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Original Research Article

Comparative Study of Effect of Dexmedetomidine and Fentanyl as Epidural Adjuvants in Abdominal Hysterectomies Using Combined Spinal Epidural Technique - A Randomised Prospective Study

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Abstract: ***Background****:* Regional anesthesia is defined as loss of sensation in a body produced by administration of anaesthetic agent to the nerves supplying that region. Regional anesthesia whether by spinal, epidural, peripheral nerve blocks offer a number of advantages. Bupivacaine has become standard agent for intrathecal anesthesia. A number of adjuvants can be added to prolong the duration of analgesia. In our study we are comparing fentanyl & dexamedetomidine as an epidural adjuvant to spinal bupivacaine in abdominal hysterectomies. ***Materials and Methods***: A total of 60 patients scheduled for abdominal hysterectomy under CSE were enrolled for this prospective randomized study which was conducted in hospital from November 2019 to October 2020. This work has been granted ethical committee approval. ***Results*****:** Two groups comprising of 30 patients each were taken randomly. Haemodynamic parameters of heart rate, blood pressure, spo2, were monitored and recorded every 5 min for first 20 minutes and then every 10 minutes till the end of surgery and thereafter postoperatively. The sensory block was assessed by bilateral pin prick method and motor blockade according to Modified Bromage Scale. Duration of anesthesia was taken as time period till VAS of 4 was recorded. ***Conclusion:*** In our study we concluded that dexmedetomidine is better adjuvant as compared to fentanyl in combined spinal epidural anaesthesia with intrathecal bupivacaine.

Keywords: Regional anesthesia, dexmedetomidine, fentanyl.

INTRODUCTION

The history of neuraxial anaesthesia dates back to 1885 when James Leonard Corning injected cocaine between the spinal processes of lower lumbar vertebrae in a dog. In 1921 Spanish military surgeon Fidel Pages developed the technique of lumbar epidural and in 1933 Achille Mario Dogliotti described the loss of resistance technique using Tuohy needle, a technique also referred to as Dogliotti's principle. Combined spinal-epidural may achieve rapid onset, profound regional blockade with the facility to modify or prolong the block (Cook TM, 2000). The rationale of using a combination of the two techniques was to associate the advantages of each technique, minimizing specific disadvantages. This technique combines the efficacy of spinal anesthesia & flexibility of epidural anesthesia.

Bupivacaine is an amide group local anaesthetic which has become a standard agent for intrathecal anaesthesia. It is the most commonly used local anaesthetic with lower incidence of postoperative complications (Pollock JE *et al.*, 1999). It reduces the risk of transient neurological syndrome and radicular symptoms. The main disadvantage of local anaesthetics is their short duration of action and delayed onset.

A number of adjuvants can be added to bupivacaine to prolong the duration of analgesia & also decrease the dose of bupivacaine. Neuraxial adjuvants such as opioids, sodium bicarbonate, adrenaline, alpha-2 adrenoceptor agonists, N-Methyl-D-Aspartate Antagonists and GABA- receptor agonists are used to improve, hasten or prolonged analgesia and decrease the adverse effects associated with high doses of local anesthetic agent. But these adjuvants have their complications like nausea, vomiting, pruritis, urinary retention and respiratory depression with opoids, hypertension and tachycardia with vasoconstriction and excessive sedation as observed with clonidine with frequent reports of adverse effects on these adjuvants. So to avoid complications of these adjuvants, the adjuvants with minimal or no side effect will be compared.

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A synergistic interaction between local anaesthetics and opoids with epidural administration has been reported (Kancho M *et al.*, 1994). Local anaesthetic and opioid combination was shown to be more effective in epidural analgesia for postoperative pain relief as their effects started rapidly and lasted longer when compared with local anaesthetic given alone. (Ozalp G *et al.,* Can J Anaesth (1998) 45: 938).

Fentanyl, a synthetic u- receptor agonist has been shown to be an effective adjuvant in epidural anaesthesia with minimal risk of side effects at usual clinical doses of 25-100ug (Naulty JS *et al.*, 1983; Paech MJ *et al.*, 1990; Halonen PM *et al.*, 1993). The main site of action of fentanyl is the substantia gelatinosa in the dorsal horn of spinal cord where it blocks the neural fibres carrying the pain impulses both at presynaptic and post synaptic levels (Cousins MJ and Mather LE, 1984). Fentanyl with hyperbaric bupivacaine improve the quality of intraoperative & early post operative block (Gupta R *et al.*, 2011).

Although opioids can provide profound perioperative analgesia with fewer central or systemic side effects, their use however has always been surrounded by controversy because of the associated adverse effects like pruritis, nausea, vomiting, urinary retention and respiratory depression (Gustafsson LL *et al.*, 1988; Ackerman WE *et al.*, 1989). But they are more with parenteral use than epidural use.

Dexmedetomidine is a selective alpha- 2 adrenoceptor agonist, which acts on pre and post synaptic sympathetic nerve terminal. It also acts on Central nervous system to decrease the sympathetic outflow and nor epinephrine release causing sedative, antianxiety, analgesic, sympatholytic & haemodynamic effects. Motor blockade tends to be denser with dexmedetomidine. Dexmedetomidine is also devoid of respiratory depression, pruritis, nausea and vomiting.

In our study, we are comparing fentanyl & dexmedetomidine as an epidural ajuvant to spinal bupivacaine using combined spinal epidural technique (CSE) in abdominal hysterectomies.

MATERIALS AND METHODS

The present study was conducted in the Postgraduate Department of Anaesthesiology and Intensive Care, Government Medical College Jammu after getting clearance from institutional ethics committee from 2019 to 2020 and prospective registration of the study protocol with the Clinical Trials Registry of India (CTRI Registration Number CTRI/2020/05/025192).

The patients enrolled were explained about the study and a written informed consent was taken from them. Sixty female patients of ASA Grade I and II, aged 30 to 60 years, scheduled for abdominal hysterectomy under CSE were enrolled for this prospective randomized study.

Exclusion Criteria:

1. ASA Grade > II
2. Patients with contraindication for neuraxial anesthesia
3. Patients with history of local anesthetic allergy
4. Obese patients (BMI>35)
5. Patients not willing for regional anaesthesia

ANESTHETIC TECHNIQUE

In the operating room, standard intra-operative monitoring was done including: SPO2, NIBP, ECG.

Under all aseptic precautions, the injection site in the lumbar region was infiltrated with local anesthetic.

In the sitting position, CSE anesthesia was performed using a needle through needle technique. The epidural space was located using loss of resistance to air with an 18G Tuohy needle at L3-L4 level.

The dural puncture at L3-L4 level was achieved with 27G pencil point needle. After confirmatory aspiration of cerebrospinal fluid, 3ml of 0.5% Hyperbaric Bupivacaine was injected intrathecally.

The spinal needle was withdrawn & a 20G epidural catheter was inserted 3-4cm into the same epidural space.

The catheter was secured & the patient was placed in supine position to attain the level of T5-T6 block & was maintained in this position till the end of surgery.

The epidural adjuvants were administered depending on the group assigned.

Group BD received dexmedetomidine 1microgram/kg body weight diluted in saline and made 10ml whereas, Group BF received fentanyl 0.5 microgram/kg body weight diluted in saline and made 10ml and both were given epidurally.

SENSORY BLOCKADE

The sensory blockade was assessed by bilateral pin prick method using a short beveled 26G hypodermic needle every 5min. for the first 30min and every 15min for the rest of the surgery. The time of onset of sensory block at T10 dermatome, peak level of sensory block, the time to reach peak level of sensory block was observed. Sensory block to reach T10 level was accepted sufficient to start the surgery.

MOTOR BLOCKADE

Degree of motor blockade according to Modified Bromage Scale was assessed every 5 min. for

30min. after epidural drug administration and then every 15min. for the rest of the surgery.

0= No motor power impairment and able to raise straight leg.
1= Unable to raise straight leg but able to flex knee.
2= Unable to flex knee.
3= Unable to flex ankle and foot (no movement).

DURATION OF ANALGESIA

Pain intensity was assessed every 30min with the help of Linear Visual Analogue Scale (VAS) using a 10cm line, 0 denoting no pain while 10 denoting worst possible pain.

Duration of analgesia was taken as time period till VAS of 4 was recorded. After this, postoperative pain was managed with rescue injection of bupivacaine 0.125% in saline total made 10ml solution.

The epidural catheter was kept for 24 hours in the postoperative period and postoperative analgesia was maintained with epidural top ups depending upon the patient's need for analgesia. The number of top up doses required were noted.

Cardiorespiratory parameters of heart rate, blood pressure, SPo2 were monitored continuously and recorded every 5min for first 20min after the epidural injection, then every 10min till the end of the surgery and thereafter 15, 30, 60 and 120min postoperatively.

PATIENTS GROUPS

Two Groups comprising of 30 patients in each group were taken randomly. Using a web based sample size calculator, the sample size in our study was 28 in each group, assuming alpha = 0.05 and beta= 0.2 or power (1-beta) = 0.8. Assuming a 5% drop out, in our study, we enrolled 30 patients in each group. Using computer generated randomization, the patients were allocated into two groups.

GROUP BD- Received 3ml of 0.5% bupivacaine (Heavy) intrathecally. Dexmedetomidine 1microgram / kg body-weight diluted in saline total making it 10ml & was given through epidural catheter.

GROUP BF- Received 3ml of 0.5% bupivacaine (Heavy) intrathecally. Fentanyl 0.5microgram/ kg body weight diluted in saline total making it 10ml & was given through epidural catheter.

In our study we compared fentanyl & dexmedetomidine as epidural adjuvants to intrathecal bupivacaine in abdominal hysterectomies using combined spinal epidural anesthesia. The study demonstrated adequate surgical anaesthesia with comparable intra-operative sensory and motor blockade in both groups. The indication of hysterectomy are numerous and depends on patient's age, clinico-pathological diagnosis and reproductive status of female.

Dexmedetomidine is a new addition to the class of alpha 2 agoinsts which has got numerous beneficial effects when used through epidural route. It does cause a manageable hypotension and bradycardia but the striking feature of this drug is the lack of opioid related side effects (Venn RM and Hell J 2000; Bloor BC *et al.*, 1989).

RESULTS

After obtaining approval from Hospital Ethical Committee, the present study was undertaken in the Department of Anaesthesiology and Intensive Care, Govt. Medical College Jammu. Informed written consent was obtained from the patients preoperatively. 60 female patients of ASA Grade I and II, aged 30-60 years, scheduled for abdominal hysterectomy under CSE were selected.

Demographic profile of the patient including age, sex, height, weight was recorded. The demographical profile in the present study was comparable to similar other studies and did not show any significant difference on statistical comparison. The type and duration of surgery were comparable in two groups with no statistical significant difference among them.

Haemodynamic Parameters

Haemodynamic parameters of heart rate, blood pressure, SPo2 were monitored continuously and recorded every 5min for first 20min after the epidural injection, then every 10min till the end of the surgery and thereafter 15, 30, 60 and 120min postoperatively.

The two groups were found to be statistically comparable as regards to the distribution of baseline haemodynamic characteristics and these groups remained mostly haemodynamically stable throughout the period of study. The Heart Rate, systolic BP and MAP in both the groups remained statistically significant between two groups at 25min and onwards. Heart rate, SBP and MAP were lower for dexmedetomidine group ($p<0.05$) as compared to fentanyl group, but hypotension (20% reduction of initial B.P) and bradycardia (H.R <55bpm) were not found in any group.

Our study results with respect to haemodynamic parameters are in accordance with those of Paech MJ *et al.*, (1990); King MJ *et al.*, (1990); Halonen PM *et al.*, (1993); Thomas H *et al.*, (1996); Cherng CH *et al.*, (2005) and Malik P *et al.*, (2006) who found no significant change in haemodynamic parameters on addition of fentanyl as compared to the control groups while providing epidural anaesthesia. Similarly stable haemodynamic parameters were recorded with dexmedetomidine. The results for dexmedetomidine were in accordance with Paula F Salgado *et al.*, (2005); Bajwa SJ *et al.*, (2011); Selim MF *et al.*, (2012). (As shown in Table 1)

Sensory Block Characteristics

The time taken in minutes for onset of sensory block at T10 level was found to be 15.17±3.82 min in group BD (Bupivacaine with Dexmedetomidine) and 20±3.93 min in group BF(Bupivacaine with Fentanyl). The difference was found to be statistically significant between two groups. Dexmedetomidine and bupivacaine group had early onset of sensory block at T10 than fentanyl and bupivacaine group. This was in accordance with Bajwa SJ *et al.,* (2011) who found that the onset of sensory analgesia and establishment of complete motor blockade was significantly earlier with dexmedetomidine versus fentanyl when combined with ropivacaine in epidural analgesia in lower limb surgeries.

Peak level of sensory block obtained (T5-T6) was obtained in 83.33% of the patients in group BD and 26.67% of the patients in group BF. The difference was found to be statistically significant among the two groups. The mean time to reach the highest level of sensory block was found to be 22.33±3.41 min in group BD and 27.33±2.86 min in group BF. The difference was found to be statistically significant (As shown in Table 2, 3 & 4).

Motor Block Characteristics

The time to attain maximum bromage score was 19.67±4.9 min in group BD (Bupivacaine with Dexmedetomidine) and 23.67±3.7 min in group BF(Bupivacaine with Fentanyl).. The difference was found to be statistically highly significant. Our results are in accordance with Bajwa SJ *et al.,* (2011) who showed that complete motor block was achieved earlier in the patients who were administered dexmedetomidine epidurally as compared to fentanyl group. Salgado PF *et al.,* (2005) concluded in their study that adding dexmedetomidine 1microgram/kg to epidural ropivacaine increases sensory and motor block duration and prolongs postoperative analgesia without causing haemodynamic instability. Gupta R *et al.,* (2011) found that there was no difference in the onset time to Bromage 3 motor block on comparing intrathecal bupivacaine-dexmedetomidine with intrathecal bupivacaine-fentanyl but the regression to Bromage 0 motor block was significantly slower on adding dexmedetomidine. These studies supported our study results.

The total duration of motor block was found to be significantly prolonged in group BD (254±35 min.) as compared to group BF (211±28.93 min). The difference was found to be statistically highly significant in two groups. In dexmedetomidine group we found longer duration of motor blockade. The results were in accordance with Al Ghanem SM *et al.,* (2009) who studied the effect of addition of 5microgram dexmedetomidine or 25microgram fentanyl intrathecally to 10 mg isobaric bupivacaine in vaginal hystrectomies and concluded that 5 microgram dexmedetomidine produces more prolonged motor and sensory block as compared with 25microgram fentanyl (As shown in Table 5).

Duration of Analgesia

The duration of analgesia as defined by the time to reach a VAS of 4 and provision of first rescue analgesia in form of epidural top up was found to be significantly different between the two groups. The mean duration of analgesia was found to be (292±29.41) min in group BD (Bupivacaine with Dexmedetomidine) and (225±33.19) min in group BF (Bupivacaine with Fentanyl). The difference was found to be statistically significant in two groups. The results were in accordance with Bajwa SJ *et al.,* (2011) who showed that both fentanyl or dexmedetomidine provided a smooth and prolonged postoperative analgesia but the effects of dexmedetomidine were more significant on statistical comparison as compared to fentanyl. In accordance with our results, Gupta R *et al.,* (2011) showed that the time to rescue analgesia was significantly longer in dexmedetomidine group as compared to fentanyl group with bupivacaine. Selim MF *et al.,* (2012) compared bupivacaine-dexmedetomidine and bupivacaine-fentanyl in epidural analgesia for patients in labour and showed that dexmedetomidine gave better maternal satisfaction for labour pains than fentanyl when used as an adjuvant drug to local anaesthetics because of its earlier onset, longer duration of analgesia and fewer side effects.

In contrast to our study, Naulty *et al.,* (1983) observed a significant prolongation in the duration of analgesia with epidural fentanyl (285 minutes) but they used 100 microgram fentanyl as compared to 0.5microgram/kg in our study. Also, King MJ *et al.,* (1990) concluded that postoperative analgesia was of longer duration in patients who received epidural fentanyl (As shown in Table 6).

Table 1: Comparison of Baseline Hemodynamic Parameters

PARAMETER	GROUP BD		GROUP BF		p-value
	MEAN	SD	MEAN	SD	
HEART RATE	77.13	6.97	75.63	6.99	0.4
SBP	126.1	9.55	129.03	8.77	0.22
DBP	81.67	7.91	80.4	8.81	0.55
MAP	96.43	8.05	96.61	6.22	0.92
SPO2	99.67	0.47	99.46	1.14	0.35

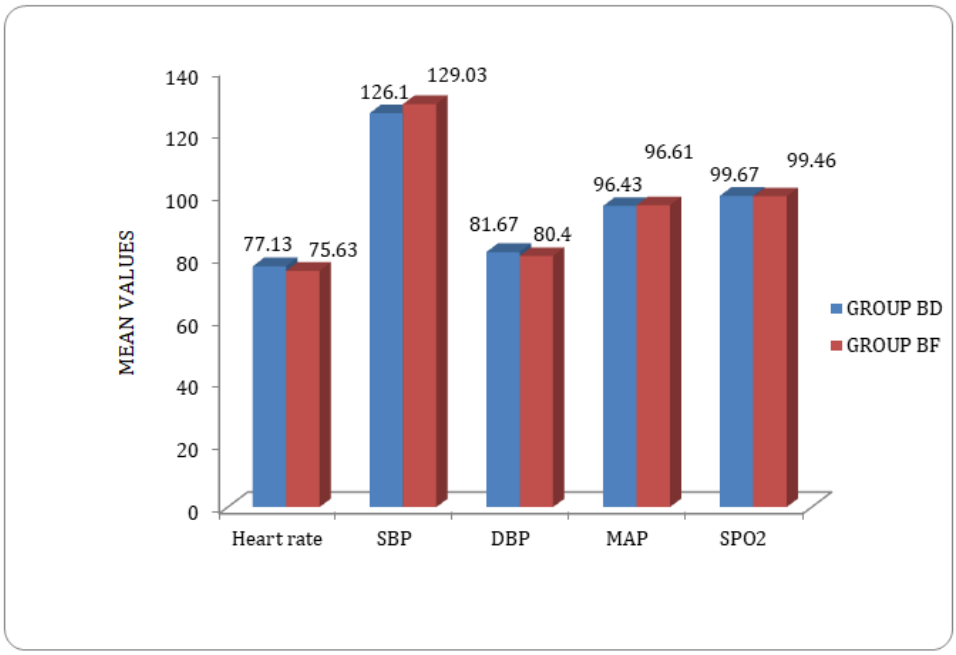

Fig 1:

Table 2: Onset at T10 (Sensory Block)

GROUP	MEAN (min)	SD	p-value
GROUP BD	15.17	3.82	0.00001
GROUP BF	20	3.93	

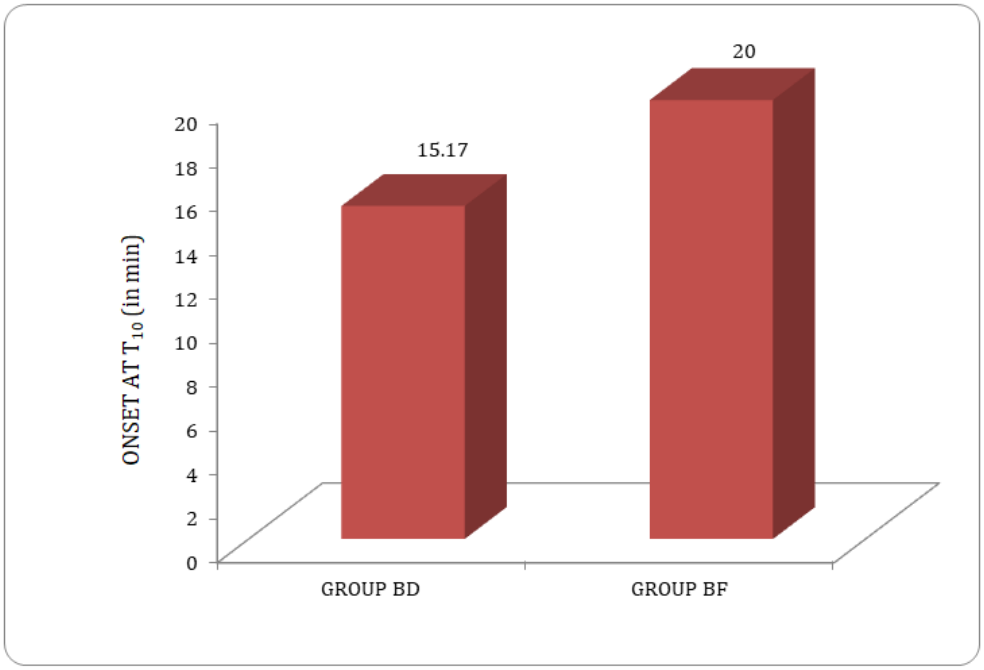

Fig 2: Bar Diagram Showing Mean Time Taken for Onset at T10 Level for Sensory Block in the Two Groups

Table 3: Highest Level of Sensory Block

Highest level	No. of patients (%)		p-value
	GROUP BD	GROUP BF	
T5-T6	25 (83.33)	8 (26.67)	0.00004
T7-T8	5 (16.67)	19 (63.33)	
T9-T10	0 (0.00)	3 (10.00)	

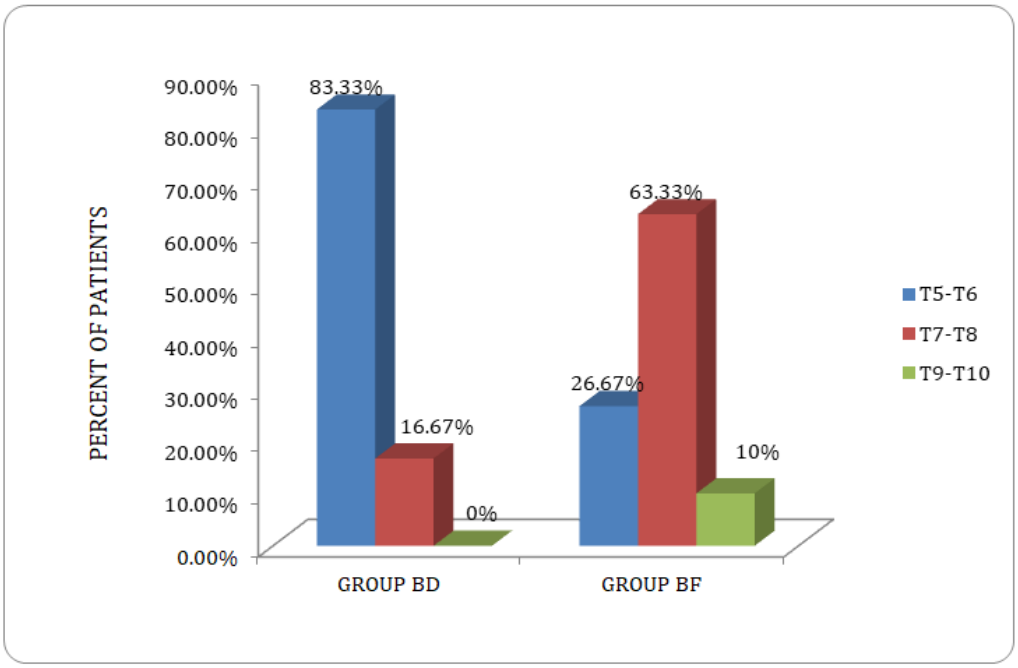

Fig 3

Table 4: Time to Reach Highest Level (Sensory Block)

GROUP	MEAN TIME (min)	SD	p-value
GROUP BD	22.33	3.41	0.00000001
GROUP BF	27.33	2.86	

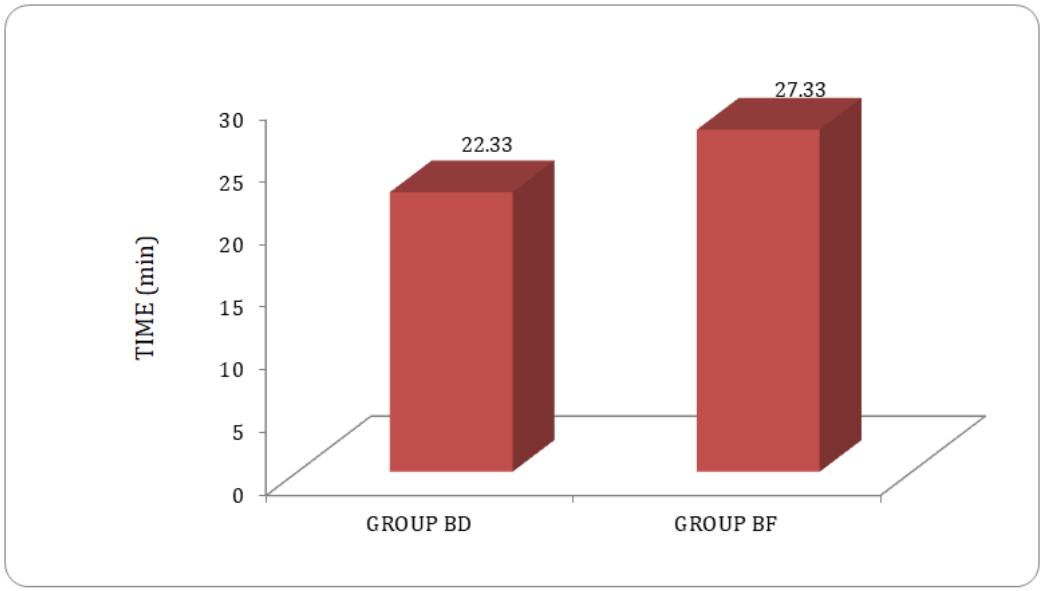

Fig 4: Bar Diagram Showing Time to Reach Highest Level (Sensory Block) For the Two Groups

Table 5: Time to Attain Maximum Bromage Score between the Study Groups

GROUP	Mean	SD	p-value
GROUP BD	19.67	4.9	0.0007
GROUP BF	23.67	3.7	

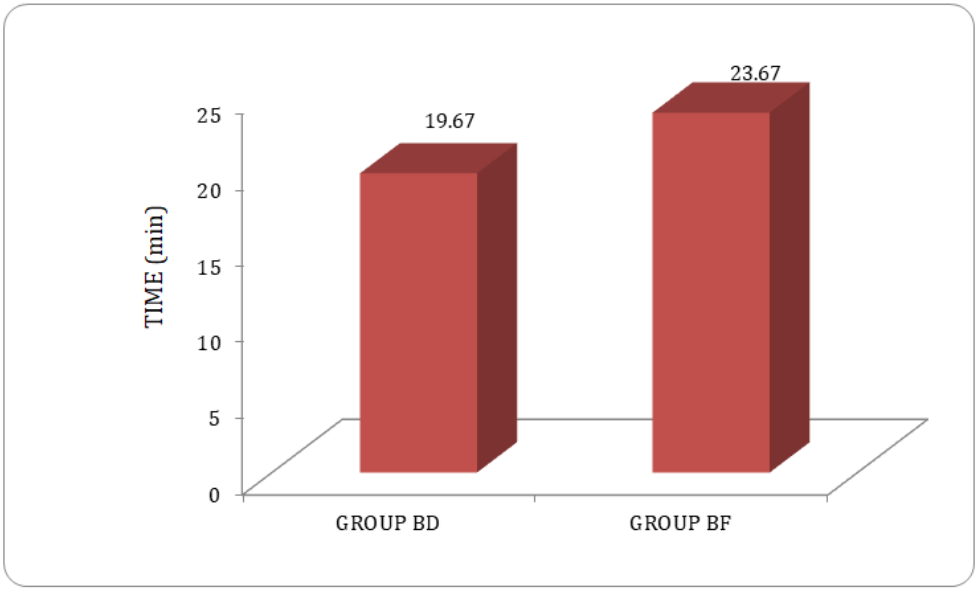

Fig 5: Bar Diagram Showing Time to Attain Maximum Bromage Score between the Study Groups

Table 6: Duration of Analgesia

GROUP	Mean	SD	p-value
GROUP BD	292	29.41	0.000001
GROUP BF	225	33.19	

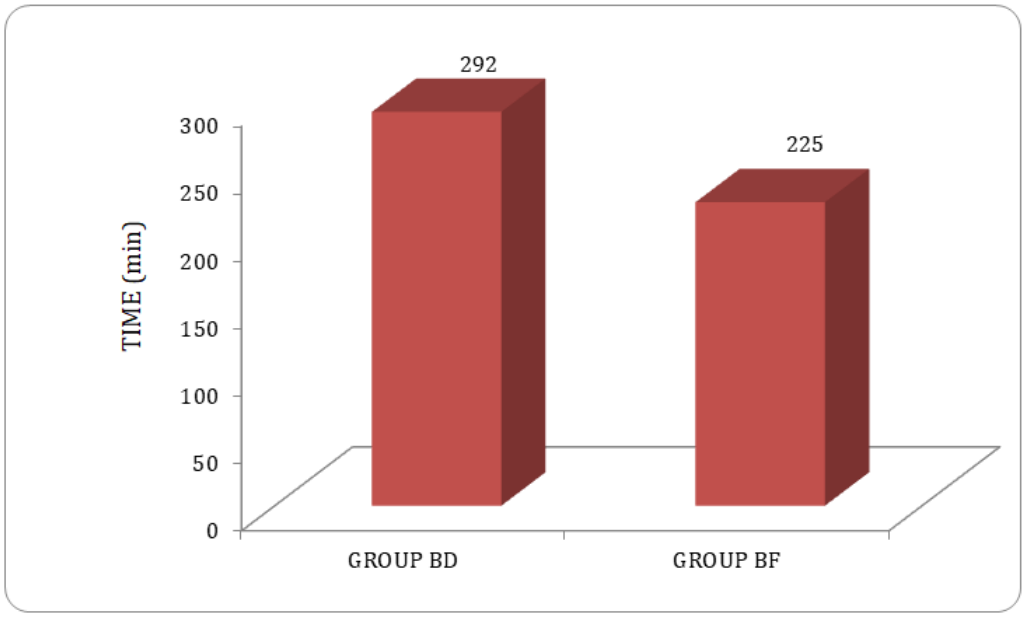

Fig 6: Bar Diagram Showing Duration of Analgesia for the Two Groups

DISCUSSION

The present study was conducted in the Postgraduate Department of Anaesthesiology and Intensive Care, GMC Jammu with the aim to study and compare effect of dexmedetomidine and fentanyl with bupivacaine using CSE technique in abdominal hysterectomies. The patients enrolled were explained about the study and a written informed consent was taken from them. Sixty female patients of ASA Grade I and II, aged 30 to 60 years, scheduled for abdominal hysterectomy under CSE were selected. Patients were kept overnight fasting prior to surgery & premedicated with Tablet Pantoprazole 40mg & Tablet Alprazolam 0.25mg orally night before surgery.

Two Groups comprising of 30 patients in each group were taken randomly. GROUP BD- Received 3ml of 0.5% bupivacaine (Heavy) intrathecally and Dexmedetomidine 1microgram / kg body-weight and GROUP BF- Received 3ml of 0.5% bupivacaine (Heavy) intrathecally and Fentanyl 0.5microgram/ kg. Adjuvants

in both the groups were given epidurally after diluting them in saline total making it 10ml in each group.

Under all aseptic precautions, the injection site in the lumbar region was infiltrated with local anesthetic. In the sitting position, CSE anesthesia was performed using a needle through needle technique. The epidural space was located using loss of resistance to air with an 18G Tuohy needle at L3-L4 level.

The dural puncture at L3-L4 level was achieved with 27G pencil point needle. After confirmatory aspiration of cerebrospinal fluid, 3ml of 0.5% Hyperbaric Bupivacaine was injected intrathecally. The spinal needle was withdrawn & a 20G epidural catheter was inserted 3-4cm into the same epidural space. The catheter was secured & the patient was placed in supine position to attain the level of T5-T6 block & was maintained in this position till the end of surgery. The epidural adjuvants were administered depending on the group assigned.

Haemodynamic parameters of heart rate, blood pressure, SPo2 were monitored continuously and recorded every 5min for first 20min after the epidural injection, then every 10min till the end of the surgery and thereafter 15, 30, 60 and 120min postoperatively.

The sensory blockade was assessed by bilateral pin prick method using a short beveled 26G hypodermic needle every 5min. for the first 30min and every 15min for the rest of the surgery. The time of onset of sensory block at T10 dermatome, peak level of sensory block, the time to reach peak level of sensory block was recorded. Sensory block to reach T10 level was accepted sufficient to start the surgery.

Degree of motor blockade according to Modified Bromage Scale was assessed every 5 min. for 30min. after epidural drug administration and then every 15min. for the rest of the surgery.

Postoperatively sedation score, sensory level and Bromage score was recorded every 15min in the recovery room. The time from epidural injection (zero minutes) to sensory regression to S1 dermatome and motor regression to Modified Bromage 0 was recorded.

Duration of analgesia was taken as time period till VAS of 4 was recorded. After this, postoperative pain was managed with rescue injection of bupivacaine 0.125% in saline total made 10ml solution. The epidural catheter was kept for 24 hours in the postoperative period and postoperative analgesia was maintained with epidural top ups depending upon the patient's need for analgesia. The number of top up doses required were noted.

Incidence of other side effects seen with epidural drug administration like pruritis, nausea, vomiting, respiratory depression, and shivering were carefully observed and recorded.

CONCLUSION

In our study we conclude that dexmedetomidine is a better adjuvant as compared to fentanyl in combined spinal epidural anaesthesia with intrathecal bupivacaine, as it produces early onset and more prolonged motor and sensory block, better sedation, prolonged analgesia, stable cardiorespiratory parameters and good patient satisfaction.

Addition of these adjuvants in neuraxial block helps in augmenting anaesthesia, early mobilization and recovery after surgery.

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