorough preanaesthetic evaluation was done and patients were explained regarding the procedure and taught to assess the intensity of pain using VAS. Group I received 15 ml ropivacaine 0.75% + 1 µg/kg dexmedetomidine epidurally. Group II received 15 ml of 0.75% ropivcaine + 1µg/kg fentany epidurally. Vitals were monitored. Sensory blockade was assessed by pin prick method, motorblockade was assessed by modified bromage scale, sedation was assessed by subjective sedation scale. Result: The onset of sensory and motor blockade was faster in group I which were 14.83±2.01mins.and 18.26±2.25mins respectively. Total duration of analgesia was significantly prolonged in group I(347±18.64) as compared to group II(211±22.68). Conclusion: Addition of dexmedetomidine to epidural ropivacaine produces rapid onset of sensory and motor blockade, prolonged duration of analgesia, less requirement of ropivacaine dose, better hemodynamic stability as compared to fentanyl.***

Keywords: Epidural analgesia, Ropivacaine, Dexmedetomidine, Fentanyl

1. Introduction

Epidural anaesthesia is a safe, effective & most commonly used technique for providing not only surgical anaesthesia but post operative analgesia also. Ropivacaine, longer acting amide drug along with fentanyl or dexmedetomidine prolong the duration of sensory and motor blockade with better hemodynamic stability. Central neuraxial adjuvant drugs, alone or in combination, are used intrathecally or epidurally for the treatment of acute and chronic painful conditions. Nowadays trend of addition of several adjuvants like ketamine, tramadol, fentanyl, clonidine, dexmedetomidine etc. in epidural analgesia to modify local anaesthetic drug effect and reduce side effects.

Dexmedetomidine, α2 agonist provides analgesia by decreasing the sympathetic outflow and noradrenaline release by acting on pre and post synaptic nerve terminal.It causes hypotension and bradycardia but it provides prolong duration of analgesia, better sedation and lack of opioid related side effects.

Fentanyl is highly lipophilic which rapidly acts on opioid receptors in substantia gelatinosa producing hyperpolarisation of nerve membrane and decreasing excitability. It has side effects like nausea, vomiting pruritus, respiratory depression, urinary retention which are less as compared to other opioids.

2. Material & methods

After approval from institutional ethical committee, this study was included 60 patients of ASA grade I & II, between the age group 20 -60 years, undergoing lower limb orthopaedic surgeries in department of anaesthesia smimer medical college and hospital, surat. Informed consent was obtained for performance of epidural anaesthesia after complete explanation about study protocol and procedure. Study design was hospital based, randomized, comparative and observational. Sample size was calculated at 80% study power, @ level 0.05 assuming difference in mean to be detected. For minimum detectable difference 30 patients were required in each group as sample size.

Inclusion criteria

- ASA grade I & II
- Age 20 -60yrs.
- Patients weight 45 -85kgs
- Patients undergoing lower limb orthopaedic surgeries.

Exclusion criteria

- Patient refusal
- Patient having contraindication of epidural anaesthesia (infection at the site of injection, spine deformity, coagulation disorders)
- Known cardiac, renal, neurological, metabolic, endocrine, psychiatric, respiratory disease.

Pre anaesthetic check up: Thorough pre anaesthetic check up was done a day before surgery and routine investigations were carried out.

All patients were kept Nil by Mouth overnight in the recovery room baseline vitals, SPO2 were recorded. IV line secured with 18 G cannula.

Premedication: Inj**.** Glycopyrrolate 0**.**004mg/kg and Inj.midazolam 0.04mg/kg IM 30 mins. before surgery.

Preloading was done with infusion of ringer lactate 10 ml/kg.

Epidural catheter was inserted in sitting position in L3-L4 interspinous space with 18 G Touhy needle using loss of resistance technique under all aseptic precaution. Patients were randomly divided into two groups to receive drugs epidurally.

Group I: 15 ml 0.75% Ropivacaine + 1µg/kg Dexmedetomidine [100µg /ml]
Group II: 15 ml 0.75% Ropivacaine + 1µg/kg Fentanyl [50µg /ml]

Just after giving epidural anaesthesia heart rate, blood pressure, SPO2 were recorded every 5 mins. at Interval for ½ hour, every 10 mins. for 1 hour, then every 15 mins. till surgery was completed. Sensory blockade was assessed by PIN PRICK METHOD. 0-No sensation. 1- Pin sensed as dull pressure. 2- Sharp pain..Motor blockade was assessed by MODIFIED BROMAGE SCALE. 0- No block. 1- Inability to raise extended leg. 2- Inability to flex leg. 3- Inability to flex ankle and foot. Sedation was assessed by SUBJECTIVE SEDATION SCALE: 0-awake, conscious, no sedation, slightly restless. 1- calm and compose. 2- awake on verbal command. 3- awake on slight gentle stimulation. 4- awake on vigorous shaking. 5- unarousable. The patients were also monitored for any complications like nausea, vomiting, bradycardia, hypotension, respiratory depression shivering, headache, dizziness and urinary retention during intra and post operative period. Hypotension is defined as systolic BP < 90 mmof Hg. Bradycardia is defined as HR <60 beats/min. Inj.Mephentermine 6 mg i.v. was used to treat hypotension whereas Inj.Atropine 0.6 mg i.v. was used to treat bradycardia. For treatment of nausea and vomiting inj. Ondansetron 4 mg was used i.v. Post operatively also HR, BP, SPO2 were recorded every hourly upto 6 hours, every 2 hourly upto 12 hours and then 4 hourly up to 24 hours. VAS 0 -10 was used for post operative pain assessment. Top up dose (8 ml 0.2% ropivacaine epidurally) was given when VAS≥4 during intra or post operatively up to 24 hours & no. of top up doses were calculated. Time for first top up dose/ rescue analgesic was also noted.

Onset of sensory blockade was defined as the time from injection of study drug to complete ablation of pin prick. Onset of motor blockade was defined as the time from injection of study drug to the time when a complete paralysis occurred, Rescue analgesia was defined as time between injection of study drug to the return of pain sensation which is tolerable (VAS≥4).

The statistical analysis was done by unpaired t- test for quantitative data and chi-square test for qualitative data.

3. Results

There was no significant difference in terms of age, weight, sex distribution and duration of surgery between the two groups (p>0.05).

Table 1: Demographic profile of patients in different groups (n =30)

P value	Group 2	Group 1	Particulars
	Mean±SD	Mean±SD	
P>0.05	40.26±13.60	35.06±11.17	Age(years)
p>0.05	58.16±8.55	55.9±5.55	Weight(kg)
	26.(86.66)	28(93.33)	Male (%)
	4 (13.33)	2 (6.66)	Female (%)
P>0.05	107.5±28.82	122.66±34.45	Duration of surgery(min)

Onset of sensory blockade at T_{10} in group I was 9.46±2.01 min and in group II was 13.96±2.42min..Maximum sensory level was achieved in a shorter period in group I which was 14.83±2.01min as compared to group II was 20.33±3.95 min. So there was difference in mean time to achieve maximum level of sensory blockade which was highly statistically significant (P<0.001)(figure 1).The mean time for sensory regression to S_1 level was 299.33±17.7 min in group I, while 171.16±22.19 min in group II. So time for sensory regression to S_1 level was prolonged in group I as compared to Group II which was highly significant (P<0.001) (table 1).

Time of onset of motor blockade was 14.9±2.10 min. in group I while 17.16±1.48 min. in group II. Time of complete motor blockade was faster in group I which was 18.26±2.25min.as compared to 24.2±4.13 in group II.(figure 2). So time of onset of motor blockade and complete motor blockade between the groups were statistically significant.(p<0.05).Time to regression of motor blockade to bromage scale 1 was 247±17.99 min in group I and 149.66±22.51 min in group II(table3).Thus difference in duration of motor blockade was highly significant between the two groups(p<0.001)

There was statistically significant fall in blood pressure and decrease in heart rate in group I as compared to group II..No significant change in O2 saturation was observed in any patient of the any groups throughout the surgery.(p>0.05).

After 20 mins of epidural injection patients attained sedation score 3 in group I as compared to group II in which sedation score was 2 till the end of surgery. None of the patients in study develop high level of sedation (score 5) intraoperatively.

Post operatively all the patients were assessed for 10 point visual analogue scale. When VAS ≥4 rescue analgesic was administered epidurally. On 1st post operative hour, there was no significant difference of VAS score between the two groups. On 2nd post operative hour mean VAS was 1.33±0.54 in group I while 3.06±1.25 in group II. So requirement of first top up was earlier in group II as compared to group I. While in group I, first top up dose was required at 3rd and 4th hour. In 5th and 6th hour mean VAS was more in group II when second top up dose was given while in group I second top up dose was given at 8th and 10th hour. Mean VAS score was statistically significant upto 10th hour post operatively after that, values of VAS remained insignificant between these two groups.(figure 3).Total duration of analgesia was longer in group I (347±18.64 min.) as compared to group II (211±22.68min.). (Figure 4) There was less requirement of dose of ropivacaine used over 24 hrs. in group I as compared

to group II.(figure 5).

Table 2: Comparison of sensory blockade

P value	Group II (MEAN ± SD)	Group I (MEAN ± SD)	Particulars
P<0.001	13.96±2.42	9.46±2.01	Time of onset of sensory blockade at T_{10}(min)
	T6-8	T4-6	Maximum sensory level achieved
P<0.001	20.33±3.95	14.83±2.01	Time to achieve the maximum sensory level(min)
P<0.001	120.66±10.88	143.33±12.05	Time to two segment regression(min)
P<0.001	171.16±22.19	299.33±17.70	Time to sensory regression at S_1(min)

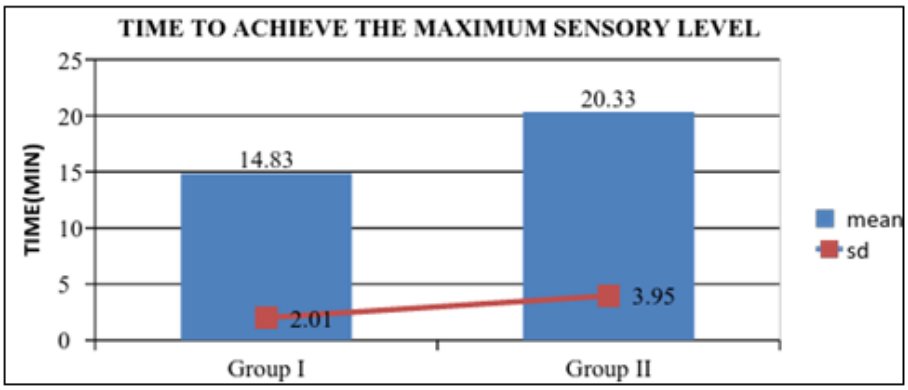

Figure 1: Maximum sensory level achieved at different time intervals in both groups

Table 3: Comparison of motor blockade

P value	Group II (MEAN±SD)	Group I (MEAN±SD)	Particulars(min)
P<0.001	17.16±1.48	14.9±2.10	Time of onset of motor blockade
P<0.001	24.2±4.13	18.26±2.25	Time to complete motor blockade:
P<0.001	149.66±22.51	247.33±17.99	Time of regression to modified bromage scale1:

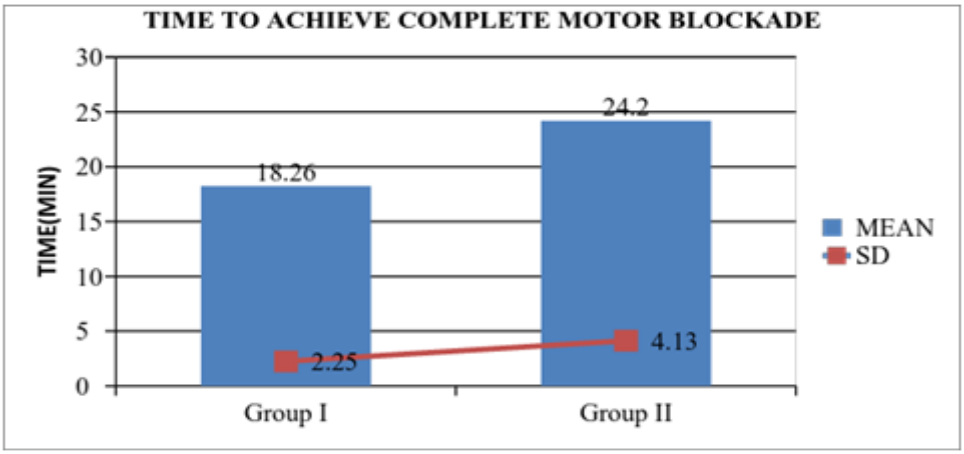

Figure 2: Complete motor blockade at different time intervals in both groups.

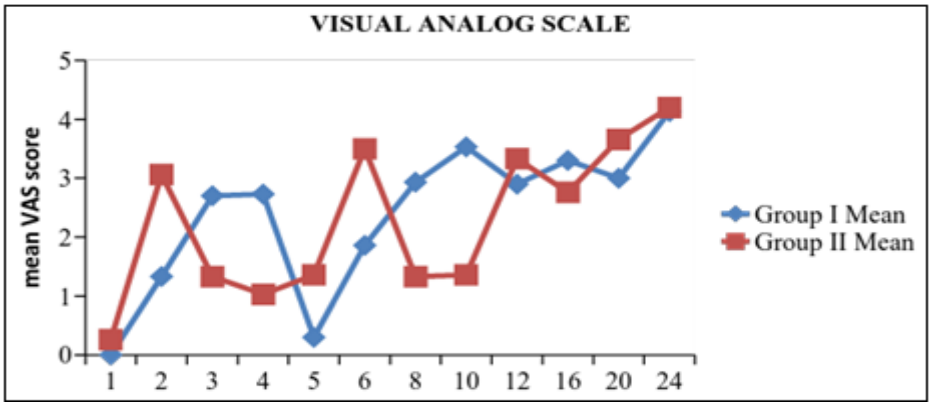

Figure 3: Mean Visual Analogue Scale at different time intervals in both groups.

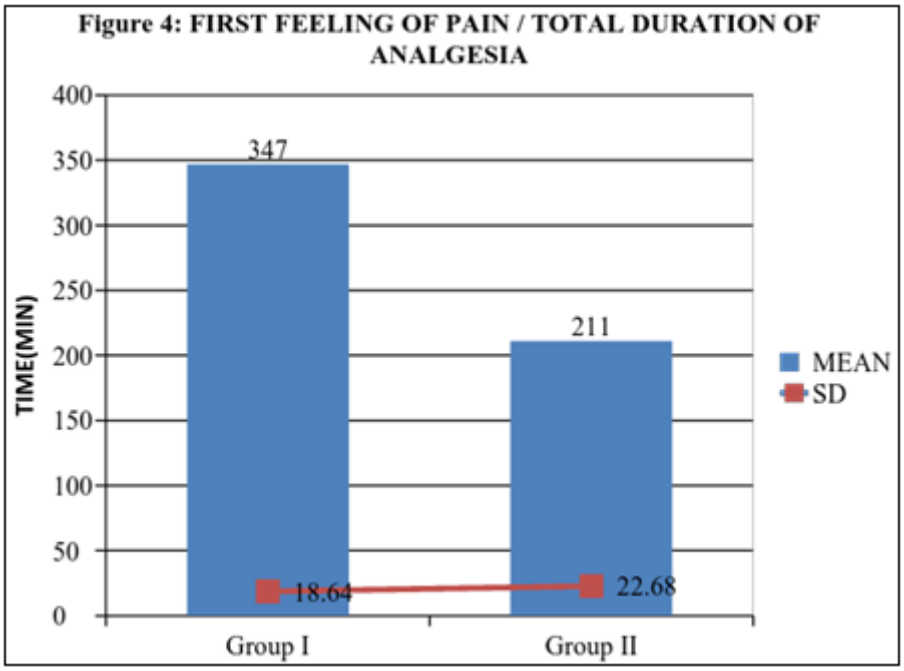

Figure 4: First feeling of pain at different time intervals in both groups

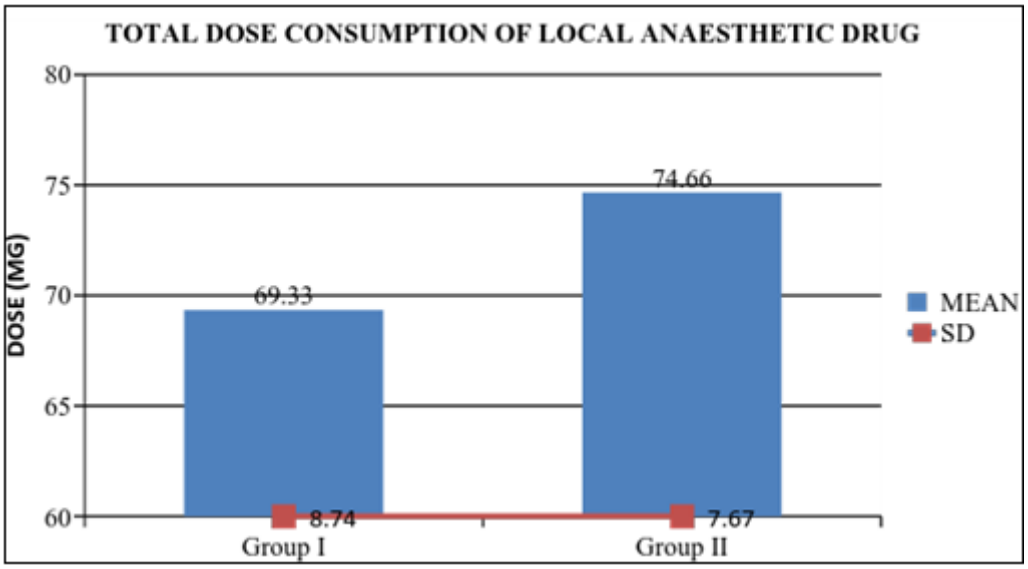

Figure 5: Total dose consumption of local anaesthetic drug in both groups

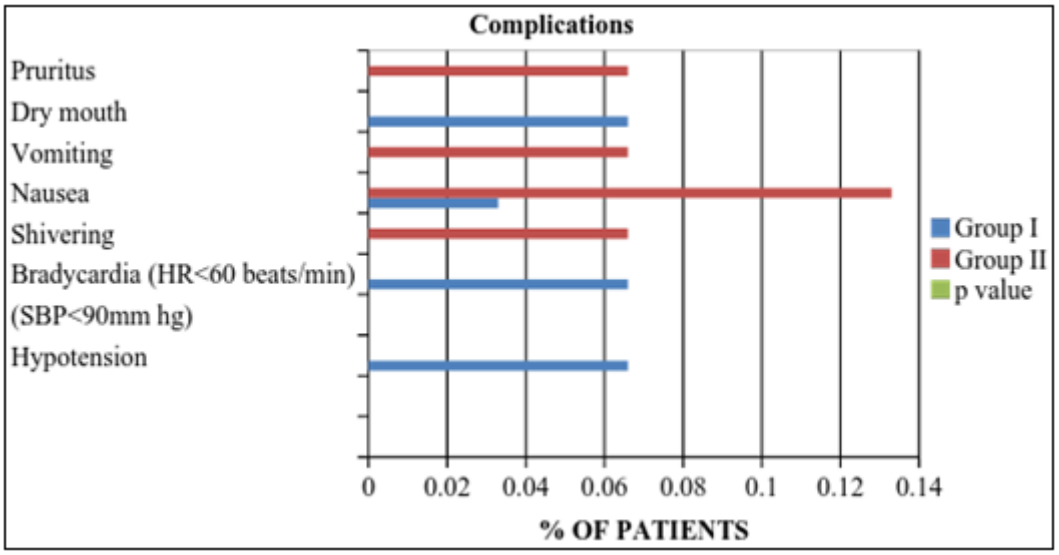

Figure 6: Complications occurred in both groups.

Hypotension and bradycardia were observed in two patients (6.6%) in group I which was treated with inj.Mephentermine 6 mg and inj.Atropine 0.6 mg i.v.respectively.Two patients (6.6%)in group I had dry mouth. Nausea was observed in one patient in group I while four in group II. Vomitting, pruritus and shivering were observed in two patients (6.6%) in group II. No hypotension and bradycardia were observed in group II(figure 6)

4. Discussion

Considerable evidence exists to implicate the role of α2 agonist which act on pre and post synaptic sympathetic nerve terminal and central nervous system to decrease the sympathetic outflow and nor epinephrine release causing sedation, analgesia, sympatholytic effect. Opioids act on substantia gelatinosa in the dorsal horn of spinal cord, where it blocks the neural fibres carrying pain impulses both at presynaptic and post synaptic level.

Bajwa S J, Arora V and their colleagues[2] were studied that addition of dexmedetomidine or fentanyl along with epidural ropivacaine provides dose sparing effects of local anaesthetic and would accelerates the onset of sensory and motor blockade and decrease the effective dose requirement of local anaesthetic. Their results correlate well with our study.

The study of Saravana Babu M S, Verma A K, Agarval A and coworkers[16] (2013) shows significant increase in post operative analgesia (407.00±47.06 min) to (345.01±35.02 min) in dexmedetomidine group as compared to clonidine group. In our study, we have noticed that enhancement of postoperative analgesia when we injected dexmedetomidine as additive to ropivacaine epidurally which was confirmed by pin prick and VAS score.

Whiteside R, Jones D, Bignell S and their collegues[18] also reported prolonged postoperative analgesia with fentanyl group but also associated with nausea and vomiting. Similarly in our study, incidence of nausea and vomiting were more in fentanyl group.

In 2010 Bajwa S J, Bajwa S K and his coworkers[20] evaluated and compared the effect of fentanyl ropivacaine combination with clonidine ropivacaine in epidural anaesthesia for lower abdominal surgeries. They observed that onset of sensory blockage to maximum sensory level was faster in fentanyl group as compared to clonidine group. In contrast to this, in our study we observed that dexmedetomidine provided early sensory and motor blockage as it is highly selective α2 agonist with receptor affinity 8 times higher than clonidine.

All of the above studies correlate well with our study, where we used dexmedetomidine and fentanyl as an adjuvant to epidural ropivacaine.

Vieira A M, Schnaider T B et al[19] evaluated the effect of epidural clonidine and dexmedetomidine in subcostal cholecystectomy for post operative analgesia and sedation, They observed that more sedation with dexmedetomidine group. Similarly to these findings we also observed that better sedation in dexmedetomidine group as compared to fentanyl group.

We observed major side effects hypotension and bradycardia in 6.6% cases in group I which is supported by studies of Jain D, Khan R M, Kumar D et al[15].

In our study nausea and vomiting were observed in 13.3% and 6.6% respectively in group II which correlates with studies of Whitside R, Jones D, Bignell S and their collegues[18].

5. Conclusion

We concluded that dexmedetomidine may be a useful alternative to fentanyl as an adjuvant to epidural ropivacaine for post operative analgesia because of its sedative, sympatholytic, analgesic & a stable hemodynamics effects.

References

[1] Atkinson R S., Rushman G.B., Davies N.J.H: Lee"s synopsis of Anaesthesia; Butterworth Heinemann publication, 11th edition; Ch-25, Spinal analgesia: intradural and extradural: 691-737
[2] Bjwa S J, Arora V et al: Comparative evaluation of dexmedetomidine and fentanyl for epidural analgesia in lower limb orthopaedic surgeries. Saudi J Anaesth 2011;5 (4): 365-370.
[3] Bromage PR: Epidural analgesia. (saunders). Identification of epidural space in epidural analgesia, 1978:196.
[4] Buggy Donal j and Smith Graham : Epidural anaesthesia and analgesia: better outcomeafter major surgery? BMJ 1999; 319 : 530-531.
[5] Collin V J: General andRegional Anaesthesia. 3rd edition (ISBN): ch-59, Epidural analgesia in principles of Anaesthesiology: 1571- 1607.
[6] Kuthiala G, Chaudhary G: Ropivacaine : A review of its pharmacology and clinical use. IndianJ Anaesth 2011; 55 (2) : 104-10.
[7] Mackintosh Carolyn: Assessment and management of patients with post operative pain. Nursing standard 2007; 22 (5): 49-55.
[8] McClure JH: Ropivacaine. Br J Anaesth. 1996;76 : 300-7.
[9] Joana Afonso, Flavio Reis et al: Dexmedetomidine: current role in anaesthesia in intensive. Rev Bras Anestesiol; Jan-Feb 2012;62 (1): 1-17.
[10] Miller RD: Opioids. Miller's Anaesthesialer's. 7 th edition. Philadelphia: Elsevier Ltd; 2010:769-824.
[11] Miller RD: Spinal, Epidural and caudal anaesthesia. Miller's Anaesthesia, 7th edition. Philadelphia: Elservier Ltd; 2010: 1611-38.
[12] Morgan E. et al: Clinical Anaesthesiology 4th edition; (Mc Graw Hill); Ch-18, Pain management: 362-372.
[13] Wylie and Churchill Davidson's: A practice of anaesthesia. 7th edition;Edward Arnild Publication; 613-617, 1211-1230.
[14] Stoelting K et al; Pharmacology and physiology in Anaesthesia practice. Anaesthesiology textbook 3rd edition (Lippincott raven).
[15] Jain D, Khan R M, Kumar D et al: perioperative effect of epidural dexmedetomidine with intrathecal bupivacaine on hemodynamic parametrs and quality of analgesia.Soth Aft J Anaesth analg 2012;189(2) : 105-

109.
[16] Saravana Babu Ms, Verma A K, Agarval A and co workers: A comparative study in the post operativespine suegeries: epidural ropivacaine with dexmedetomidine andropivacaine with clonidine for podt operative analgesia.Indian J Anaesth 2013;57(4):371-376.
[17] Farouk s. et al: pre incisional epidural magnesium provides pre-emptive andpreventive analgesia in patients undergoing abdominal hysterectomy.Br J Anaesth 2008;101(5):694-699.
[18] Whiteside R, Jones D, Bignell S et al: Epidural ropivacaine with fentanyl following major gynaecological surgery: the effect of volume and concentration on pain relief and motor impairement. Br J Anaesth;2000;84(6): 720-724.
[19] Vieira AM, Schnaides T B et al: Epidural clonidine or dexmedetomidine for post cholecystectomy analgesia and sedation..Rev Bras Anaesth; 2000;Aug54(4): 473-8.
[20] Bajwa S J, Bajwa S K et al: dexmedetomidine and clonidine in epiduran anaesthesia: A comparative evaluation. Indian J of anaesth 2011;Mar-Apr;55(2): 116-121.