

Randomized, Prospective Double Blinded Control Trial Comparing the Efficacy of Fentanyl and Dexmedetomidine with Low Dose 0.42% Hyperbaric Levo-Bupivacaine for Elective Anorectal Surgeries under Saddle Block

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Abstract

Background: About 90% of the anorectal surgeries is performed in day care surgery basis. Most of the time benign anorectal surgeries will be done under saddle anaesthesia. Saddle anaesthesia is a type of spinal anaesthesia, that localizes to the lowermost sacral spinal segments allowing for preservation of lower extremity motor function and faster recovery.

Methods: 240 ASA I&II Who were posted for elective benign anorectal surgeries were selected randomly by sealed envelope method. The study groups randomly divided into three groups (n=80). Group LD Received 4.2mg of 0.42% hyperbaric Levobupivacaine +10µg Dexmedetomidine. Group LF Received 4.2mg of 0.42% hyperbaric Levobupivacaine + Received 4.2mg of 0.42% hyperbaric Levobupivacaine 25µg fentanyl, Group C 4.2mg of 0.42% hyperbaric Levobupivacaine +0.5 ml NS (Total of 1.5 ml).

Results: Sensory onset and motor onset assessed, sensory onset in Group LD (2.41±0.724) min Group LF (2.01±0.464) min and Group C (3.8±1.141) min. Group LD has significantly faster sensory onset compared to Group LF and Group C (P<0.001). The total duration of analgesia in Group LD (314.54±54.719) min, Group LF (200.98±17.916) min, Group C (185.71±9.096) min (P<0.001), which was statically highly significant without motor block. Time for 1st void of urine in Group LD (242.56±36.82), in Group LF (135.90±10.93) min, in Group C (100.25±13.48) min (P<0.001), which was statistically highly significant, without any haemodynamic changes throughout the procedure.

Conclusion: Low dose hyperbaric levobupivacaine with adjuvants like dexmedetomidine and fentanyl can aid no or least motor block with stable hemodynamic status and prolonged post operative analgesia with early ambulation.

Keywords: Saddle Block, Levobupivacaine, dexmedetomidine, Fentanyl.

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Background

Subarachnoid block is the most commonly used anaesthetic technique for perianal surgeries since it is easy to perform, economical, provides prolonged postoperative analgesia and shorter

hospital stay. Using only spinal anaesthesia with local anaesthetics associated with shorter duration of action, postoperative pain management becomes a big problem, hence various adjuvants have

been tried along with local anaesthetic agents to provide good anaesthesia and prolonged postoperative analgesia [1-4]. Adjuvants like opioids, alpha 2 adrenergic receptor agonists, Dexamethasone (preservative free), cholinesterase inhibitor like Neostigmine, benzodiazepines like Midazolam are commonly used. Adding adjuvants to the local anaesthetics will reduce the dose of local anaesthetics and avoid intraoperative visceral and somatic pain [5].

Dexmedetomidine is a S-enantiomer of medetomidine, with highly selective α_2 adrenergic receptor agonist, with relatively high ratio of α_2/α_1 (1620:1) compared to clonidine (220:1) [6,7]. Dexmedetomidine has been safely used as an adjuvant for subarachnoid block in infra umbilical procedures such as anorectal, urological, and orthopedic surgeries. Dexmedetomidine mostly act at spinal and supraspinal levels, so that it can prolong the duration of both motor and sensory blockade with less side effects [3-8]. Dexmedetomidine also attenuate the stress response to the surgery and anaesthesia.

Fentanyl is a lipophilic synthetic opioid and a strong agonist at μ receptors. It is 80 times more potent than Morphine. Its potency is due to its high lipophilicity, because of this it can penetrate CNS more easily [9]. Fentanyl is most commonly used intrathecal opioid (10 to 30 mcg), it has got rapid onset with short duration of action (4-6 hrs). Because of its minimal cephalic spread it is least likely to cause delayed respiratory depression.

Levobupivacaine hydrochloride is a pure S(-)-enantiomer of racemic Bupivacaine with less effect on cardiovascular and CNS when compared to Bupivacaine [10]. Both hyperbaric and hypobaric Levobupivacaine have been used in anorectal surgeries. Hyperbaric local anaesthetics used for spinal anesthesia might cause hypotension because of high level of block. It can be reduced by using low dose of local anesthetics along with various adjuvants like Opioids and α_2

agonists [11]. Saddle block is a selective subarachnoid block with low dose of hyperbaric local anaesthetics to block sacrococcygeal nerve roots, which is commonly used for peri anal surgeries [11-14].

Materials and Methods

After obtaining institutional ethical clearance approval, an informed written consent of 250 patients of age group 18 to 60 years belonging to ASA physical class I and II posted for elective anorectal surgeries was taken. Selection of study population is based on sealed envelope method of sampling. The study population was randomly divided into three groups.

Group LD – received 4.2 mg of 0.42% hyperbaric Levobupivacaine(1ml) with 10 mcg of Dexmedetomidine (0.5ml)

Group LF – received 4.2 mg of 0.42% hyperbaric Levobupivacaine(1ml) with 25 mcg of Fentanyl (0.5ml)

Group C – received 4.2 mg of 0.42% hyperbaric Levobupivacaine (1ml) without additive, (0.5ml) Normal Saline.

Inclusion Criteria

Patient aged between 18-60 years belonging to ASA class I and II without any comorbid disease, were admitted for elective anorectal surgeries.

Pre-anaesthetic evaluation is done one day prior to surgery and a written informed consent is taken. Patient is advised to take Tab. Ranitidine 150 mg and Tab. Alprazolam 0.5 mg on the night before surgery and advised to be nil oral 6 hrs prior to surgery. On the day of surgery iv line is taken with 18 G cannula, and the patient is preloaded with 15 ml per kg body weight of Ringer lactate half an hour before anesthesia.

In the operating room multichannel monitor is connected to the patient to monitor for pulse rate, NIBP, ECG, MAP and SPO₂. Patient is positioned in sitting posture. Under aseptic precautions subarachnoid block is performed at L3-L4

interspace through a midline approach, by using 25 G Quincke's spinal needle. After confirming the free flow of CSF, study drug is injected into subarachnoid space. Patient is made to sit for 5 minutes after spinal anaesthesia.

Preparation of the study drug

Under aseptic precaution 2.5 ml of isobaric Levobupivacaine 0.5% loaded in 5 ml syringe, to this 0.5 ml of 50% Dextrose is added by using Insulin syringe. Total 3 ml of the study drug hence contains 12.5 mg of Levobupivacaine and 250 mg of Dextrose. Out of 3 ml, 1 ml along with adjuvant (Fentanyl / Dexmedetomidine) is given intrathecally. 0.5 ml of Saline is added instead of adjuvant in control group. Each ml of this study drug contains 4.2 mg of Levobupivacaine and 83.33 mg of Dextrose.

The following parameters are noted – onset and duration of sensory block, motor block (if any), two segment regression time, time for rescue analgesia and time of first void of urine, any side effects like hypotension, bradycardia, nausea, vomiting, pruritis and sedation (by modified Ramsay sedation score). All patients were monitored during the period of surgery and perioperatively.

Definitions

- Onset of sensory blockade: It is defined as time taken from the completion of the injection of the drug till the patient does not feel the pin prick at S2 level.
- Time taken for maximum sensory blockade: It is defined as time from the completion of the injection of the drug to the maximum sensory block attained.
- Onset of motor blockade: Onset time of motor blockade is defined as the time required from the completion of injection of the study drug till patient develops Bromage 1 motor block.
- Duration of two segments sensory

regression: Time taken from maximum level of sensory block attained to two segment regression from the maximum level of sensory block.

- Postoperative sedation assessed by Modified Ramsay sedation scale.
- Hypotension: It is defined as reduction in systolic blood pressure more than 30 % of baseline readings treated with iv fluids and incremental dose of Injection Mephenteramine.
- Bradycardia: Heart rate less than 50 beats per minute, treated with Injection Atropine 0.6 mg iv.

Statistical Methods

Sample size is calculated with alpha = 5%, admissible error-10% using confidence interval approach the sample size for $p=0.306$ is 80 per group.

Data was entered into the Microsoft excel data sheet and analyzed using SPSS 22 version software. Categorical data was represented in the form of frequencies and proportions. Chi square test or Fischer's exact test (for 2*2 tables only) was used as a test of significance for qualitative data.

Continuous data was represented as mean and standard deviation. Independent T test was used as test of significance to identify the mean difference between two quantitative variables.

ANOVA was used as test of significance to identify the mean difference between more than two quantitative variables.

P value (probability that the result is true) of < 0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Results

Demographic data of the present study like age, sex, weight, height, BMI and total duration of surgery were comparable among the groups, which was not statistically significant. (P value 0.694, 1, 0.674, 0.503, 0.542 and 0.387 respectively).

Sensory Characteristics

Table 1: Comparison

	Groups	Mean±Std Deviation (in mins)	P value
Time of onset of sensory Block	LD	2,41±0.724	<0.001
	LF	2.01±0.464	
	C	3.80±1.141	
Time of maximal level of sensory Block	LD	4.58±0.823	<0.001
	LF	4.01±1.611	
	C	4.88±0.333	
Time of two segment regression	LD	47.34±9.480	<0.001
	LF	37,04±7.836	
	C	32.00±5.634	
Total duration of analgesia	LD	314.99±54.719	<0.001
	LF	200.99±17.916	
	C	185.71±9.096	
Time of rescue analgesia	LD	366.38±53.427	<0.001
	LF	241.60±24.420	
	C	216.44±14.760	

Table 1 shows comparison of time of onset of sensory block, Time of maximal level of sensory block, Time of two segment sensory regression, Total duration of analgesia and Time of rescue analgesia among all three groups.

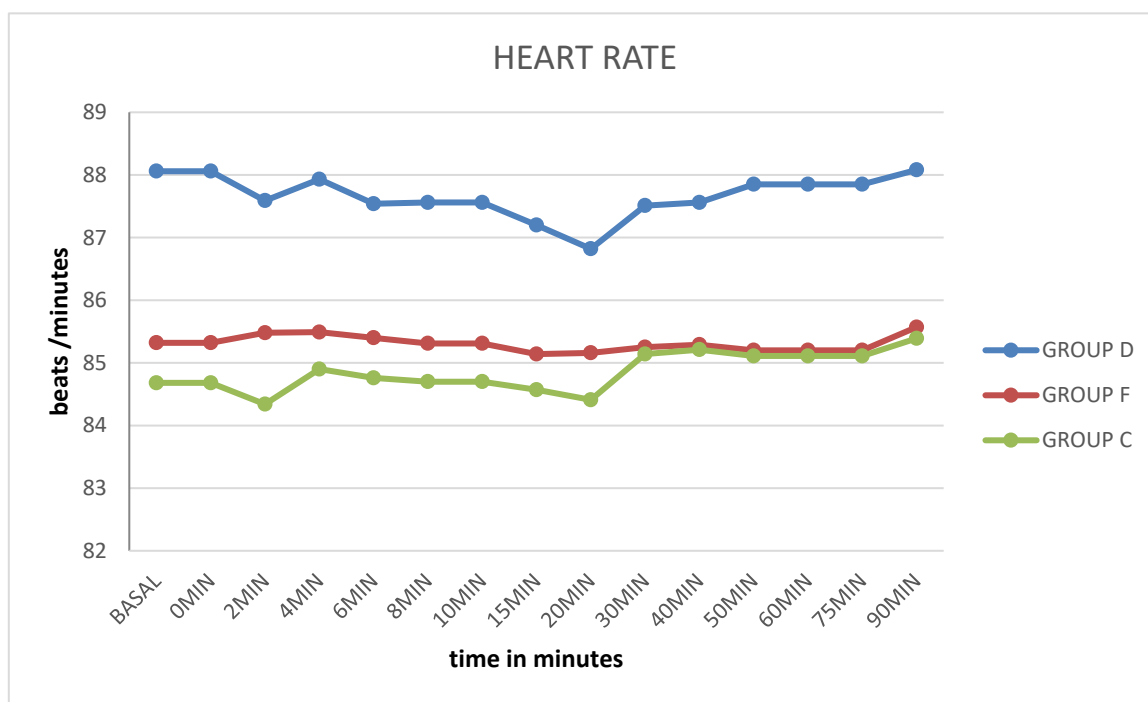


Figure 1: Comparison of heart Rate at various interval among the entire three groups

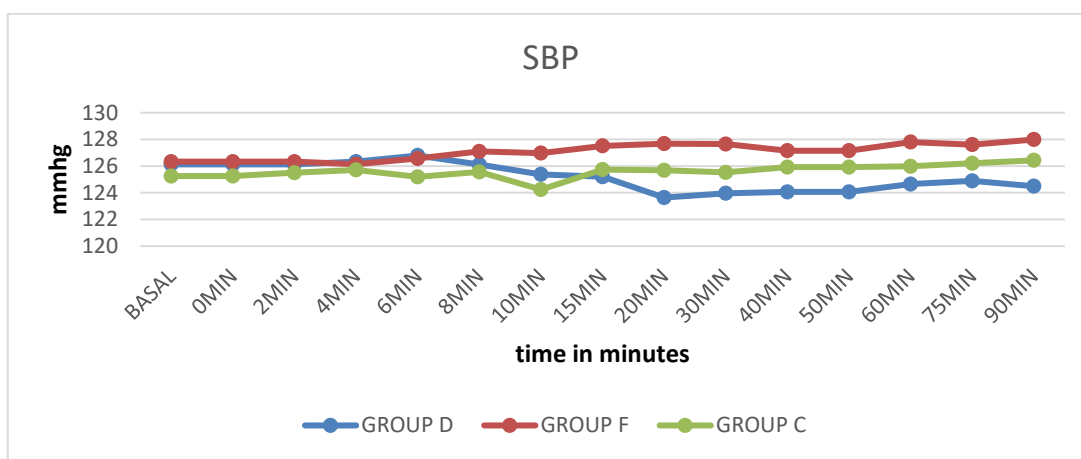


Figure 2: Graph showing Comparison of mean SBP at various intervals among all three groups

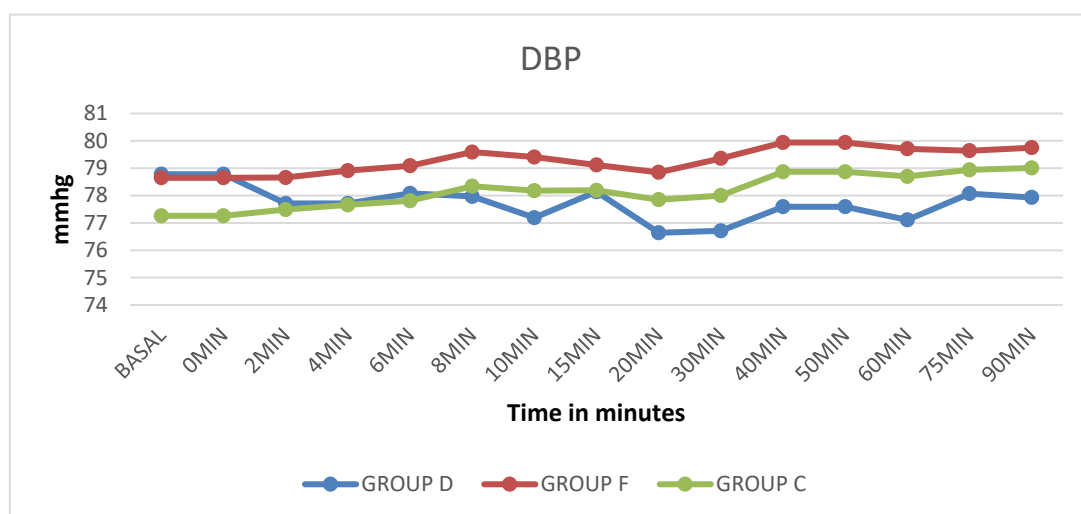


Figure 3: Graph showing Comparison of mean DBP at various intervals among all group

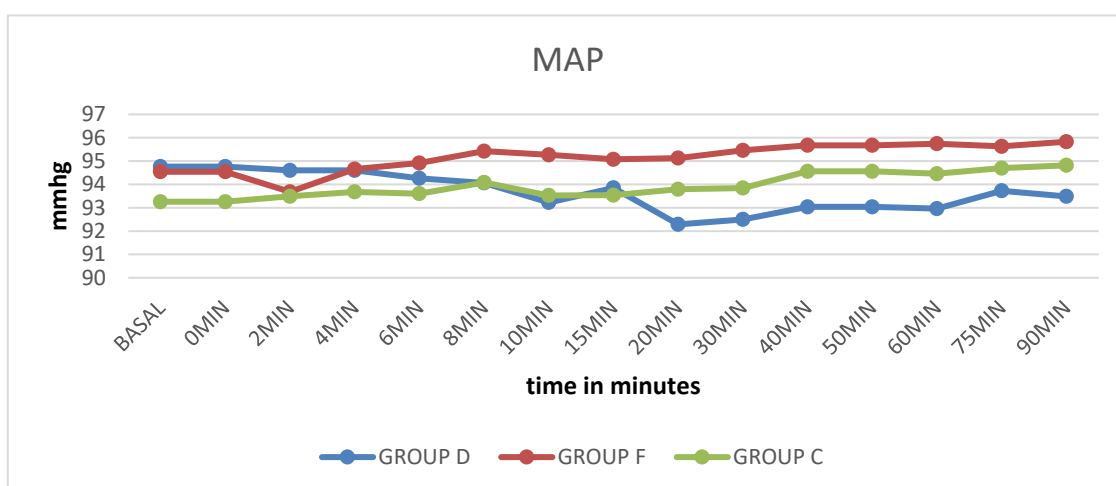


Figure 4: graph showing Comparison of mean MAP at various intervals among all the group

Discussion

Saddle spinal block is the most commonly performed anaesthesia technique for peri

anal surgeries in adult patients. Using low dose of intrathecal hyperbaric local

anaesthetics in sitting position limits the sympathetic block allows early recovery and ambulation. However low dose of hyperbaric local anaesthetics does not prolong the post operative analgesia when used solely. Therefore, saddle block with low dose of hyperbaric local anaesthetics with adjuvants like Fentanyl and Dexmedetomidine are ideal for ambulatory surgeries. They provide good anaesthesia and prolonged post operative analgesia [10,15]

Demographic data of present study like age, sex, weight, height, BMI and total duration of surgery were comparable among the three groups, which was not statistically significant among the groups (P value 0.694, 1, 0.674, 0.503, 0.542 and 0.387 respectively)

The sensory onset time in present study in Group LD (2.41 ± 0.724), Group LF (2.01 ± 0.464), Group C (3.80 ± 1.141) in minutes. The onset is earlier in Group LF when compared to LD and C (Group LF earlier than LD than C). $P < 0.001$ which is statistically highly significant. Though they have used different dosage and different time for posture our study can be comparable with Z Kazak *et al* [10] study and Honca M *et al* [1] study, they also had a similar type of results. We have achieved maximum level of sensory block early in Group LF (4.01 ± 1.611) when compared to Group LD (4.58 ± 0.823) and Group C (4.88 ± 0.33) $P < 0.001$ which was statistically highly significant ($P < 0.001$). In present study, time of two segment sensory regression earlier in control group (Group C 32.00 ± 5.634), when compared to Group LF (37.04 ± 7.836), Group LD (47.34 ± 9.480) which was statistically highly significant ($P < 0.001$), which can be comparable with Gurbet *et al* study [9], Honca M *et al* [1], they also achieved similar results.

Total duration of analgesia in present study, Group LD achieved prolonged duration of Analgesia when compared to Group LF and Group C (314.99 ± 54.719 , 200.99 ± 17.916 , 185.71 ± 9.096

respectively), which was statistically highly significant (P value < 0.001). Our study can be comparable with Shashikala TK *et al* [3] study, but they have used low dose of Bupivacaine and achieved similar results.

Time for rescue analgesia in present study, in Group LD (366.38 ± 53.427) minutes was prolonged when compared to Group LF (241.60 ± 24.420) and Group C (216.44 ± 14.760) minutes, which was statistically highly significant. Our study can be comparable with SS Netthra *et al* [7] study, Shashikala TK *et al* [3] study, but they have used low dose of Hyperbaric Bupivacaine. Our study can also be comparable with Honca M *et al* [1] and Kazak Z *et al* [10], but they have used different dose of similar drug.

In present study, none of the individuals developed motor block in all the three groups. None of the patients in all the three groups showed any significant hemodynamic changes. Time for first void of urine was prolonged in Group LD (242.56 ± 36.826), when compared to Group LF (135.90 ± 10.935), Group C (100.25 ± 13.485) min, which was statistically highly significant ($P < 0.001$), which can be comparable with Honca M *et al* study [1], Z Kazak *et al* [10], Gurbet *et al* study [9], SS Nethra *et al* study [7] and Wassef *et al* study [11], though they got different void times, could be due to different dosage and sitting time. In our study we have not noticed any adverse effects like Bradycardia, Hypotension, Nausea, Vomiting, Respiratory Depression, Sedation and Urinary Retention in any of the patients among all three Groups. We have noticed pruritis in 4 patients and shivering in 1 patient in Group LF which was not statistically significant.

Conclusion

Using Saddle Spinal Block with Low dose of Hyperbaric Local Anesthetics along with adjuvants like Dexmedetomidine and Fentanyl limits the Sympathetic Block and

offers prolonged analgesia with minimal hemodynamic side effects. Early mobilization and shorter Hospital stay are added advantages in Anorectal Surgeries.

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