**Original Research Article**

# A control study comparing efficacy of plain bupivacaine, bupivacaine with fentanyl and bupivacaine with dexmedetomidine intra thecally on spinal block characteristics in lower abdominal surgical procedures

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International Archives of Integrated Medicine, Vol. 8, Issue 2, February, 2021.
**Available online at http://iaimjournal.com/**
**ISSN: 2394-0026 (P)** **ISSN: 2394-0034 (O)**
**Received on:** 20-01-2021 **Accepted on:** 27-01-2021
**Source of support:** Nil **Conflict of interest:** None declared.
**How to cite this article:** V Manorema, James Joseph. A control study comparing efficacy of plain bupivacaine, bupivacaine with fentanyl and bupivacaine with dexmedetomidine intra thecally on spinal block characteristics in lower abdominal surgical procedures. IAIM, 2021; 8(2): 9-18.

## Abstract

**Introduction:** Lower abdominal and lower limb surgeries may be performed under local, regional (spinal or epidural), or general anesthesia, but neuraxial blockade is the preferred mode of anesthesia. A spinal block is still the first choice because of its rapid onset, superior blockade, low risk of infection from the catheter *in situ*, fewer failure rates, and cost-effectiveness. However, postoperative pain control is a major problem because spinal anesthesia using only local anesthetics is associated with a relatively short duration of action, and thus early analgesic intervention is needed in the postoperative period. Several adjuvants have been studied to prolong the effect of spinal anesthesia. Various adjuvants have been used with local anesthetics in spinal anesthesia to avoid intraoperative visceral and somatic pain and to provide prolonged postoperative analgesia. Dexmedetomidine, the new highly selective α2-agonist drug, is now being used as a neuraxial adjuvant. This study aimed to evaluate the onset and duration of sensory and motor block, hemodynamic effect, postoperative analgesia, and adverse effects of dexmedetomidine given intrathecally with hyperbaric 0.5% bupivacaine.

**Aim of the study:** To compare the effect of plain bupivacaine vs bupivacaine with fentanyl vs bupivacaine with dexmedetomidine administered intrathecally for lower abdominal surgeries.

**Materials and method:** This study was done in a prospective double-blinded randomized manner. It was conducted at our institute between March 2018 to August 2018 after approval from the ethical committee of the institution and written informed consent. 90 American society of Anesthesiology I patients undergoing elective lower abdominal surgeries under spinal anesthesia were recruited. The volume of the drug, size of the syringe, color of the drug of interest was similar in the three groups. The final volume of injected solutions was 3.0 ml into three groups. In the premedication room pulse rate, BP, RR, and spO2 were monitored. An IV line was secured with an 18G cannula. Preloading was done with RL 500 ml - 1000 ml) over 20-30 mts.

**Results:** 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±0.53min and in Group F was 2.93±0.58 min. And in group D was 2.67+0.48min. There was statistically no significant difference among the 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 group D was 4.77+0.68. There was no statistically significant difference among the three groups $p < 0.345$. The time taken to achieve Bromage 3 from the time of SAB was tested by a modified Bromage scale. The mean time taken in Group B was 6.63 ± 0.56 min, group F was 6.67+0.55 min and group D was 6.53+0.68 There was statistically no significant difference among the three groups $p < 0.669$. The mean time taken for the return of cold sensation to S1 level was 305.63±44.50 min in Group B, in Group F was 358.97 ±46.74 mins and in the group, D was 457.30+54.28. The mean duration of return of motor block to Bromage scale zero [0] was 231.33±40.77 min in Group F and Group D was 279.43±56.01 and in the group, B was 171.83+39.98 mins. There was a statistically significant difference among the three groups in the mean duration of motor block $p < 0.0001$. The quality of surgical anesthesia was excellent in all patients. There was no statistically significant difference among the three groups $p < 1$.

**Conclusion:** Intrathecal Dexmedetomidine supplementation of the spinal block seems to be a good alternative to intrathecal fentanyl since it produces prolonged sensory block and motor block. This type of block may be more suitable for lower abdomen and lower extremities surgeries with a prolonged duration.

## Key words

Analgesia, Dexmedetomidine, Fentanyl, Motor block, Sensory block, Spinal anesthesia.

## Introduction

Spinal anesthesia is used extensively for lower abdominal and lower extremity surgeries because it has distinct advantages over general anesthesia [1]. Lignocaine and Bupivacaine are the commonly used local anesthetic agents for spinal anesthesia [2]. The adjuvants like opioids and α2 agonists 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 whilst reducing the incidence and severity of side effects. Surgery on the bowel, uterus, and other genital organs performed under the spinal or epidural block is often accompanied by visceral pain, nausea, and vomiting [3]. Fentanyl in various doses when added to spinal Bupivacaine increase the duration of analgesia and reduce intra operative nausea and vomiting [4]. Dexmedetomidine is an α2-agonist that is approved as an intravenous sedative and co-analgesic drug [5]. Most of the clinical studies about intrathecal α2 adrenoreceptor agonists 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 on spinal block

characteristics in lower abdominal surgical procedures [6].

## Materials and methods

This study was done in a prospective double-blinded randomized manner. It was conducted at our institute between March 2018 to August 2018 after approval from the ethical committee of the institution and written informed consent. 90 American society of Anesthesiology I patients undergoing elective lower abdominal surgeries under spinal anesthesia were recruited. The volume of the drug, size of the syringe, color of the drug of interest was similar in the three groups. The final volume of injected solutions was 3.0 ml into three groups. In the premedication room pulse rate, BP, RR, and spO2 were monitored. An IV line was secured with an 18G cannula. Preloading was done with RL 500 ml – 1000 ml over 20-30 mts.

**Inclusion criteria:**

- Patients in the age group of 30 and above, both sexes, ASA I.

**Exclusion criteria:**

- Hypersensitivity to the study drug.
- Renal or hepatic dysfunction.
- Uncontrolled labile hypertension and diabetes mellitus.

Patients were randomly allocated into Group B (n=30), Group F (n=30), Group D (n=30).

**Group B (n=30):** Patients in this group received 3ml of 0.5% hyperbaric bupivacaine of total volume 3.0ml.

**Group F (n=30):** Patients in this group received 2.5 ml of 0.5% hyperbaric bupivacaine + 25µg (0.5 cc) of Fentanyl to a total volume of 3.0 ml intrathecally.

**Group D (n=30):** Patients in this group received 2.5ml of 0.5% hyperbaric bupivacaine + 5 µg (0.5cc) 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/0.5ml, and preservative-free fentanyl 50mics/1ml 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, color of the drug of interest was similar in the three groups. The final volume of injected solutions was 3.0 ml into three groups.

**Statistical analysis**

This statistical analysis was done by IBM SPSS 20.0 software. The descriptive statistics of the variables studied as represented as two-way tables. The categorical factors were represented by the number and Frequency (%) of cases. The continuous variable measures of central frequency (like median, mean, mode) and deviation (SD and range). The difference in the proportion is tested for statistical significance using the nonparametric chi-square test for variables measured on a nominal scale. For variables measured on a continuous scale, a one-way analysis of variance is employed.

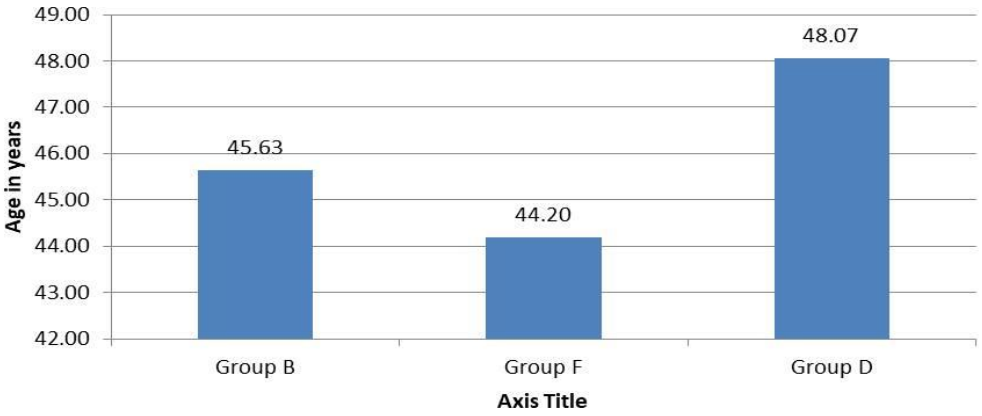
## Results

The three groups were comparable concerning their age, height, and weight. There was no statistically significant difference among the three groups in demographic aspects (**Graph – 1**).

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 and 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 the three groups ($p < 0.153$) as per **Graph - 2**.

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 group D was4.77+0.68. There was no statistically significant difference among the three groups $p < 0.345$ (**Table – 1**).

**Graph – 1:** Distribution of mean age (year) by groups.




**Graph – 2:** Distribution of mean onset of sensory block (t10) in mins by groups.

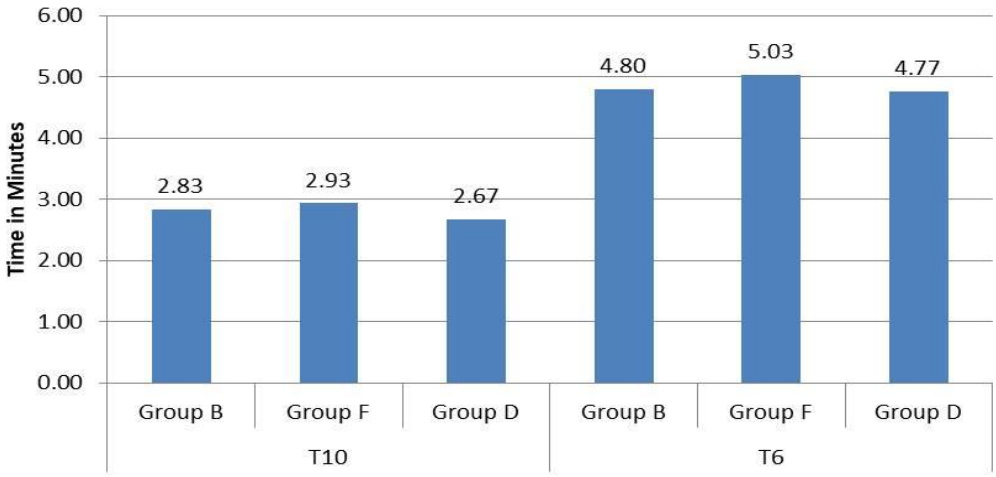
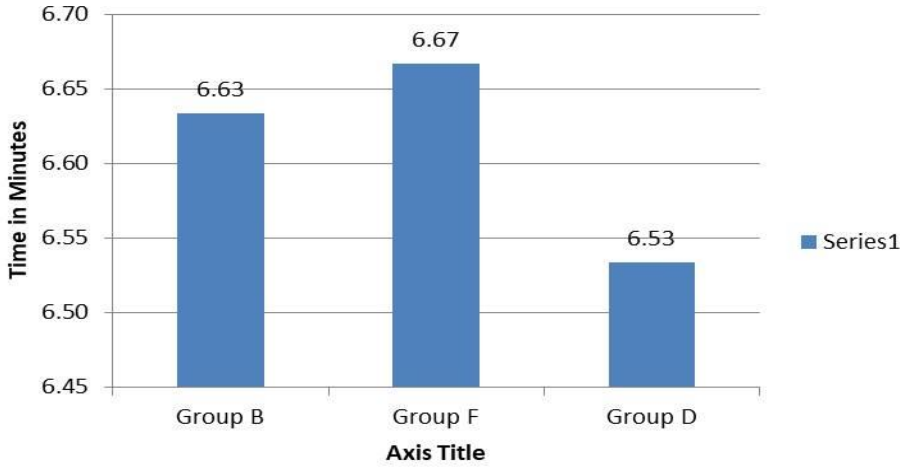


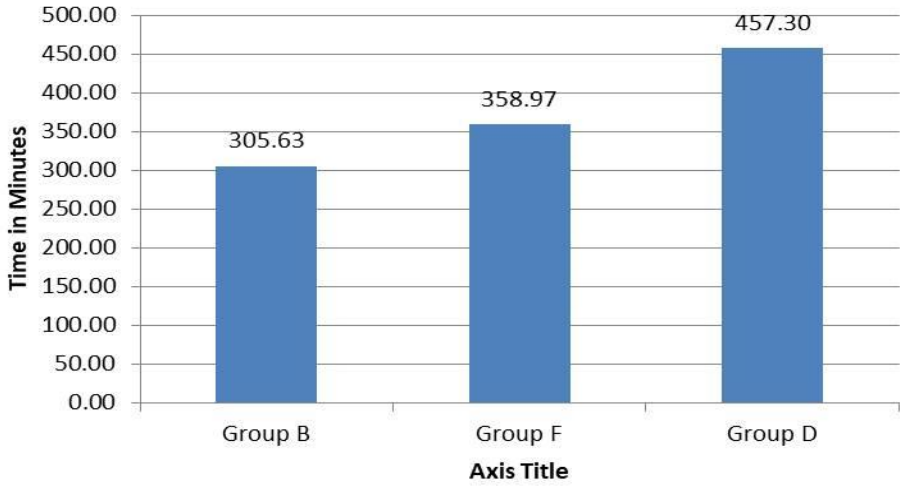

**Table – 1:** Distribution o mean onset of sensory block (t6) in mins by groups.

| The onset of Sensory Block | Group | Mean | Std. Deviation | P-value |
|---|---|---|---|---|
| | Group B | 4.80 | 0.76 | |
| | Group F | 5.03 | 0.85 | |
| T6 | Group D | 4.77 | 0.68 | 0.345 |

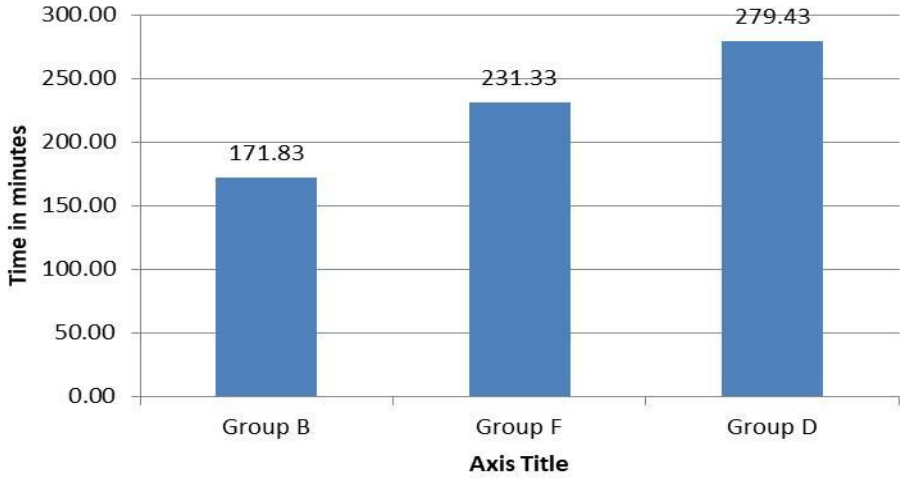
**Graph – 3:** Distribution of mean time to reach motor block (bromage 3) min by groups.



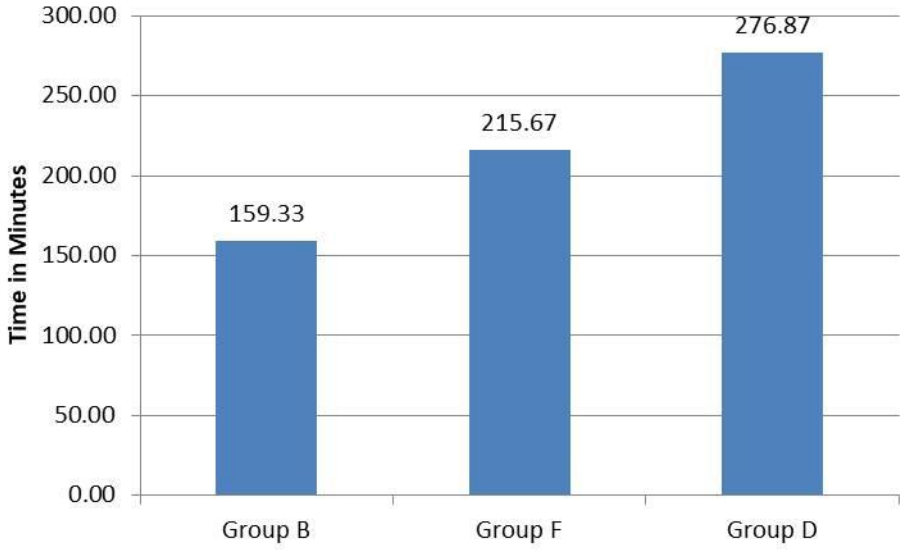
**Graph – 4:** 10 distribution of meantime for regression of sensory block (s1) in mins by groups.




**Graph – 5:** Distribution of mean time for regression of motor blockade (bromage 0) in mins by groups.




**Graph – 6:** Distribution of meantime for rescue analgesia in mins by groups.



**Graph – 7:** Maximum grade of motor block by groups.

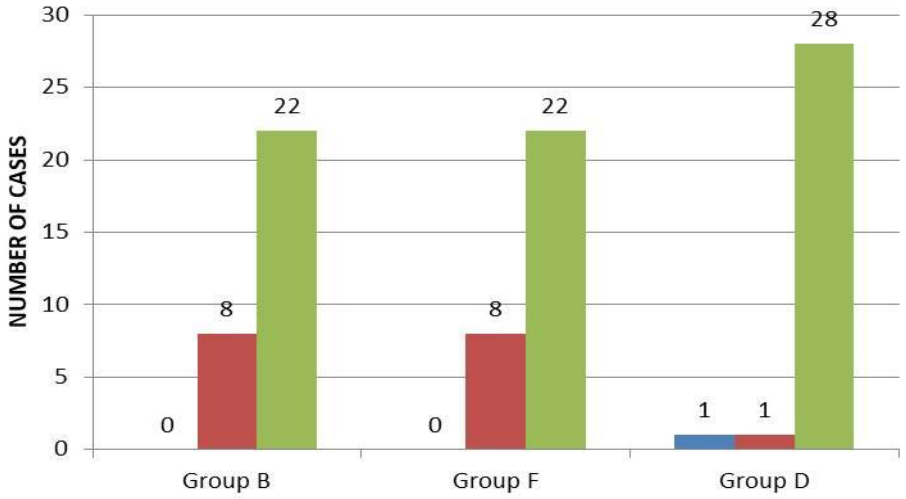
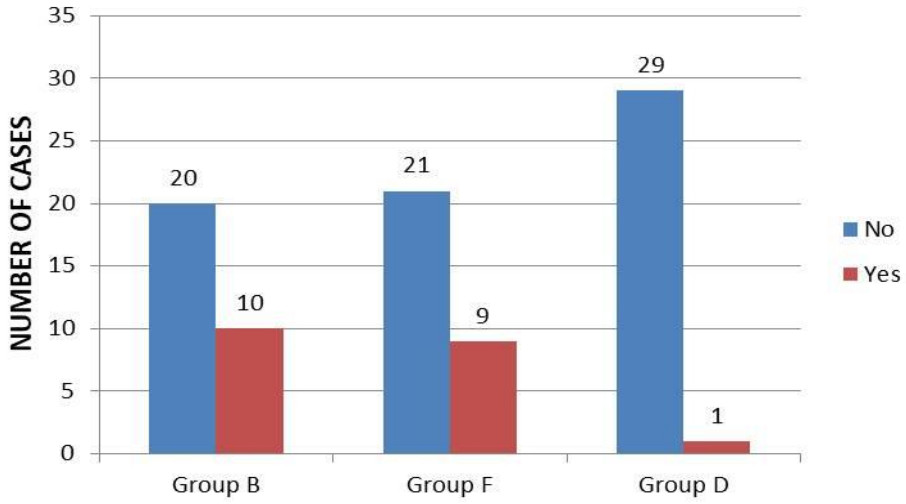


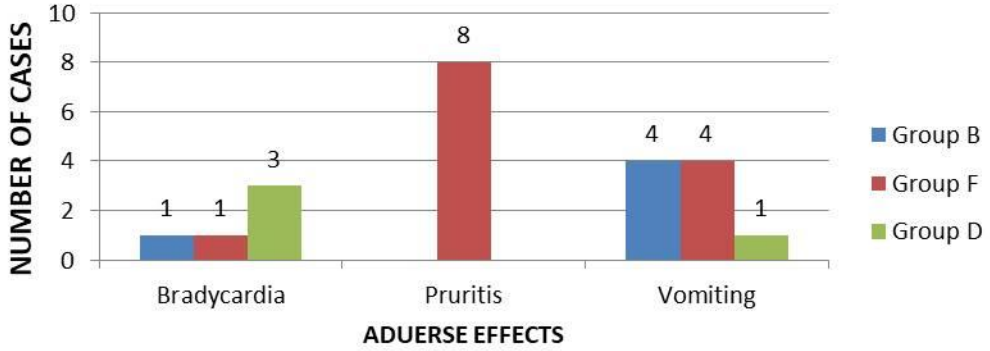

**Table – 2:** Maximum level of sensory block by (t4-t6) groups.

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

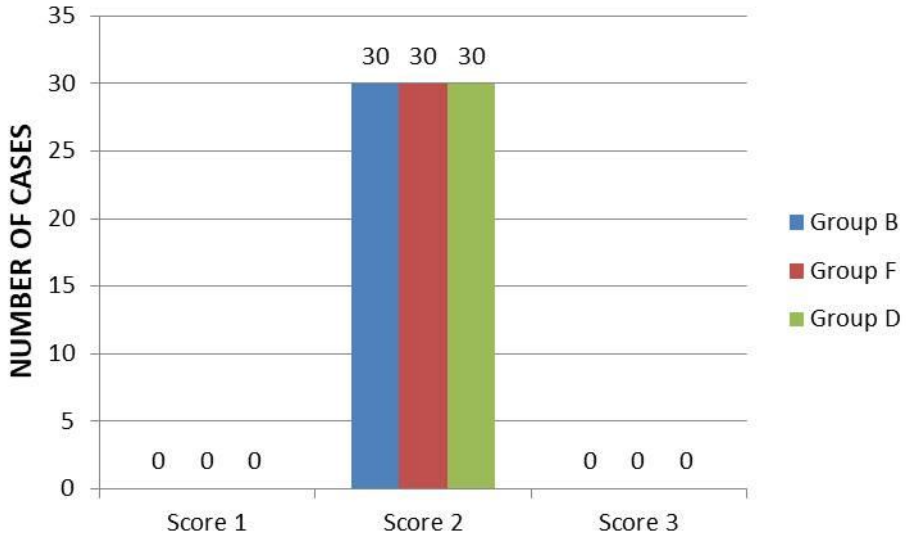
**Graph – 8:** Distribution of cases by hypotension in both groups.




**Graph – 9:** Distribution of cases by groups and side.



**Graph – 10:** Distribution of cases by sedation score.




The time taken to achieve Bromage 3 from the time of SAB was tested by a modified Bromage scale. The mean time taken in Group B was 6.63 ± 0.56 min, group F was 6.67+0.55 min and in the group, D was 6.53+0.68. There was statistically no significant difference among the three groups $p < 0.669$ (**Graph – 3**).

The mean time taken for the return of cold sensation to S1 level was 305.63±44.50 min in Group B, in Group F was 358.97 ±46.74 mins and in the group, D was 457.30+54.28. There was a statistically significant difference among the three groups in the duration of sensory block $p < 0.0001$ (**Graph – 4**).

The mean duration of return of motor block to Bromage scale zero (0) was 231.33±40.77 min in Group F and Group D was 279.43±56.01 and in the group, B was 171.83+39.98 mins. There was a statistically significant difference among the three groups in the mean duration of motor block $p < 0.0001$ (**Graph – 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 mins in Group F and Group D was 276.87±49.32 mins and in the group, B was 159.33±36.79. There was a statistically significant difference among the three groups in the duration of time for demand analgesia $p < 0.0002$ (**Graph – 6**).

The maximum degree of motor block in both groups was Grade 3. There was no statistically significant difference among the three groups in the maximum Grade of motor block $p < 1$ (**Graph – 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 and 10% in Group D and 16.6% in group B. T6 was 86.6% in Group F and 90% in Group D and 80% in group B which was statistically not significant < 1 (**Table – 2**).
The incidence of Hypotension in Group F was 30% and in the group, D was 3.33%, group B was 33.3% which was significant statistically $p < 0.029$ (**Graph – 8**).

The incidence of Bradycardia in Group F was 3.33% and in the group, D was 10% and in the group, B was 3.33% and there was a statistically significant difference in the three groups $p < 0.30$. The incidence of pruritus in Group F was 26.66% and in Group D and B no case of pruritus was observed. There was a statistically significant difference in the three groups $p < 0.002$. The incidence of vomiting in Group F

13.3%% and Group D 3.33% and group B 13.3% which was statistically not significant p < 0.44 (**Graph – 9**).

The incidence of sedation score 2 was 100% in three groups was statistically not significant p<1 (**Graph – 10**).

## Discussion

Hyperbaric Bupivacaine and its efficacy as an adjuvant to subarachnoid Bupivacaine were studied in 90 patients undergoing elective open appendicectomy and hernioplasty surgeries [7]. Elia N, et al. who compared the effect of 5µg Dexmedetomidine Vs fentanyl 25µg in intraoperative analgesia and the duration of sensory and motor block when added to 10mg intrathecal plain Bupivacaine and observed that there is no statistically significant difference between the two groups as regards the onset time of sensory block at T10 level [8]. Feldman HS, et al. did a comparative study of adding intrathecal 5µg Dexmedetomidine and 5µg of sufentanil to 10 mg of heavy Bupivacaine found that there is no statistically significant difference in the onset of sensory block T10 level Group D = 5.5±3.7, where Group 57 = 6.2±1.3 p < 0.69.In our study, the meantime to the onset of sensory Block (T10 level) was 2.93 ± 0.58 mins in Group F and 2.67 ± 0.48 mins in Group D and 2.83+0.53 mins 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 5µg of Dexmedetomidine to Hyperbaric Bupivacaine did not shorten the onset of sensory block (T10 level) when compared to the addition of 25µg of fentanyl to Hyperbaric Bupivacaine. The onset of sensory block (T10 level) was similar in the three groups [9]. Gertler R, et al. found that there is statistically no significant difference for the maximal sensory Block for 12mg Bupivacaine 0.5% alone or combined 3 µg of Dexmedetomidine or 30µg of clonidine (p = 0.3) [10]. Hammargren WR, et al. who found that the addition of 5 µg of Dexmedetomidine and 25 µg of fentanyl with 10 mg of isobaric Bupivacaine intrathecally had no significant difference in the meantime 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 meantime to reach T6 level was 5.03 ± 0.85 mins in Group F and 4.77 ± 0.68 mins in Group D, and 4.80+0.76 mins in group B as shown in **Figure - 8**. There is no statistically significant difference among the three groups to reach peak level T6 [11]. Hanks GW, et al. found that there is statistically no significant difference with 5µg of Dexmedetomidine and 5µg of sufentanyl to 10mg of heavy Bupivacaine in the meantime to achieve bromage 3 scores.In our study, the meantime to achieve Bromage 3 score was 6.67 ± 0.55 mins a Group F and 6.53 ± 0.68 mins in Group D, and 6.63+0.56 mins in group B as shown in **Figure - 9**. There is no statistically significant difference among the three groups [12]. The addition of 25µg fentanyl or 5µg Dexmedetomidine to 12.5 mg of Bupivacaine does not affect the onset of motor block. Hannaway AM, et al. found that the addition of 5 µg of Dexmedetomidine to 10 mg of isobaric Bupivacaine 274.83 ± 73.4 significantly prolong the duration of sensory blockade while 25 µg of fentanyl to 10 mg of isobaric Bupivacaine was 179.5±47.4. There was a statistically significant difference among the two groups p < 0.00 (Intrathecal Dexmedetomidine when combined with spinal Bupivacaine prolongs the sensory block by depressing the release of c-fibers transmitters and by hyperpolarization of postsynaptic dorsal horn neurons) [13]. Hess R R, et al. 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 mins in Group F, 457.30 ± 54.28 mins in group D, and 305.63+44.5 mins in group B. There is a statistically significant difference among the three groups p <0.0001. The addition of 5µg 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 postsynaptic dorsal horn neurons [14]. Ibrahim, F.A. found that the addition of 5µg of Dexmedetomidine to 2 ml of heavy Bupivacaine and 5µg of sufentanyl 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 mins in Group F and 279.643 ± 56.01 mins in Group D and 171.83+39.98 mins in group B. There is a statistically significant difference among the three groups p <0.0001. The addition of 5µg of Dexmedetomidine to 0.5% Bupivacaine significantly prolonged the duration of motor block [15]. Jansen PA, et al. 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 [16]. Jansen PA, et al. found that hypotension was more in the fentanyl group than in the Dexmedetomidine group but it did not reach a significant difference. Meanwhile, hypotension occurred 25-30 minutes after spinal injection in 2 patients in the Dexmedetomidine group and one patient in the fentanyl group had mild episodes of Hypotension in PACU [17]. In our study, the incidence of Hypotension was 30% in Group F and 3.3% in Group D, and 33.3% in group B. Hypotension was mild to moderate in the three groups which were statistically significant differences p < 0.029. The most significant side effect reported about the use of intrathecal α2 adrenoreceptor agonists is bradycardia. But in the present study, these side effects were not significant because the small dose of intrathecal 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. Liem, Karel F, et al. found that intrathecally administrated α2 agonists have 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 of one patient in Group D. In our study sedation was not statistically significant in three groups [19, 20].

## Conclusion

The addition of Dexmedetomidine intrathecally did not affect the onset of sensory or motor block when compared with fentanyl. The incidence of side effects was limited to the occurrence of Hypotension, Bradycardia vomiting in the groups that received Dexmedetomidine intrathecally. The incidence of pruritus was more in the groups that received fentanyl intrathecally. Intrathecal Dexmedetomidine supplementation of the spinal block seems to be a good alternative to intrathecal fentanyl since it produces prolonged sensory block and motor block. This type of block may be more suitable for lower abdomen and lower extremities surgeries with prolonged duration.

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