E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.02.486

Research Article

Comparative Evaluation of Two Different Doses of Dexmedetomidine as an Adjunct to Levobupivacaine in Subarachnoid Block for Lower Abdominal Surgeries

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Received: 04.07.26, Revised: 06.08.26, Accepted: 08.09.26

ABSTRACT
Background: Spinal anaesthesia is the preferred mode of anaesthesia for lower abdominal and lower limb surgeries. Levobupivacaine is being increasing used for spinal anaesthesia nowadays. Dexmedetomidine which is a potent α_2 agonist is being used as an adjunct to various local anaesthetics.
Aim: In this study, we aimed to compare two different doses of dexmedetomidine when added to Levobupivacaine in terms of onset, duration of sensory and motor block and post operative analgesia.
Method: A prospective, randomized study was carried out which included 100 patients between 18-65 years, of ASA I and II who underwent lower abdominal surgeries. Group D1 received 3ml levobupivacaine 0.5% +2.5mcg dexmedetomidine (in 0.5ml normal saline) total volume 3.5 ml and Group II D_2 received 3ml levobupivacaine 0.5% + 5mcg dexmedetomidine (in 0.5 ml of normal saline) total volume 3.5 ml. Sensory and motor block onset time, block reaching time to T6 dermatome, highest dermatome level of sensory block, two dermatome regression time, time to achieve complete motor block, VAS score at 2, 4 and 6 hours post spinal.
Results: Sensory block onset time, block reaching time to T6 dermatome and time to achieve complete motor blockade was same in both groups. Whereas motor block onset time was earlier in group D2 (p=0.003), two dermatome regression time was longer in group D2(p<0.001), and VAS score at 4 and 6 hrs was better in group D2(p-values 0.013 and <0.001 respectively).
Conclusion: We conclude that 5 mcg dose of dexmedetomidine has early onset of motor block, longer two dermatome regression and better VAS scores at 4 and 6 hours.

Keywords: Dexmedetomidine, Levobupivacaine, Spinal Anesthesia, Lower Abdominal Surgeries.

INTRODUCTION
Spinal anaesthesia using levobupivacaine was introduced in the 1980s.(1) Levobupivacaine, an S(−)-enantiomer of bupivacaine, with racemic bupivacaine or other local anesthetics, either isobaric or hyperbaric, has been used for obstetrics, orthopedics, herniorrhaphy, and transurethral surgeries.(2-5)Levobupivacaine is less cardiotoxic than bupivacaine.[1] Many adjuncts like fentanyl, ketamine, tramadol, neostigmine, magnesium sulphate, clonidine etc. have been used to prolong the analgesic effect of local anaesthetics.. Intrathecal alpha 2 agonists prolong the duration of action of local anaesthetics and reduce the required dose.Dexmedetomidine is a more selective alpha 2 adrenoceptor agonist and has been used recently as an adjunct to intrathecal local anaesthesia.(6-8)
Dexmedetomidine has synergistic action with local anesthetics used for spinal anesthesia. Use of dexmedetomidine combined with local anesthetics prolong the duration of sensory blockade in comparison to local anesthetics alone, aiding in reduced sensitivity to pain and prolonged analgesia.[9] Dexmedetomidine produces its analgesic effect by blocking the release of C-fiber transmitters at the level of the spinal cord so it is a useful adjuvant for spinal anesthesia.[10] Dexmedetomidine produces dose-dependent anxiolysis, analgesic and sedative effects and blunts the sympathetic nervous system response to surgery.[11] Dexmedetomidine has an opioid-sparing effect

and provides analgesia without respiratory depression and airway obstruction.[10]
In this study, we aimed to study and compare two different doses of dexmedetomidine in terms of onset, duration of sensory and motor block, and post operative analgesia in patients undergoing lower abdominal surgeries.

MATERIAL AND METHODS

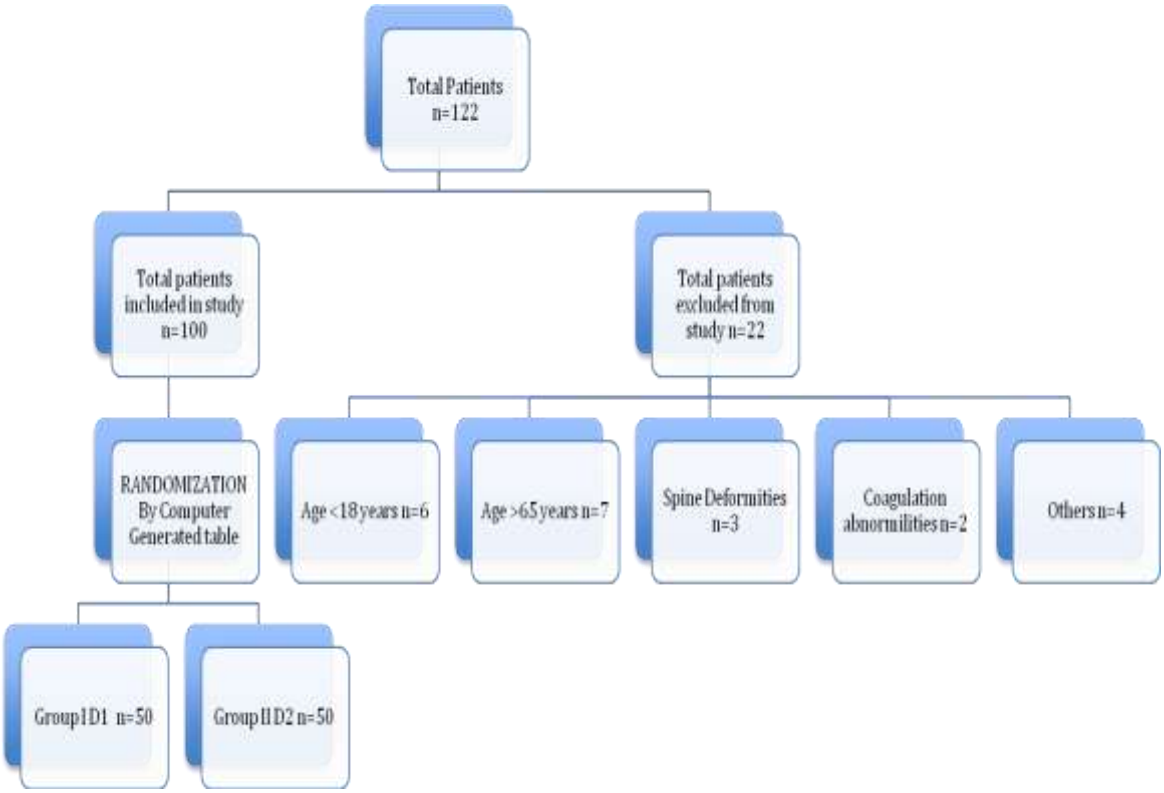
The present prospective randomised study was carried out between august 2017 to july 2018 after getting approval from Institutional Ethical Committee of our instituteity.100 ASA grade I and II patients aged between 18-65 years of either sex posted for lower abdominal surgeries, giving written and informed consent were enrolled in the study. Patients refusal to be a part of the study, previous spinal surgeries (technically difficult subarachnoid block), deformities of spine, infection of spinal site, abnormalities in coagulation, local anaesthetic allergy or allergy to study medications, Neuromuscular diseases, patients with hematological, neurological and psychiatric diseases and patients with heart block, dysarrthymias, labile hypertension were the exclusioncriteria from the study.
All patients were randomly divided into two groups based on computer generated table: Group I D_1(n=50) and Group II D_2 (n=50). Group I D_1 patients received 3ml levobupivacaine 0.5% +2.5mcg dexmedetomidine (in 0.5ml normal saline) and Group II D_2 patients received 3ml levobupivacaine 0.5%+ 5mcg dexmedetomidine (in 0.5 ml of normal saline) total volume was 3.5 ml in both groups and drugs used in both groups were of same brand.
After the patient was taken in the operation theatre, intravenous line with 20 G cannula was secured in non-dominant hand. Monitoring was done using multi parameter monitor. Baseline systolic, diastolic and mean blood pressure, pulse rate and arterial oxygen saturation were recorded. All patients were preloaded with 10 ml/kg of balanced salt solution 15 minutes before the establishment of block. Under all aseptic precautions, a midline spinal puncture was performed at L3/L4 interspace (given at L2/L3, if due to an anatomical reason it would not be possible at L3/L4) with 25-G pencil-point needle in the sitting position and the anaesthetic drug was injected over a span of 15 s with hole in the spinal needle facing upward and the patients were returned to the supine position.Motor blockade was assessed by using Bromage Scale {0 = No motor block (free movement of legs and feet) ,1= just able to flex knees with free movement of feet , 2= Inability to raise extended leg or flex knees but able to move feet , 3=Complete motor block of limb i.e. unable to move legs or feet}.Sensory blockwas assessed by pinprick test using a short bevelled sterile 26G hypodermic needle along the midclavicular line, bilaterally. Sensory level and bromage scale were recorded after giving spinal every 2 minutes for a period of 20 minutes then every 30 minutes till 170 minutes post spinal. Sensory block onset time, Block reaching time to T6 dermatome, Highest dermatome level of sensory block, Two dermatome regression time , Motor block onset time, Time taken to achieve complete motor blockade (bromage 3), VAS score after giving spinal at 2 hours, 4 hours and 6 hours were recorded in the two groups. Hemodynamic parameters were recorded preoperatively, 15 minutes after preloading and then every 1 minute for 10 minutes, every 5 minutes till 60 minutes and then every 15 minutes till 150 minutes post spinal. Hypotension was defined as systolic blood pressure of <90 mm of Hg or >20% decrease from baseline value which was treated with inj. mephentermine 6 mg i.v. in bolus dose. Tachycardia was defined as heart rate >100/min and bradycardia as heart rate <50/min, or >25% decrease in baseline values; it was treated with inj. atropine 0.02 mg/kg i.v. in bolus dose. The patients were asked to evaluate their pain on standard 10 point visual analogue pain scale (VAS 0 = no pain, VAS 10 = worst possible pain) every 2 hours after spinal anaesthesia was given till 6 hours i.e. 2 hours after spinal, 4 hours after spinal and 6 hours spinal anaesthesia. Throughout the procedure patients were observed for any side effects like nausea, vomiting, shivering, pain or any other adverse event and were managed accordingly.

Statistical analysis:

Thesample size was calculated using the study by Esmaoglu et al.[12] A minimum of 100 patients or 50 patients for each group were recruited. 5% margin of error (type I error:α=0.05), 80% power (type II error: 1-β=0.80) were taken. Statistical analysis was done using SPSS version 18.0 (SPSS Inc., Chicago, IL, USA) software. Arithmetic mean and standard deviation were used. Chi Square Test was used for testing the association between variables. Unpaired t-test was used to compare the means of two unmatched groups

or two independent set of data. P value <0.05 was considered statistically significant.

Consort Chart



RESULTS

Both the groups were comparable in terms of demographic profiles i.e. age, weight, gender and ASA grade (Table 1)

Table – 1: Distribution of Subjects according to Demographic Profiles & ASA Grades

Variable	Group-D1	Group-D2	t/chi sq-value	p-value
age (Mean±SD)	41.82 ± 15.99	38.32 ± 13.08	1.20	0.234
weight (Mean±SD)	60.22 ± 8.17	58.46 ± 7.25	1.14	0.257
Gender : No. (%)				
Female	16 (32%)	14 (28%)	0.19	0.663
Male	34 (68%)	36 (72%)		
ASA Grade : No. (%)				
Grade – 1	19 (38%)	11 (22%)	3.05	0.081
Grade – 2	31 (62%)	39 (78%)		

The sensory block onset time was same for all the patients in both the groups. The block reaching time to t6 dermatome in group D1 was 8.09±3.09 mins, while in group-D2 it was 8.40±2.18 mins. Although block reaching time to T6 was earlier in group D1 but it was not statistically significant (P value=0.561). The two dermatome regression time was prolonged in group D2 (153.72 ± 12.46 mins) as compared to Group DI (109.52 ± 12.23 mins) and was statistically significant with P value<0.001. The motor block onset time was earlier in group D1 (1.16±0.37 mins) as compared to group-D2 (1.00±0.00 min) and significant difference was found in motor block onset time between the two groups (P value=0.003) The time taken to achieve complete motor blockade in group D1 was

3.28±1.60 min, while in group-D2 it was 3.52±1.64 min. No significant difference was found in time taken to achieve complete motor blockade between the two groups (p=0.462). (Table 2).

Table – 2: Intergroup Comparison of Sensory and motor block parameters

Parameter	Group-D1		Group-D2		t-value	p-value
	Mean	SD	Mean	SD		
sensory block onset time(min)	2.00	0.00	2.00	0.00	NA	NA
block reaching time to t6(min)	8.09	3.09	8.40	2.18	-0.58	0.561
two dermatome regression time (mins)	109.52	12.23	153.72	12.46	-10.86	**<0.001**
motor block onset time (min)	1.16	0.37	1.00	0.00	-3.06	**0.003**
time taken to achieve complete motor blockade (mins)	3.28	1.60	3.52	1.64	-0.74	0.462

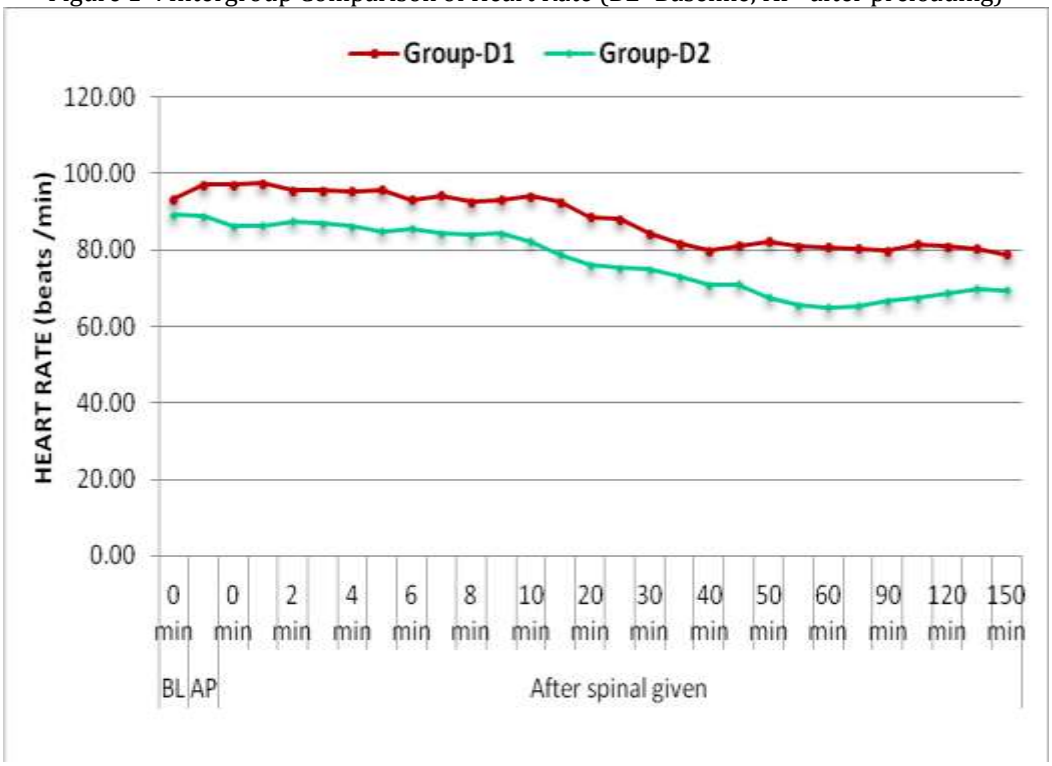
The highest level of sensory block reached in group D1 was T6 which was achieved by 94% of patients whereas it was T4 in group D2 which was achieved by 18% of patients and the difference in proportion was statistically significant (P value= 0.002). (Table 3).

Table – 3: Intergroup Comparison of highest dermatome level of sensory block

highest dermatome level of sensory block	group - D1		group - D2		chi sq	p-value
	No.	%	No.	%		
t4	0	0.0%	9	18.0%	12.409	**0.002**
t6	47	94.0%	41	82.0%		
t8	3	6.0%	0	0.0%		

Statistically significant differences were observed in heart rate between the two groups from the time spinal was given till 150 minutes post spinal. (Figure 1)

Figure 1–: Intergroup Comparison of Heart Rate (BL- Baseline; AP- after preloading)



No significant difference was observed in SBP (except at 90 mins post spinal), DBP, MBP (except at 105 mins post spinal) and SpO_2. (figure 2,3,4,5)

Figure 2–: Intergroup Comparison of Systolic Blood Pressure (BL- Baseline; AP- after preloading)

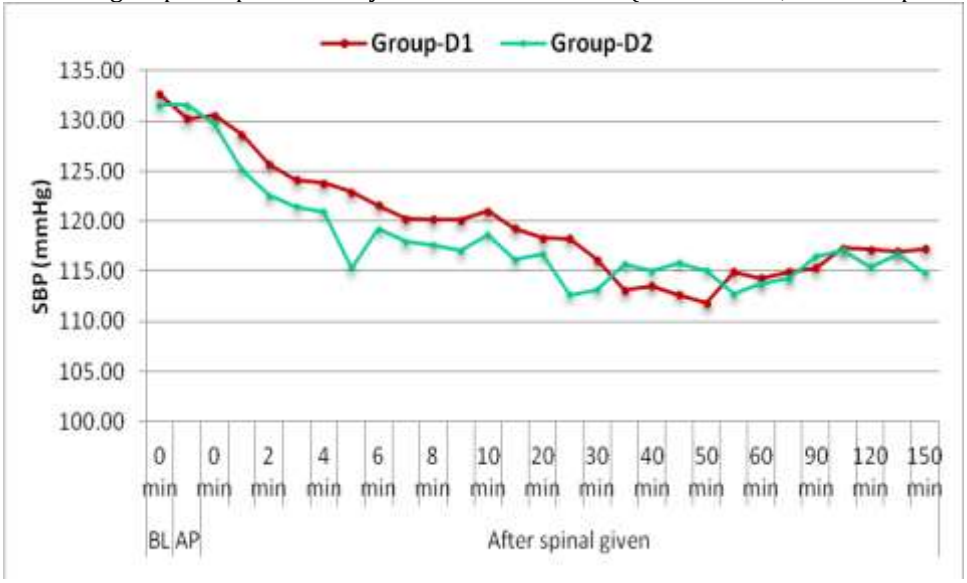


Figure 3: Intergroup Comparison of Diastolic Blood Pressure (BL- Baseline; AP- after preloading)

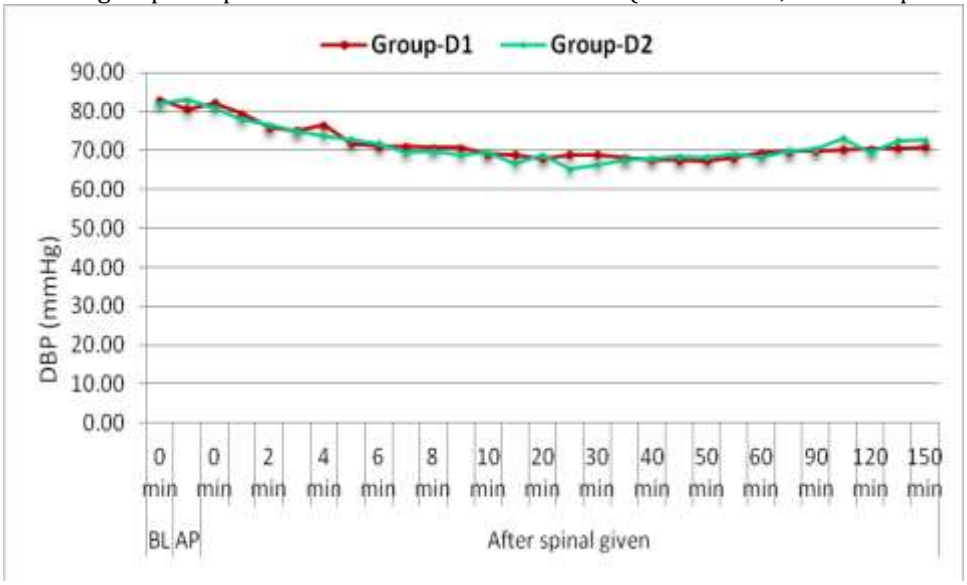


Figure 4– : Intergroup Comparison of MAP (BL- Baseline; AP- after preloading)

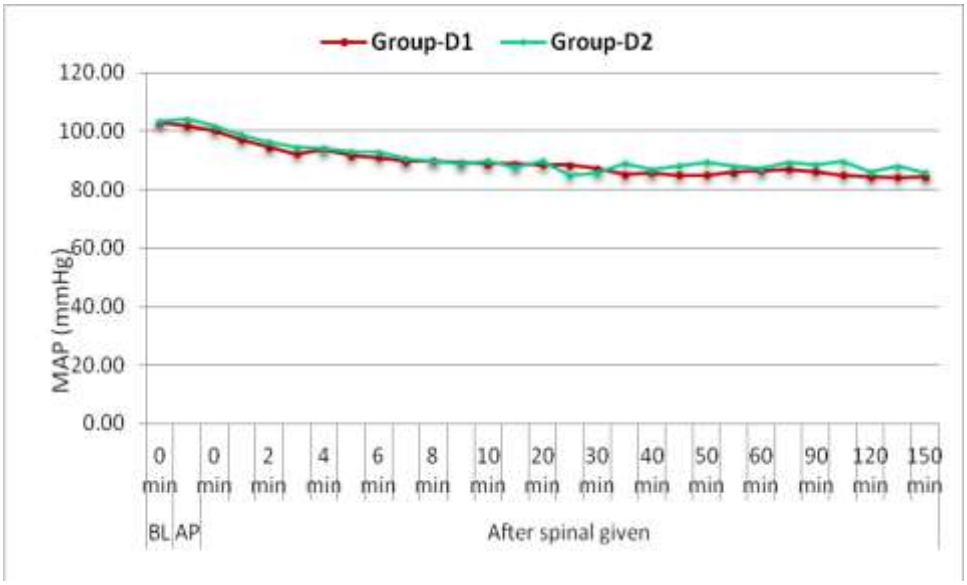
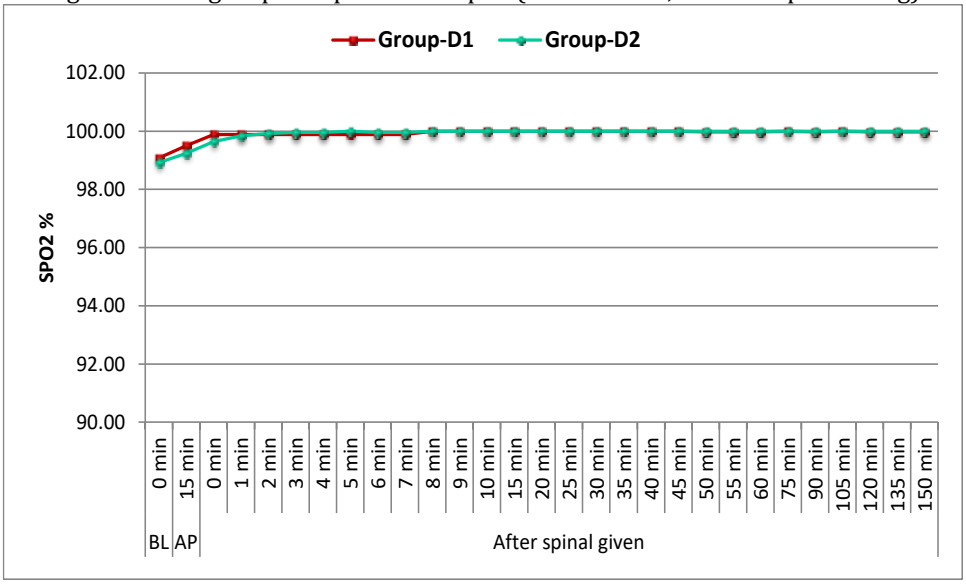


Figure 5: Intergroup Comparison of SpO_2 (BL- Baseline; AP- after preloading)



The mean VAS in D1 group at 2 hrs after spinal was 0.00±0.00 which was increased to 1.12±0.77 at 4 hrs and further increased to 3.66±0.75 at 6 hrs whereas mean VAS in D2 group at 2 hrs after spinal was 0.00±0.00 which was increased to 0.72±0.83 at 4 hrs and further increased to 2.02±0.84 at 6 hrs. The significant difference was observed in VAS score at 4 hrs and 6 hrs with P -values 0.013 and <0.001 respectively. (Table 4) (figure 6)

Figure 6: Intergroup comparison of VAS score

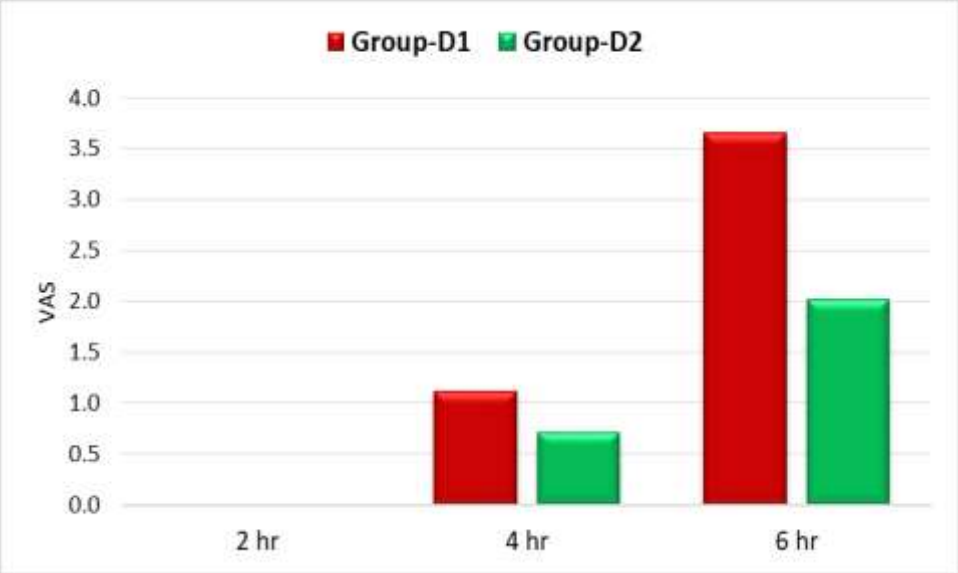


Table 4: Intergroup comparison of Pain (VAS)

VAS	Group-D1		Group-D2		U-value	p-value
	Mean	SD	Mean	SD		
2 hr	0.00	0.00	0.00	0.00	1250.00	1.000
4 hr	1.12	0.77	0.72	0.83	912.00	**0.013**
6 hr	3.66	0.75	2.02	0.84	225.00	**<0.001**

DISCUSSION

In the present study, it was observed that higher dose of dexmedetomidine as used in Group II (5 mcg) had earlier onset, prolonged duration of sensory and motor block as well as better post operative analgesia as compared to Group I in which 2.5 mcg dose was added to Levobupivacaine for patients undergoing lower abdominal surgeries.

In our study it was seen that the onset of sensory block in both the groups was the same and time to reach T6 dermatome in both the groups was not statistically significant. Similar result was found in the study by Esmaoglu et al[12] who also observed that time to reach T10 dermatome in both their groups was similar and statistically insignificant. Whereas Kataria et al[13] had observed that addition of dexmedetomidine to Levobupivacaine hastened the onset of sensory block. Mustafa et al[14] also observed that onset and progression of sensory block was shorter with higher dose of dexmedetomidine which showed dose dependent effect on onset and progression of sensory block. In our study no significant difference was observed when time to reach T6 dermatome was compared between the two groups, could be because the dose used in the two groups is too less and because of the dilution of dexmedetomidine to make appropriate concentration.

Highest dermatome level achieved in our study, in group D1 was T6 whereas it was T4 in group D2. This was somewhat similar to results by Esmaoglu et al[12] and Kataria et al[13] who had observed higher level of sensory block in groups with dexmedetomidine along with Levobupivacaine as compared to normal saline with Levobupivacaine.

We observed prolonged two dermatome regression time in the group with higher dose of dexmedetomidine. This was consistent with other studies of esmaoglu et al[12] and Mustafa et al[14] who observed that addition of dexmedetomidine to Levobupivacaine prolonged two dermatome regression time and higher dose of dexmedetomidine with bupivacaine had prolonged two dermatome regression time, respectively.

Onset of motor block was observed earlier with higher dose of dexmedetomidine in our study which was consistent with the studies of Esmaoglu et al[12], Kataria et al[13] and Mustafa et al.[14] Whereas no significant difference was observed between the groups in our study in terms of time to achieve complete motor blockade. This was supported by studies of Esmaoglu et al[12] and kataria et al.[13]

In the post operativeperiod, , lower VAS scores were observed in group D2 at 4 hours and 6 hours as compared to group D1. These results were consistent with the findings of Kataria et

al.[13] Various other studies have also supported that addition of dexmedetomidine to Levobupivacaine has better degree of analgesia.[12,15-18,21,22]

In our study significant difference was observed in heart rate between the two groups from the time spinal was given to 150 minutes post spinal. This may be attributed to the type of surgery which could have led to blood loss and therefore variation in heart rate.Changes in heart rate were significant but not as extreme that could have led to severe hemodynamic instability . The increase in heart rate can also be attributed to anxiety or less fluid input to the patient.

No significant differences were observed in SBP(except at 90 mins post spinal), DBP, MAP (except at 105 mins post spinal) and SpO_2 between the two groups.

Bradycardia was observed in two patients of group D1 and 5 patients of group D2 but the results were not statistically significant. Somewhat similar results were obtained by Kataria et al[13] who observed that more number of patients had bradycardia who received dexmedetomidine with Levobupivacaine than normal saline with Levobupivacaine.

No other complication like hypotension, itching, nausea and vomiting were observed in any patient of either group.

Keeping the whole study into consideration it may be concluded that 5 mcg dose of dexmedetomidine has an early onset of motor block, higher level of sensory block, prolonged duration of sensory block as assessed by two dermatome regression time, better post operative analgesia and stable hemodynamic profile.

Despite all the effective measures taken, we came across few limitations in this study. Duration and type of surgery were not included as a parameter.

Ethical committee approval: Ethical committee approval was received for this study from Institutional Ethical Committee of King Georges Medical University with letter number-2966 (provisionally approved) and Institutional Ethical Committee letter number –167 (approved)

Conflict of interest :none

Financial support and sponsorship: none

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