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A COMPARATIVE STUDY OF EPIDURAL LEVOBUPIVACAINE 0.125% WITH DEXMEDETOMIDINE AND LEVOBUPIVACAINE 0.125% WITH FENTANYL FOR POSTOPERATIVE ANALGESIA IN HIP PROSTHESIS AND TOTAL HIP REPLACEMENT SURGERIES

Anaesthesiology

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ABSTRACT

Aim: The aim of this study was to compare the efficacy of Epidural Levobupivacaine 0.125% with Dexmedetomidine and Levobupivacaine 0.125% with Fentanyl as an adjuvant in Hip Prosthesis and Total Hip Replacement Surgeries. **Method:** In this prospective randomized double-blind study fifty-eight patients with ASA grade I and II of either sex between 18 to 60 years scheduled for hip prosthesis and total hip replacement surgeries were randomly divided into two groups (n=29). Surgery was conducted under combined spinal epidural anaesthesia. Group L+D received 10 ml of Levobupivacaine 0.125% with 1µg/kg of Dexmedetomidine while Group L+F received 10 ml of Levobupivacaine 0.125% with 1 µg/kg of Fentanyl given epidurally in the post-operative period. Duration of analgesia using VAS score, pulse rate, blood pressure, SpO2, sedation level and patient's satisfaction score were recorded periodically. Any complications were noted. Statistical analysis was performed using SPSS Ver.23.0 statistical analysis software, Chi-Square Test, Mann-Whitney U test and Unpaired t test. **Results:** There was no significant difference between the demographic characteristics between the two groups. The mean duration of analgesia in group L+D was 439±88.05 minutes while in group L+F it was 272±51.52 minutes which was statistically significant (p value<0.001). The sedation and patient's satisfaction score was significantly better in Group L+D than Group L+F. **Conclusion:** Dexmedetomidine seems to be a better alternative to Fentanyl as an epidural adjuvant due to its longer duration of analgesia and better hemodynamic stability.

KEYWORDS

Epidural analgesia, Levobupivacaine, Dexmedetomidine, Fentanyl

INTRODUCTION

Early postoperative mobilization and rehabilitation with minimally associated pain and discomfort is the most desirable feature in modern orthopaedic surgeries.[1] Epidural analgesia is a common technique for postoperative management with advantages like early mobilization, decreased chances of deep vein thrombosis, decreased rehabilitation time, decreased pulmonary complications, reduced chances of cardiac ischaemia and reduced postoperative ileus which leads to reduced stay in hospital. [2]

Levobupivacaine, an amide type of local anaesthetic agent which is a pure S (-) enantiomer of Bupivacaine has less cardiovascular and central nervous systemic toxicity which makes it a better alternative to Bupivacaine. Its low lipid solubility leads to greater sensory motor differentiation by blocking sensory Aδ and C nerve fibers rather than Aβ fibers which are motor fibers. Hence, it is a useful drug for postoperative analgesia.[3]

Fentanyl, a synthetic opioid which acts via µ 1 & µ 2 receptors is highly lipophilic and 100 times more potent than Morphine. Due to its lipophilicity, it minimizes rostral migration so postoperative respiratory depression is less common. It has a rapid onset of action, less risk of hypotension, absence of active metabolites, less adverse haemodynamic effects. Fentanyl has both presynaptic and postsynaptic effects in the dorsal horn and affects the modulation of nociceptive input but do not cause motor or sympathetic blockade.[4] Fentanyl is also known to reduce the minimum effective local anaesthetic or analgesic concentration due to its dose sparing effect, thereby reducing their side effects.[5]

Dexmedetomidine is a highly selective α2 adrenergic receptor agonist with a relatively high α2/α1 activity (1600:1). It has anxiolytic, sedative, analgesic and sympatholytic properties. Dexmedetomidine's epidural effects due to its high affinity for α2 adrenergic receptors in spinal cord prolongs analgesic actions of local anaesthetics by reducing systemic absorption caused by local vasoconstriction mediated by α2 C receptors in smooth muscles of epidural venous plexus.[6] During epidural administration cephalad spread into meninges may be responsible for sedation which is mediated by binding to α2 A receptors in Locus Coeruleus and diminishing the release of norepinephrine [7] which proves useful in postoperative analgesia. This study will be undertaken to evaluate the analgesic efficacy of Levobupivacaine 0.125% with Dexmedetomidine and Levobupivacaine 0.125% with Fentanyl given through lumbar epidural route in lower limb orthopaedic surgeries specifically Hip Prosthesis (Bipolar Modular) and Total Hip Replacement (THR).

MATERIALS AND METHODS

Present study was carried out in Swaroop Rani Nehru Hospital associated with Moti Lal Nehru Medical College, Prayagraj over a period of one year from May 2020 to May 2021 after approval from Institutional Ethical Committee and obtaining written and informed consent from all patients conducted on 58 patients aged 18-60 years of either sex of ASA Grade I and II.

Study Design:

It was a Prospective, Randomized, double blind, non-placebo study

Sample Size:

The required sample size was calculated using the following formula as proposed by Kirkwood BR et al [8]

Randomization:

Patients were randomized on the basis of a computer generated table of random number generated by using Microsoft Excel SPSS Version 23.0

Double blinding:

Double blinding was achieved by three different anaesthesiologists – one for preparation of the study drug, second for administration of the drug and third for data collection. Hence, the observer and patient both were unaware of the study.

The study included patients who confirmed the following criterias:

Inclusion Criteria:

1. Those who gave written informed consent
2. Patients between 18-60 years of age, of either sex
3. ASA grade I and II patients
4. Patients undergoing elective unilateral THR and Prosthetic repair of the hip joint

Exclusion Criteria:

1. Patient's refusal

2. Infections at the site of epidural administration
3. ASA Grade III and above
4. Bleeding disorders and hemocoagulopathies
5. Morbid Obesity (BMI >40kg/m^2).
6. Severe systemic diseases of cardiovascular, cerebrovascular, hepatic, pulmonary or renal insufficiencies
7. Known allergy to study drugs

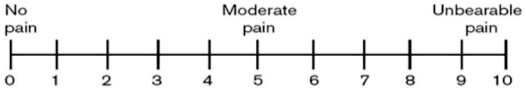
Group Allocation:

Total number of 58 patients of either sex selected for the study were randomly divided into two groups – Group L+ D and Group L+ F based on computer generated table of random numbers and each group was allotted twenty nine patients (n = 29) each.

Group L+D	n = 29	Patients received epidural bolus of 10 ml of Levobupivacaine 0.125% plus Dexmedetomidine 1µg/kg
Group L+F	n = 29	Patients received epidural bolus of 10ml Levobupivacaine 0.125% plus Fentanyl 1µg/kg.

METHODOLOGY

A detailed pre-anaesthetic evaluation where history, general and systemic examination, airway assessment, examination of spine for any deformity or infection was done for all patients planned for this study. Age, weight, height and side of surgery were also noted. All baseline parameters like Pulse Rate (PR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), SpO2, Respiratory rate (RR) were recorded. All patients were investigated for Complete Blood Count, Blood Grouping, Erythrocyte Sedimentation Rate, Blood sugar, Kidney Function Test, Liver Function Test, 12 Lead Electrocardiography, Chest X-Ray and 2D Echocardiography if necessary. All patients were kept nil per oral from midnight prior to the day of surgery and were given Tab. Ranitidine 150 mg and Tab, Alprazolam 0.5 mg both orally as pre-medications. A written and informed consent was obtained from all the patients. Patients were explained about epidural analgesia procedure and Visual Analogue Scale (VAS).(9) The patient was shown a 11 cm horizontal scale marked 0 – 10 on a blank paper and told that "0" represented "No Pain" and "10" represented "Worst possible pain".



On the day of surgery, an intravenous line was accessed by 18 Gauge intravenous cannula and Ringer Lactate solution was infused at a rate of 15-20 ml/kg/hr over a period of 20 minutes before giving the combined spinal epidural anaesthesia. Patients were attached to standard American Society of Anaesthesiologists (ASA) monitors and all pre-operative parameters were recorded. With the patient sitting position, following strict aseptic techniques, 2- 3 ml of 2% Lignocaine Hydrochloride was infiltrated locally into the skin and subcutaneous tissue. An 18 Gauge Tuohy needle was inserted following identification of the epidural space at L3-4 or L4-5 space using "loss of resistance to water technique" technique, 20 Gauge epidural catheter was inserted and advanced 4 cm into the epidural space in a cephalad direction and multi orifice catheter was inserted through the cephalad directed tip of the epidural needle to a depth of 3-5 cm into the epidural space. If there was no blood or cerebrospinal fluid (CSF) on aspiration from the epidural catheter, a 3-ml test dose of 2% Lignocaine & Adrenaline was administered through the catheter and the catheter was secured. One to three minutes after the test dose, the subarachnoid block was given one lumbar intervertebral space below that of the epidural puncture site with 25G Quincke's Babcock needle using 3 ml of 0.5% hyperbaric Bupivacaine. A urinary catheter was inserted, all pre-operative surgical draping, patient positioning and preparation were done all within 30 minutes of giving spinal anaesthesia, after which surgery was allowed to proceed. Time of skin incision was noted as 1 min of Intra operative observation. PR, SBP, DBP, RR and SpO2 were monitored intraoperatively and noted every 15 minutes. Intraoperative intravenous fluid therapy consisted of Ringer Lactate and Normal Saline 0.9% or 5% Dextrose as clinically indicated. Intraoperatively, hypotension was defined as SBP <90 mmHg and was treated with bolus of 3-6 mg of Inj. Mephentermine sulphate i.v. Bradycardia was defined as PR <60 beats per minute and was treated with bolus doses of 0.4 -0.6 mg Inj. Atropine Sulphate i.v. This study included only those patients with operative duration of < 2 hours. After surgery patients were shifted to Post Anaesthetic Care Unit (PACU) and bolus epidural analgesic doses were given based on group allocation. In group L+F, 10 ml of 0.125% Levobupivacaine with Fentanyl at 1µg/kg body weight was administered and in group L+D, 10 ml of 0.125% Levobupivacaine plus Dexmedetomidine at 1 µg/kg body weight was given at 2 hours period from the time of spinal anaesthesia. This dose was defined as first initial bolus dose and time was noted. The adequacy of analgesia was assessed 5 min after the first initial bolus dose of study drug administered. Analgesia was considered adequate if Visual Analogue Scale (VAS) was <3. Duration of analgesia was defined as time from first bolus dose to time of achieving VAS >3 which was assessed every 15 min, 30 min, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, 18 hours and 24 hours post operatively. Simultaneously, the patient's level of comfort and sedation was noted using Ramsay Sedation Scale (RSS),(10) satisfaction score was noted using Likert Verbal Rating Scale (LVRS)(10) and degree of motor blockade by Bromage Scale(11)

Within the 24 hour post-operative period after initial bolus dose of the test drug any patient who complained of pain and had VAS >3 was administered 5ml of Rescue Analgesia (RA) in the form epidural 0.125% Levobupivacaine. If patient still complained of pain, injection Paracetamol 1000 mg was given. Any complications were noted and recorded within the study period.

Statistical Analysis

Statistical analysis was done using SPSS (Statistical Package for the Social Sciences) version 23. Data was summarized as mean and standard deviation for numerical variables and percentages for categorical variables. Analysis of variance (ANOVA) of the data for various parameters were done using student's paired t-test for intergroup comparison and unpaired t-test for intergroup comparison. Qualitative data (ASA grades, degree of motor block and complications) were compared using Chi-square test incorporating Fisher's exact test. Satisfaction score, VAS Score, Sedation Score and SpO2 were analyzed by Mann-Whitney U test. A "p" value of <0.05 will be considered as significant.

RESULTS AND OBSERVATIONS

Table 1. Demographic parameters of both groups.

Variables		Group L+ D (n=29)	Group L+ F (n=29)	P value	Significance
Age (years) (Mean ± SD)		49.86±11.93	52.41±9.52	0.372	Not Significant
Sex	Male	21 (72.4%)	20 (69.0%)	0.773	
	Female	8 (27.6 %)	9 (31.0%)		
ASA	Grade I	10 (34.5%)	9 (31.0%)	0.780	
	Grade II	19 (65.5%)	20 (69.0%)		
Height (cm) (Mean ±SD)		164.21±5.84	164.52±5.60	0.837	
Weight (Kg) (Mean ± SD)		63.62 ± 7.18	62.21 ± 5.79	0.413	

Demographic data and clinical characteristics were comparable between two groups and were found to be statistically insignificant. (Table 1)

Table 2. Intergroup Comparison of Hemodynamic Variables in Post-operative Period

Variables	Time Period	Group L + D		Group L + F		Significanc (P value)	
		Mean	SD	Mean	SD		
PR (beats/min)	30min	74.41	8.18	76.31	9.57	0.421	Not Significant
	1hr	71.79	8.30	77.10	7.56	0.014	Significant
	2hr	71.17	6.71	77.10	7.05	0.002	Significant
	4hr	71.86	7.50	78.52	7.07	0.001	Significant
	8hr	73.24	7.34	78.97	7.83	0.006	Significant
	12hr	76.24	8.37	79.14	8.86	0.206	Not Significant
	18hr	77.41	8.57	79.38	8.64	0.388	Not Significant
	24hr	80.34	8.49	80.66	8.79	0.892	Not Significant
SBP (mmHg)	30min	110.55	6.88	116.59	7.67	0.003	Significant
	1hr	108.69	7.53	116.69	8.13	<0.001	Significant
	2hr	108.17	6.86	117.00	7.25	<0.001	Significant

	4hr	108.76	6.77	114.90	21.05	0.141	Not Significant
	8hr	111.34	6.96	118.83	6.54	<0.001	Significant
	12hr	115.93	5.99	118.48	6.32	0.120	Not Significant
	18hr	117.10	5.23	119.52	5.39	0.089	Not Significant
	24hr	119.00	5.33	120.69	6.33	0.276	Not Significant
DBP (mmHg)	30min	68.90	5.89	74.17	6.21	0.002	Significant
	1hr	68.55	5.60	73.72	7.11	0.003	Significant
	2hr	68.31	6.11	73.10	6.60	0.006	Significant
	4hr	69.38	5.98	73.59	5.05	0.005	Significant
	8hr	69.90	6.20	74.48	6.50	0.008	Significant
	12hr	71.31	5.59	73.66	5.56	0.115	Not Significant
	18hr	71.59	4.35	74.83	4.68	0.008	Significant
	24hr	74.14	4.66	75.93	5.51	0.186	Not Significant
SpO2 (%)	30min	98.48	0.78	98.76	0.58	0.109	Not Significant
	1hr	98.38	0.62	98.66	0.61	0.060	Not Significant
	2hr	98.21	0.68	98.62	0.73	0.013	Significant
	4hr	98.28	0.70	98.76	0.51	0.007	Significant
	8hr	98.62	0.49	98.79	0.49	0.202	Not Significant
	12hr	98.79	0.49	98.83	0.47	0.775	Not Significant
	18hr	98.86	0.52	98.90	0.41	0.740	Not Significant
	24hr	98.90	0.56	98.86	0.44	0.839	Not Significant

Intergroup Comparison of PR of both groups showed significant changes with lower PR not amounting to bradycardia observed in the Group L+D in the post-operative period at 1 hour, 2 hours, 4 hours and upto 8 hours (p value <0.05). There were also significant changes in both the SBP and DBP at different time intervals in the post-operative period with lower readings found in the Group L+D as compared to Group L+F (p value <0.05). The mean SpO2 level of Group L+D was significantly more than the Group L+F at the post-operative period at 2hrs and 4 hrs and it was statistically significant. (p value <0.05) (Table 2).

Table – 3 : Intergroup Comparison of Duration of Analgesia and need for RescueAnalgesia

Group	Group L+D		Group L+F		Significance	
	Mean	SD	Mean	SD	p-value	
DURATION OF ANALGESIA (Min)	439.66	88.05	272.41	51.52	<0.001	Significant
RESCUE ANALGESIA	1.79	0.41	2.76	0.58	<0.001	Significant

The mean duration of analgesia in group L+D was 439.66±88.05 minutes while the mean operative duration of group L+F was 272.41±51.52 minutes. The mean duration analgesia of group L+D was significantly more than the group L+F (p<0.001). The mean rescue analgesia in group L+D was 1.79±0.41 while the mean rescue analgesia of group L+F was 2.76±0.58. A significant difference was found in mean rescue analgesia between the two groups (p<0.001). (Table 3)

The mean VAS score at 30 min post op was 0.69±0.47 in group L+D and 1.10±0.31 in group L+F. After that it was gradually increased in both groups. Significant differences were observed from 30 min to 8 hr, where the mean VAS score of L+D group was less than the L+F group. (Figure 1)

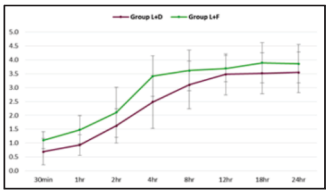


Figure 1. Intergroup Visual Analogue Score Comparison

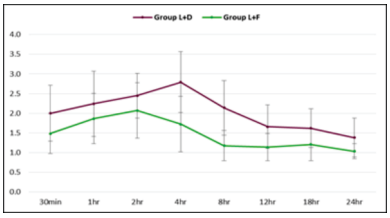


Figure 2. Intergroup Ramsey Sedation Score Comparison

The mean RSS score at 30 min post op was 2.00±0.71 in group L+D and 1.48±0.51 in group L+F. After that it was gradually increased upto 8 hr in group L+D and upto 2 hr in group L+F. Significant differences were observed from 30 min to 24 hr, where the mean RSS score of L+F group was less than the L+D group. (Figure 2)

The mean LVRS score showed significant differences only from 4 hr and onwards (p<0.05) where it was more in L+D group than the L+F group. No significant difference was found in proportion of degrees of motor block between the groups.

Table 4: Intergroup Comparison of Complications

COMPLICATIONS (If any)	Group L+D		Group L+F		chi sq	p-value	
	No.	%	No.	%			
Dry Mouth	8	27.6%	0	0.0%	31.00	<0.001	Significant
Headache	2	6.9%	0	0.0%			
Hypotension	7	24.1%	0	0.0%			
Nausea	2	6.9%	6	20.7%			
Vomiting	1	3.4%	3	10.3%			
Pruritis	0	0.0%	11	37.9%			
Nil	9	31.0%	9	31.0%			

As shown in Table 4, there was significant differences found in proportion of various complications between the groups **(p<0.001).** Dry mouth, headache and hypotension was found only in group L+D. Nausea was observed 6.9% in group L+D, 20.7% in group L+F, while vomiting was observed 3.4% in group L+D, 10.3% in group L+F. Pruritis was observed only in group L+F.

DISCUSSIONS

Epidural analgesia offers superior pain relief and early mobilization, especially when combined with an adjuvant.[13] The addition of opioid provides a dose-sparing effect of local anesthetic and superior analgesia, but there is always a possibility of an increased incidence of pruritus, urinary retention, nausea, vomiting, and respiratory depression.[14]

Dexmedetomidine is a new addition to the class of α-2 agonist which has got numerous beneficial effects when used through epidural route.[15] It acts on both pre- and post-synaptic sympathetic nerve terminal and central nervous system, thereby decreasing the sympathetic outflow and norepinephrine release causing sedative, antianxiety, analgesic, sympatholytic, and hemodynamic effects.[16,17] Dexmedetomidine causes a manageable hypotension and bradycardia, but the striking feature of this drug is the lack of opioid-related side effects such as respiratory depression, pruritus, nausea, and vomiting.[18]

Epidural fentanyl binds to opioid receptors after crossing the dura, or it can be absorbed systemically, and exert its action through the supraspinal route. Although the mechanism postulated for its action in labor is spinal opioid receptor binding, several other studies comparing epidural versus intravenous fentanyl have shown no differences in analgesia, serum levels, or side effects, suggesting that the epidural route may exert its action through systemic absorption.[19]

The present study was carried out with an aim to evaluate the efficacy of epidural dexmedetomidine with levobupivacaine versus epidural fentanyl with levobupivacaine for postoperative pain relief. Demographic variables such as age, height, weight, gender and ASA Grade of two groups were matched and did not show significant difference between two groups, thus indicating that the two groups were matched.

The two groups were found to have some hemodynamic differences throughout the study. Epidural dexmedetomidine appeared to cause a slight lowering of PR at various time points in the Postoperative period

which was found significant, although treatment for bradycardia was not needed, and this was similar to other studies with epidural dexmedetomidine and fentanyl shown by *Prakash et al*[20] who used 0.25% bupivacaine as the principal drug with the same dose of dexmedetomidine or fentanyl as adjuvants. The decrease in Pulse Rate caused by α-2 agonist can be explained on the basis of their central action where they decrease the sympathetic outflow and norepinephrine release[21] We noticed that our patients had significant hypotension in the post-operative period which was prolonged in Group L+D than Group L+F, and this was endorsed in a few studies.[22,23] *Soliman R et al*[24] had used an infusion of 2 µg/ml in an infusion of 0.125% bupivacaine postoperatively in knee surgeries and documented a 20% incidence of hypotension. This was significantly higher than the group that received fentanyl at the same dose. *Mahendru et al*[25] also found that adjuvant dexmedetomidine provided a better hemodynamic stability as compared to fentanyl when used as adjuvant to epidural bupivacaine. Although there was decrease in heart rate and blood pressure in the group L+D in our study, it never was less than 20% of the baseline values which proved that the use of α-2 agonists provide a hemodynamic stability during the postoperative periods. The mean SpO2 level of Group L+D was significantly more than the Group L+F at the postoperative period but there was no incidence of respiratory depression. This finding was similar to earlier studies where researchers have found complete absence of clinically detectable respiratory depression in the previous multiple human studies.[26,27]

The mean duration of analgesia was significantly higher in the dexmedetomidine group. The mean duration of analgesia in group L+D was 439.66±88.05 min while the mean operative duration of group L+F was 272.41±51.52 min. In our study, the dosing of dexmedetomidine and fentanyl was calculated to 1 µg/kg. Bajwa SJ et al[27] and Gill RS et al[28] have compared 1 µg/kg dexmedetomidine and fentanyl and 2 µg/Ml infusion with local anesthetic for lower limb surgery and not specifically for THR or hip prosthesis. This finding correlated with the results of other workers who compared the postoperative analgesic effects of dexmedetomidine administered epidurally in the perioperative period.[27]

The onset of analgesia as measured by the VAS, after bolus administration was similar in both groups, and scores were <3 in group L+D in upto 8 hours while it was <3 for upto 4 hours in Group L+F clearly providing an advantage with the use of dexmedetomidine. This again correlates with the peak onset time for analgesia described in other studies.[27,29]

Dexmedetomidine exerts its sedative effects through activation of the presynaptic α-2 adrenoreceptors in the locus coeruleus, leading to inhibition of release of norepinephrine, along with it, inhibition of adenylate cyclase may lead to hypnotic response[30] In our study the Ramsey sedation score was found to be significant in the dexmedetomidine group more than the fentanyl group, which was supported by *Salgado et al*[29] who found that patients were more sedated with dexmedetomidine group.

The LVRS used to determine patient's satisfaction to the analgesia were found to be more significant in the hours after 4 hours upto 24 hours showing the better analgesia provided in Dexmedetomidine group than fentanyl group. With respect to motor block, incomplete motor block upto grade 1 were seen in dexmedetomidine group as compared to that in fentanyl group, and this difference was not statistically significant.

In regard to complications, both the groups exhibited a striking significant picture. The maximum number of patients in the Fentanyl group complained of pruritis, nausea and vomiting as compared to Group Dexmedetomidine which showed no such side effects. The subjects in Dexmedetomidine had dry mouth and mild hypotension which is a known side effect of α-2 agonists and this observation was quite similar to study conducted by *Bajwa SJ et al*[15]. The side effects of both these drugs were quite favourable as none of the patient in either group had profound deep sedation or respiratory depression which correlates very well with other studies.[7,17]

The findings in this study showed that Dexmedetomidine with the drug-dose schedule used in the present study is a safe, better and hemodynamically stable drug that can be used as adjuvant in epidural anesthesia with similar safety profile as for fentanyl but with a relatively better analgesic and sedative profile. The findings showed that the side effects were well under control for both the adjuvants.

Limitations Of The Study

1. Sample size was small and the exact dose equivalence of Dexmedetomidine and Fentanyl was used for all patients according to body weight. Therefore, further research was needed to know the efficacy of both the drugs.
2. There was no control group using only Levobupivacaine 0.125% to compare with Group L+D and Group L+F.

CONCLUSIONS

Our study concluded that Epidural Levobupivacaine 0.125% with Dexmedetomidine provided prolonged duration of analgesia, better sedation and better hemodynamic stability compared to Epidural Levobupivacaine 0.125% with Fentanyl. We conclude that Dexmedetomidine as an adjuvant is a better alternative to Fentanyl for postoperative epidural analgesia in Hip Prosthesis and Total Hip Replacement surgeries.

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