

Comparing Efficacy of Plain Bupivacaine, Bupivacaine with Fentanyl, and Bupivacaine with Dexmedetomidine Intrathecally in Lower Abdominal Surgical Procedures: A Double-Blind Randomized Control Study

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Abstract

Introduction: The potentiating effect of short-acting lipophilic opioid fentanyl and a more selective α_2 agonist dexmedetomidine is used to reduce the dose requirement of bupivacaine and its adverse effects and also to prolong analgesia.

Aim: The aim of this study is to compare the effect of plain bupivacaine versus bupivacaine with fentanyl versus bupivacaine with dexmedetomidine administered intrathecally for lower abdominal surgeries.

Methods: Group B ($n = 30$): Patients in this group received 3 ml of 0.5% hyperbaric bupivacaine of total volume of 3.0 ml. Group F ($n = 30$): Patients in this group received 2.5 ml of 0.5% hyperbaric bupivacaine + 25 μg (0.5 cc) of fentanyl to a total volume of 3.0 ml intrathecally. Group D ($n = 30$): Patients in this group received 2.5 ml of 0.5% hyperbaric bupivacaine + 5 μg (0.5cc) of preservative-free dexmedetomidine to a total volume of 3.0 ml intrathecally.

Results: The time taken to achieve a sensory level of T10 and T6 was statistically insignificant among 3 groups. There was a statistically significant difference among three groups in the mean duration of motor block $P < 0.0001$. There was a statistically significant difference among three groups in the duration of time for demand analgesia $P < 0.002$.

Conclusion: Intrathecal dexmedetomidine supplementation of spinal block seems to be a good alternative to intrathecal fentanyl since it produces prolonged sensory block and motor block.

Key words: Bupivacaine, Dexmedetomidine, Fentanyl, Spinal anesthesia

INTRODUCTION

Spinal anesthesia is used extensively for lower abdominal and lower extremity surgeries because it has distinct advantages over general anesthesia.^[1,2] Lignocaine and bupivacaine are the commonly used local anesthetic agents

for spinal anesthesia. The adjuvants such as opioids and α_2 agonist are sometimes combined with local anesthetic for spinal anesthesia. The rationale for combining adjuvants to local anesthetic drugs is to lower the dose of each agent and maintaining analgesic efficacy while reducing the incidence and severity of side effects. Surgery on the bowel, uterus, and other genital organs performed under spinal or epidural block is often accompanied by visceral pain, nausea, and vomiting.^[3-5] Fentanyl in various doses when added to spinal bupivacaine increases the duration of analgesia and reduces intraoperative nausea and vomiting. Dexmedetomidine is an α_2 -agonist that is approved as an intravenous sedative and co-analgesic drug. Most of the clinical studies about intrathecal α_2 adrenoreceptor agonist

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are related to clonidine. The present study was designed to evaluate the efficacy and adverse effects of plain bupivacaine, bupivacaine with fentanyl, and bupivacaine with dexmedetomidine intrathecally in lower abdominal surgical procedures.^[6-9]

Aim

The aim of this study is to compare the effect of plain bupivacaine versus bupivacaine with fentanyl versus bupivacaine with dexmedetomidine administered intrathecally for lower abdominal surgeries.

MATERIALS AND METHODS

This study was done in prospective double-blinded randomized manner. It was conducted at our institute between March 2017 and August 2017 after approval from the ethical committee of the institution and written informed consent. 90 American Society of Anesthesiology (ASA) I patients undergoing elective lower abdominal surgeries under spinal anesthesia were recruited.

Inclusion Criteria

Patients in the age group of 30 and above, both sexes, and ASA I were included in the study.

Exclusion Criteria

Hypersensitivity to the study drug, renal or hepatic dysfunction, uncontrolled labile hypertension, and diabetes mellitus were excluded from the study.

Group B (*n* = 30): Patients in this group received 3 ml of 0.5% hyperbaric bupivacaine of total volume of 3.0 ml. Group F (*n* = 30): Patients in this group received 2.5 ml of 0.5% hyperbaric bupivacaine + 25 µg (0.5 cc) of fentanyl to a total volume of 3.0 ml intrathecally. Group D (*n* = 30): Patients in this group received 2.5 ml of 0.5% hyperbaric bupivacaine + 5 µg (0.5 cc) of preservative-free dexmedetomidine to a total volume of 3.0 ml intrathecally. In this study, 0.5% hyperbaric bupivacaine in 8% dextrose, dexmedetomidine hydrochloride 50 mics/0.5 ml, and preservative free fentanyl 50 mics/1 ml were used. Intrathecal drugs were prepared by an anesthesiologist not involved in the study and were administered by another anesthesiologist who was blinded and performed spinal anesthesia. The volume of the drug, size of the syringe, and color of the drug of interest were similar in three groups. The final volume of injected solutions was 3.0ml in three groups. Surgical anesthesia was graded as excellent if there was no complaint of pain at any time during surgery. Good if there was minimal pain or discomfort which was relieved by a small dose of intravenous pentazocine 0.5 mg/kg and poor if GA has to be administered.

In post-anesthesia care unit (PACU), pain was assessed every 15 min. When the patient reaches the pain score 2, diclofenac 75 mg injection was given. Duration of effective analgesia was defined as the time interval between onset of SAB and the time to reach pain score 2. Patients were shifted to the post-operative ward after complete resolution of motor blockade.

RESULTS

The three groups were comparable with respect to their age, height, and weight. There was no statistically significant difference among three groups in demographic aspects [Table 1].

Three groups were similar in respect of diagnosis and ASA. (*P* = 0.99) which is not statistically significant. Three groups were similar in types of surgeries and statistically no significant difference among three groups *P* = 0.72.

The time taken to achieve a sensory level of T10 from the time of SAB was tested by alcohol swab (loss of cold sensation). The mean time taken in Group B was 2.83 ± 0.53 min, in Group F was 2.93 ± 0.58 min, and in Group D, was 2.67 ± 0.48 min. There was statistically no significant difference among three groups (*P* = 0.153).

The time taken to achieve a peak sensory level of T6 from the time of SAB was tested by alcohol swab. The mean time taken in Group B was 4.80 ± 0.76 min, in Group F was 5.03 ± 0.85 min, and in Group D was 4.77 ± 0.68 min. There was no statistically significant difference among three groups *P* = 0.345 [Table 2].

The time taken to achieve Bromage 3 from the time of SAB was tested by modified Bromage scale. The mean time

Table 1: Distribution of mean duration of surgery (in min) by groups

Group	n	Mean±SD	P value
Group B	30	70.83±22.40	0.841
Group F	30	69.07±25.16	
Group D	30	72.01±20.50	

SD: Standard deviation

Table 2: Distribution of mean onset of sensory block (T10 and T6) in min by groups

Onset of sensory block	Group	Mean±SD	P value
T10	Group B	2.83±0.53	0.153
	Group F	2.93±0.58	
	Group D	2.67±0.48	
T6	Group B	4.8±0.76	0.345
	Group F	5.03±0.85	
	Group D	4.77±0.68	

SD: Standard deviation

taken in Group B was 6.63 ± 0.56 min, in Group F was 6.67 ± 0.55 min, and in Group D was 6.53 ± 0.68 min. There was statistically no significant difference among three groups $P = 0.669$ [Table 3].

The mean time taken for return of cold sensation to S1 level was 305.63 ± 44.50 min in Group B, 358.97 ± 46.74 min in Group F, and 457.30 ± 54.28 min in Group D. There was a statistically significant difference among three groups in the duration of sensory block $P < 0.0001$ [Table 4].

The mean duration of return of motor block to Bromage scale zero (0) was 231.33 ± 40.77 min in Group F, 279.43 ± 56.01 in Group D, and 171.83 ± 39.98 min in Group B. There was statistically significant difference among three groups in the mean duration of motor block $P < 0.0001$ [Table 5].

The mean time for demand analgesia (defined as the time at which patient demands some mode of pain relief) was 215.67 ± 42.39 min in Group F, 276.87 ± 49.32 min in Group D, and 159.33 ± 36.79 min in Group B. There was statistically significant difference among three groups in the duration of time for demand analgesia $P < 0.002$ [Table 6].

The maximum degree of motor block in both groups was Grade 3. There was no statistically significant difference

among three groups in the maximum Grade of motor block $P > 1$ [Table 7].

The range of maximum level of sensory block was T4–T6 in three groups. The median of the onset of sensory block was T6 in three groups. T4 was 13.3% in Group F, 10% in Group D, and 16.6% in Group B. T6 was 86.6% in Group F, 90% in Group D, and 80% in Group B which was statistically not significant > 1 [Table 8].

Quality of surgical anesthesia was excellent in all patients. There was no statistically significant difference among three groups $P > 1$ [Table 9].

The incidence of hypotension in Group F was 30%, 3.33% in Group D, and 33.3% in Group B which was significant statistically $P = 0.029$ [Table 10].

The incidence of bradycardia in Group F was 3.33%, 10% in Group D, and 3.33% in Group B, and there was statistically significant difference in three Groups $P = 0.30$. The incidence of pruritus in Group F was 26.66%, and in Groups D and B, no case of pruritus was observed. There was statistically significant difference in three groups $P = 0.002$. The incidence of vomiting was 13.3% in Group F, 3.33% in Group D, and 13.3% in Group B which was statistically not significant $P = 0.44$ [Table 11].

The incidence of sedation score 2 was 100% in three groups which was statistically not significant $P > 1$ [Table 12].

Table 3: Distribution of mean time to reach motor block (Bromage 3) min by groups

Group	Mean±SD	P value
Group B	6.63±0.56	0.669
Group F	6.67±0.55	
Group D	6.53±0.68	

SD: Standard deviation

Table 4: Distribution of mean time for regression of sensory block (S1) in min by groups

Group	Mean±SD	P value
Group B	305.63±44.50	<0.0001
Group F	358.97±46.74	
Group D	457.30±54.28	

SD: Standard deviation

Table 5: Distribution of mean time for regression of motor blockade (Bromage 0) in min by groups

Group	Mean±SD	P value
Group B	171.83±39.98	<0.0001
Group F	231.33±40.77	
Group D	279.43±56.01	

SD: Standard deviation

Table 6: Distribution of mean time for rescue analgesia in min by groups

Group	Mean±SD	P value
Group B	159.33±36.79	<0.0001
Group F	215.67±42.39	
Group D	276.87±49.32	

SD: Standard deviation

Table 7: Maximum grade of motor block by groups

Group	B1	B2	B3
Group B	0	8	22
Group F	0	8	22
Group D	1	1	28

Table 8: Maximum level of the sensory block by T4–T6 groups

Group	T6	T8	T10	T11	T12	P value
Group B	14	10	3	1	2	0.303
Group F	14	10	3	1	2	
Group D	24	5	1			

Table 9: Distribution of cases by groups and quality of surgical anesthesia

Group	Excellent	Good
Group B	30	0
Group F	30	0
Group D	30	0

Table 10: Distribution of cases by hypotension in both groups

Group	No	Yes	P value
Group B	20	10	0.029
Group F	21	9	
Group D	29	1	

Table 11: Distribution of cases by groups and side effects

Group	Group B	Group D	Group F	P value
Bradycardia	1	3	1	0.3
Pruritus	0	0	8	0.002
Vomiting	4	1	4	0.44

Table 12: Distributions of cases by sedation score

Group	Score 1	Score 2	Score 3
Group B	0	30	0
Group F	0	30	0
Group D	0	30	0

DISCUSSION

Subarachnoid block is a commonly used anesthetic technique for lower abdominal surgeries. There has been a growing interest in the use of analgesic additives to spinal local anesthetics. Alpha-2 agonist like dexmedetomidine has been shown to prolong the duration of both sensory and motor blockade and to provide extended post-operative analgesia. In this study, 5 µg of dexmedetomidine was added to 12.5 mg (2.5 ml) of 0.5% hyperbaric bupivacaine or 25 µg of fentanyl added to 12.5 mg (2.5ml) of 0.5% hyperbaric bupivacaine, and its efficacy as an adjuvant to subarachnoid bupivacaine was studied in 90 patients undergoing elective open appendectomy and hernioplasty surgeries. Al-Ghanem^[10] who compared the effect of 5 µg dexmedetomidine versus fentanyl 25 µg in intraoperative analgesia and the duration of sensory and motor block when added to 10 mg intrathecal plain bupivacaine and observed that there is no statistically significant difference between the two groups as regard to the onset time of sensory block at T10 level. Benha *et al.*^[11] did a comparative study of adding intrathecal 5 µg dexmedetomidine and 5 µg of sufentanil to 10 mg of heavy bupivacaine and found

that there is no statistically significant difference in the onset of sensory block T10 level Group D = 5.5 ± 3.7, where Group F = 6.2 ± 1.3 P = 0.69. In our study, the mean time to onset of sensory block (T10 level) was 2.93 ± 0.58 min in Group F, 2.67 ± 0.48 min in Group D, and 2.83 ± 0.53 min in Group B. There is no statistically significant difference among the three groups in the onset of sensory level P = 0.153. The addition of 5 µg of dexmedetomidine to hyperbaric bupivacaine did not shorten the onset of sensory block (T10 level) when compared to the addition of 25 µg of fentanyl to hyperbaric bupivacaine. The onset of sensory block (T10 level) was similar in three groups.

Kanazi^[12] found that there is statistically no significant difference for the maximal sensory block for 12 mg bupivacaine 0.5% alone or combined 3 µg of dexmedetomidine or 30 µg of clonidine (P = 0.3). Al-Mustafaq^[13] found that addition of intrathecal dexmedetomidine in increasing doses 5 µg (10 mg) of dexmedetomidine with 12.5 mg of spinal bupivacaine increased the level of sensory block as the dose of dexmedetomidine increases.

Benha *et al.*^[11] found that there is statistically no significant difference for the maximal sensory block when compared with 5 µg of dexmedetomidine and 5 µg of sufentanil to 10 mg of heavy bupivacaine. In our study, the median of the upper limit block was T6 in Group B, Group D, and Group F. There was no statistically significant difference among the three groups in the maximum level of sensory block. The addition of dexmedetomidine to hyperbaric bupivacaine did not increase the speed of sensory level when compared with 25 µg of fentanyl to hyperbaric bupivacaine.

Al-Ghanem^[10] who found that addition of 5 µg of dexmedetomidine and 25 µg of fentanyl with 10 mg of isobaric bupivacaine intrathecally had no significant difference on the mean time to reach peak sensory level 19.34 ± 2.87 in Group D and 18.39 ± 2.46 in Group F, P = 0.12. In our study, the mean time to reach T6 level was 5.03 ± 0.85 min in Group F, 4.77 ± 0.68 min in Group D, and 4.80 ± 0.76 min in Group B. There is no statistically significant difference among the three groups to reach peak level T6. Benha *et al.*^[11] found that there is statistically no significant difference with 5 µg of dexmedetomidine and 5 µg of sufentanil to 10 mg of heavy bupivacaine on the mean time to achieve Bromage 3 score. In our study, the mean time to achieve Bromage 3 score was 6.67 ± 0.55 min in Group F, 6.53 ± 0.68 min in Group D, and 6.63 ± 0.56 min in Group B. There is no statistically significant difference among the three groups. The addition of 25 µg fentanyl or 5 µg dexmedetomidine to 12.5 mg of bupivacaine has no effect on the onset of motor block.

Al-Ghanem^[10] found that the addition of 5 µg of dexmedetomidine to 10 mg of isobaric bupivacaine 274.83 ± 73.4 significantly prolongs the duration of sensory blockade while 25 µg of fentanyl to 10 mg of isobaric bupivacaine was 179.5 ± 47.4. There was statistically significant difference among the two groups, $P < 0.001$ (intrathecal dexmedetomidine when combined with spinal bupivacaine prolongs the sensory block by depressing the release of c-fibers transmitters and by hyperpolarization of post-synaptic dorsal horn neurons). Kanazi^[12] found that the addition of 3 µg of dexmedetomidine to 12 mg of intrathecal bupivacaine or 30 µg of clonidine significantly prolonged the sensory block. Al-Mustafa^[13] studied that there is a significant difference in the duration of sensory block among three groups who received spinal bupivacaine 12.5 mg alone or combined with 5 µg of dexmedetomidine or with 10 µg of dexmedetomidine. He concluded that dexmedetomidine has a dose-dependent effect on the onset and regression of sensory and motor block when used in SAB. In our study, the duration of sensory block was 358.97 ± 46.74 min in Group F, 457.30 ± 54.28 min in Group D, and 305.63 ± 44.5 min in Group B. There is statistically significant difference among the three groups $P < 0.0001$. The addition of 5 µg of dexmedetomidine to hyperbaric bupivacaine significantly prolonged the duration of sensory block. (Intrathecal dexmedetomidine when combined with spinal bupivacaine prolongs the sensory block by depressing the release of c-fibers transmitters and by hyperpolarization of post-synaptic dorsal horn neurons).

Al-Ghanem^[10] found in their study that 5 µg of dexmedetomidine to 0.5% hyperbaric bupivacaine prolonged effect of motor blockade that 25 µg of fentanyl to 0.5% hyperbaric bupivacaine intrathecally. Kanazi^[12] observed that addition of 12 mg of bupivacaine supplemented with dexmedetomidine and 12 mg of bupivacaine with 30 µg of clonidine intrathecally produces similar prolongation in the duration of motor block when compared 12 mg of bupivacaine alone. (The prolongation of motor block produced by subarachnoid hyperbaric bupivacaine combined with 5 µg of dexmedetomidine results from binding this agonist to motor neurons in the dorsal horn of the spinal cord). Benha *et al.*^[11] found that the addition of 5 µg of dexmedetomidine to 2 ml of heavy bupivacaine and 5 µg of sufentanil to 2 ml of heavy bupivacaine produces a significant difference in the duration of motor blockade. In our study, the mean duration of motor block was 231.33 ± 40.77 min in Group F, 279.643 ± 56.01 min in Group D, and 171.83 ± 39.98 min in Group B. There is a statistically significant difference among the three groups, $P < 0.0001$. The addition of 5 µg of dexmedetomidine to 0.5% bupivacaine significantly prolonged the duration of motor block.

Benha *et al.*^[11] found that the quality of surgical anesthesia was better in patients received 5 µg sufentanil to 2 ml of heavy bupivacaine when compared to 5 µg of dexmedetomidine to 2 ml of heavy bupivacaine. In our study, the quality of surgical anesthesia was excellent in three groups. There is no statistically significant difference among the three groups, $P > 1$.

Benha *et al.*^[11] found that the addition of 5 µg of dexmedetomidine to 10 mg of hyperbaric bupivacaine and 5 µg of sufentanil to 10 mg of hyperbaric bupivacaine intrathecally produces no significant difference in the duration of pain relief Group SF = 265.8 ± 112.3 and Group D = 240. 2±77.3 min ($P = 0.8$). In our study, the mean time for rescue analgesia is 215.67 ± 42.39 min in Group F, 276.87 ± 49.321 min in Group D, and 159.33 ± 36.79 min in Group B ($P < 0.0001$) which was statistically significant difference in the duration of analgesia by three groups.

Kanazi^[12] studied that the addition of dexmedetomidine or clonidine to bupivacaine did not cause a significant decrease in the blood pressure intraoperatively or postoperatively. Intrathecal local anesthetics block the sympathetic outflow and reduce the blood pressure. The sympathetic block is usually near maximal with the doses used for spinal anesthesia. The addition of a low dose of α2 agonist to a high dose of local anesthetics does not further affect the near maximal sympatholysis.

Ibrahim *et al.*^[11] found that the addition of 5 µg of dexmedetomidine to spinal bupivacaine and 5 µg of sufentanil to spinal bupivacaine did not produce a significant difference in the incidence of hypotension.

Al-Ghanem^[10] found that hypotension was more in fentanyl group than in the dexmedetomidine group, but it did not reach a significant difference. Meanwhile, hypotension occurred 25–30 min after spinal injection in 2 patients in the dexmedetomidine group and one patient in fentanyl group had mild episodes of hypotension in PACU.

In our study, the incidence of hypotension was 30% in Group F, 3.3% in Group D, and 33.3% in Group B. Hypotension was mild to moderate in three groups which was statistically significant difference, $P = 0.029$. The most significant side effects reported about the use of intrathecal α2 adrenoreceptor agonists is bradycardia. However, in the present study, these side effects were not significant because small dose of intrathecal dexmedetomidine was used.

Benha *et al.*^[11] found that there is statistically no significant difference in the incidence of bradycardia in both the groups with 5 µg of sufentanil to 10 mg

of 0.5% bupivacaine and 5 µg of dexmedetomidine to 10 mg of 0.5% bupivacaine. Al-Ghanem^[10] found that there is statistically no significant difference in the incidence of bradycardia among two groups of 5 µg of dexmedetomidine to 10 mg of isobaric bupivacaine and 25 µg of fentanyl to 10 mg of isobaric bupivacaine intrathecally. In our study, the incidence of bradycardia was 10% in Group D, 3.33% in Group F, and 3.33% in Group B ($P = 0.3$) which is a statistically significant difference among three groups.

Benha *et al.* found that there is a significant difference in the incidence of pruritus in the sufentanil group. Al-Ghanem^[10] found that there is statistically significant difference in the incidence of pruritus. Pruritus after intrathecal fentanyl is reported to be 40–70%, but it was only 13% in the present study which can be explained by the fact that pruritus is a benign subjective symptom which is under reporting and usually needs to treatment. Bogra *et al.*^[14] found that there is statistically significant difference in the incidence of pruritus with 10 mg of fentanyl, 12.5 mg of fentanyl, added to hyperbaric bupivacaine. In our study, the incidence of pruritus was 26.67% in Group F, 0% in Group D, and 0% in Group B. There is a statistically significant difference among three groups, $P = 0.002$.

Kanazi^[12] found that intrathecally administrated $\alpha 2$ agonist has a dose-dependent sedative effect. The doses of clonidine and dexmedetomidine selected in their study were at the lower end of the dosing spectrum. This explains the lack of sedative effects between the study Groups B and C and the intraoperative anxiety one patient in Group D. In our study, sedation was not statistically significant in three groups $P > 1$.

CONCLUSION

Intrathecal dexmedetomidine supplementation of spinal block seems to be a good alternative to intrathecal fentanyl since it produces prolonged sensory block and motor block. It is evident that this type of block may be more suitable for lower abdomen and lower extremities surgeries with prolonged duration.

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