

A COMPARATIVE STUDY OF ANALGESIC EFFICACY OF I.V DEXMEDETOMIDINE VS INTRATHECAL DEXMEDETOMIDINE AS ADJUVANT TO HYPERBARIC BUPIVACAINE IN SURGERIES UNDER GOING SPINAL ANAESTHESIA

Anaesthesiology

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ABSTRACT

Background: Recent research focus on the role of α 2agonist as adjunct to local anesthetic agents. α 2agonist augment the action of local anaesthetics in regional blockade by interrupting the neural transmission of painful stimuli in A delta and C fibers as well as by increasing the conductance of K^+ ion in the nerve fibres. Dexmedetomidine is a highly selective α 2agonist with analgesic properties and produces minimal respiratory depression with arousable sedation. It potentiates the effect of local anaesthesia and decreases its required dose, thus our study focused on the role and efficacy of dexmedetomidine as adjuvant in spinal anaesthesia. Aim of study was to access the analgesic efficacy of intrathecal dexmedetomidine and intravenous dexmedetomidine in patients undergoing lower abdominal surgeries except cesarean section. Efficacy was assessed in terms of time of onset of sensory and motor block, total duration of sensory and motor block, time for two segment regression, time for first dose of rescue analgesia, total analgesia consumption in milligram in both groups, Ramsay sedation score, vas score. **Material And Method** study was conducted in silchar medical college by dept of anaesthesiology and critical care, silchar after obtaining ethical committee clearance. Our study was a prospective randomized single blinded study. After obtaining informed written consent from patients, the patients were randomly divided into two groups - **Group A (i.v)**: 45 patient received i.v dexmedetomidine 0.5 microgram per kg in 10 ml of 0.9 percent NS over a period of 15 minutes given 20 mins before spinal Anaesthesia with bupivacaine heavy 12.5 mg (2.5 ml) + 0.3 ml NS in sitting and lateral position. **Group B (I.T)**: 45 patient given 10 ml of 0.9 percent NS i.v over a period of 15 mins given 20 mins before giving spinal Anaesthesia was given using 0.5 percent bupivacaine heavy 12.5 mg (2.5 ml) + 3 microgram of dexmedetomidine (0.3 ml) in sitting position / lateral position. **Result** mean duration of surgery and mean BMI of patients taken in both study was comparable. Mean duration of sensory block in group A (i.v) 342.69 +/- 5.6 mins but in group B (I.T) was 450.11 +/- 6.011 mins. Time for two segment regression in group A (I.v) 139 +/- 6.2 min but in group B (I.T) it was 171.56 +/- 5.7 min. Even time for request for 1st dose analgesia in group A (i.v) was 3.8 +/- 0.88 hours whereas in group B (I.T) it was 5.7 +/- 1.8 hours. So we can conclude, group B (I.T) dexmedetomidine was better in providing analgesic efficacy than group A (I.V). **Conclusion** To conclude, intrathecal dexmedetomidine 3 μ g is more efficacious as compared to intravenous dexmedetomidine 0.5 μ g/kg as adjuvant to subarachnoid block as duration of both sensory and motor block was increased with prolonged duration of analgesia and less requirement for rescue analgesia. Therefore we conclude that intrathecal dexmedetomidine is more efficacious than i.v dexmedetomidine as adjuvant to bupivacaine heavy in surgeries under spinal anaesthesia.

KEYWORDS

INTRODUCTION:

Post operative pain management has been a major challenge for anesthesiologist and there has been constant struggle to bring out best possible anesthetic technique with least side effects. Regional anaesthesia and analgesia has the potential to provide excellent operating condition and prolong postoperative pain relief. Post operative pain control is a major problem because spinal anaesthesia using only local anaesthesia is associated with relatively short duration of action and thus early analgesic intervention is needed in post operative period. Various adjuncts such as benzodiazepines, opioids, ketamine, neostigmine and many other drugs have been used with local anaesthetics to provide better post operative analgesia, thereby facilitating rehabilitation and accelerating functional recovery. But these adjuncts which are given intrathecally [especially opioids] are associated with side effect which limit their use. Recent research focused on the role of α 2agonist as adjunct to local anesthetic agents. α 2agonist augment the action of local anaesthetics in regional blockade by interrupting the neural transmission of painful stimuli in A delta and C fibers as well as by increasing the conductance of K^+ ion in the nerve fibres. Administration of α 2 agonist through the intrathecal route act as an adjuvant drug to local anaesthetics and provides an analgesic effect in postoperative pain relief. Dexmedetomidine is a highly selective α 2agonist with analgesic properties and produces minimal respiratory depression with arousable sedation. It potentiates the effect of local anaesthesia and decreases its required dose, thus our study focused on the role and efficacy of dexmedetomidine as pain adjuvant in spinal anaesthesia.

AIM AND OBJECTIVES:

AIMS: To assess the analgesic efficacy of intrathecal dexmedetomidine and intravenous dexmedetomidine in patients undergoing lower abdominal surgeries and orthopaedic surgeries under spinal anaesthesia. Efficacy is assessed in terms of

OBJECTIVES:

1. Time Of Onset Sensory Block
2. Time Of Onset Of Motor Block

3. total Duration Of Sensory Block
4. total Duration Of Motor Block
5. Time For Two Segment Regression
6. time For First Dose Of Rescue Analgesia
7. Total Analgesia Consumption In Milligram In Both Groups
8. Ramsay Sedation Score
9. Vas Score
10. Haemodynamic

MATERIALS AND METHODS:

Study Design: Hospital based observational study.

Study Setting: silchar medical college and hospital

Study Duration: June, 2021 to May, 2022.

Study Population:

Patient undergoing infraumbilical surgeries

Study Type:

patient were randomly allocated into two groups was unaware of route of administration of dexmedetomidine, spinal anaesthesia injection was given by anaesthesiologist who do not participate in recording patient's data the patient and the anaesthesia provider were blinded to the study thus our study was randomised double blinded prospective study. We had taken a sample size of 90 patients and will divide them randomly into two groups (group A and group B), each containing 45 patients.

The patients classified as per American Society of Anaesthesiologists (ASA) class I and II of either sex aged 18 to 60 years scheduled for surgery undergoing spinal anaesthesia. The sample size considering primary outcome as duration of postoperative analgesia, to detect difference of 130 mins between two groups with a level of significance 0.05 and power of 80%, a sample size of 42 patient was required. therefore we recruited 90 patients in our study, keeping in view of drop outs.

group A (i.v) ; 45 patient received i.v dexmedetomidine 0.5 microgram per kg in 10 ml of 0.9percent ns over a period of 15 minutes given 20 mins before spinal Anaesthesia with bupivacaine heavy 12.5 mg (2.5 ml) + 0.3 ml NS in sitting or lateral position.

Group B (I.T); 45 patient received 10 ml of 0.9 percent NS i.v over a period of 15 mins given 20 mins before giving spinal Anaesthesia with 0.5 percent bupivacaine heavy 12.5 mg (2.5 ml) + 3 microgram of dexmedetomidine (0.3 ml) in sitting position orlateral position.

Selection of cases:

Inclusion criteria: Patients who gave informed written consent for the study

- Patients aged between 18 to 60 years.
- Patients with ASA grade I and II.
- Patient with lower abdominal / lower limb surgeries

• IExclusion criteria:

- Patients with ASA grade III and IV
- Allergy to study drug
- Any bleeding disorders
- Uncontrolled diabetes mellitus
- Pregnant women undergoing caesarean section
- Pre-existing peripheral neuropathy
- Renal and liver disease

Pre anaesthetic evaluation was done one day prior to surgery. A detailed system wise clinical examination including airway was done. Basic laboratory investigations like complete blood count , urine analysis , blood sugar , kidney function test , chest x-ray, viral markers and ECG were conducted. Echocardiography, serum electrolytes, PT/INR were advised as required .

All patients were premedicated with tab alprazolam 0.25 mg orally and tab ranitidine 150 mg at bed time on the previous night of surgery and all patients were kept NPO for 8 hrs prior to surgery..

On the day of the surgery, on arrival in the operation theatre, body weight of all patients were recorded. Basic monitoring devices including ECG, NIBP, pulse oximeter were connected and baseline values of haemodynamic variables heart rate (HR) , mean arterial pressure (MAP) and peripheral oxygen saturation (SPO2) were recorded.

Anaesthetic Technique:

For stimulation of the ulnar nerve, 'Idmed ToFscan' neuromuscular transmission monitor was attached and the ECG electrodes are applied at the volar aspect of the wrist . The distal electrode 'negative' (black) was placed about 1 cm proximal to proximal wrist crease The proximal electrode ' positive' (red) was placed 2 -5 cm proximal to the distal electrode along the path of the ulnar nerve. An IV line was secured with an appropriate IV cannula (18G or 16 G) in one of the hand and all patients were preloaded with crystalloids ringer lactate solution @ 8 ml/kg/ hr .

Pre-medication:

In the pre-operative room, patient's height weight was noted and an intravenous line will be secured with 18G cannula on the unaffected arm. The patient was connected with standard monitors and baseline E.C.G. (Electrocardiography), NIBP (Non-invasive blood pressure) and SpO2 (Oxygen saturation) was recorded.

The patient was premeditated 30 minutes before surgery with

- Inj. Ranitidine 100mg IV stat
- Inj. Ondansetron 4mg IV stat

Anaesthesia method

- The pre anaesthetic check-up of the patient was done before the day of surgery
- Boyles machine and suctioning equipment were checked on the day of operation, difficult airway cart and drugs for general anaesthesia were kept ready which may require for failed spinal block
- Before start of the procedure patients' pulse, rate blood pressure and saturation were recorded all patients were preloaded with 500ml of ringer lactate
- The drugs were prepared by an anaesthesiologist who did not take part in the study , spinal injections were given by anaesthesiologist who did not participate in recording patients data . the patient and anaesthesia provider were blinded to the drug

- Drug preparation : group A : 1ml of dexmedetomidine contains 50µg of drug. So, 1ml of dexmed was diluted in 10ml syringe with distilled water to make concentration 5microgram/ml than 1ml again taken from 5µg concentration per ml and diluted again in 10ml distilled water to make concentration 0.5µg/ml.
- Group b : 1ml of dexmedetomidine contains 50µg concentration , so 1ml was diluted in 10ml syringe with distilled water to make concentration 5microgram/ml, from 5microgram concentration 1ml was withdraw with insulin syringe. 1ml of insulin syringe contains 5µg of dexmedetomidine. Insulin syringe contain demarcation upto 100u , for 3µg drug we will withdraw 60u from insulin syringe.
- Under all aseptic condition lumbar puncture was performed with 25gauge quincke needle in l3-l4 space through midline approach Group A : 45 patient received i.v dexmedetomidine 0.5 microgram per kg in 10 ml of 0.9percent ns over a period of

METHODS AND MATERIAL

Department of Anaesthesiology, SMCH Page | 65 15 minutes given 20 mins before spinal Anaesthesia with heavy bupivacaine 12.5 mg (2.5 ml) + 0.3 ml NS in sitting and lateral position

- Group B : 45 patient given 10 ml of 0.9 percent ns i.v over a period of 15 mins given 20 mins before spinal Anaesthesia will be given using 0.5 percent bupivacaine heavy 12.5 mg (2.5 ml) + 3 microgram of dexmedetomidine (0.3 ml) in sitting position / lateral position.
- All patients were given oxygen at 4l/ min .
- Hypotension was controlled by mephentermine injection
- Bradycardia was corrected by providing inj glycopyrrolate .

All patients were assessed for – 1. Time for onset of sensory analgesia at t10 level highest level of sensory analgesia

2. duration of analgesia (time from sensory blockade to First dose of rescue analgesia)
3. total consumption of analgesia including rescue analgesia in the duration of 24 hour
3. time for two segment regression was noted
4. duration of motor and sensory block was assessed in

PACU

5. All duration of pain was calculated considering the time of spinal anaesthesia at time of administration zero.
6. pulse rate, systolic and Diastolic pressure were recorded at 5, 10, 15, 20, 120 mins
7. Sensory block was assessed by pin prick method after placing the patient in supine position the sensory level were assessed by pin prick method using 25 g needle along mid clavicular line at 3,6,9,12,20,25 and 30 mins after giving spinal anaesthesia. the time to reach the sensory level up to t10 dermatome and the time of regression to s1 segment was recorded.

The onset of sensory block will be assessed with pin prick sensation:

- Grade 0 : Sharp pain felt
- Grade 1 : Analgesia , dull sensation felt
- Grade 2 : Anaesthesia , no sensation felt

METHODS AND MATERIAL

Department of Anaesthesiology, SMCH Page | 66

8. Assessment of motor blockade will be carried out by modified Bromage scale : Motor level was assessed using Modified Bromage scale at 5th minute and every 20 min after the end of surgery.
 - BROMAGE0-Able to move hip, knee, ankle.
 - BROMAGE1-Unable to move hip, but is able to move knee and ankle.
 - BROMAGE2-Unable to move hip and knee but is able to move the ankle.
 - BROMAGE3-Unable to move hip, Knee and ankle Duration of motor block was recorded till our patient reached to Bromage scale 3
9. Assessment of sedation will be done based upon Ramsay sedation scale: Ramsay Level of sedation scale.
 - Awake and anxious, agitated, or restless
 - Awake, cooperative, accepting ventilation, oriented, tranquil
 - Awake; responds only to commands
 - Asleep; brisk response to light glabellar tap or loud noise
 - Asleep; sluggish response to light glabellar tap or loud noise
 - Stimulus but does not respond to painful stimulus

- Asleep; no response to light glabellar tap or loud noise 10. Assessment of pain was evaluated using 10 cm visual analog scale (VAS) advocated by revill and robinson in 1976 '0' represents no pain and VAS score >4 considered to be the time for request first rescue analgesia. Below is the pictorial depiction of vas score 0

Statistical Analysis:

All recorded data were entered using MS Excel software and analyzed using SPSS version-21 software for determining the statistical significance. All data were presented in terms of Mean $\pm$ SD and in percentage. The tests employed were unpaired t test and chi-square test. P value taken for significance is 0.05.

$p > 0.05$ – Statistically Not Significant (NS) $p < 0.05$ – Statistically Significant (S)

RESULTS AND OBSERVATIONS :

Demographic variables including age, sex, height, weight, ASA physical status, mean duration of surgery, type of surgery were comparable in both groups and were statistically not significant ($p > 0.05$). (TABLE-1)

Mean Onset time, Mean duration of action, intubating conditions, haemodynamic effects and signs of histamine release in both groups were assessed and recorded during the study.

Table-1: Demographic Profiles Of Study Population

1.	Group			p value
	Group A IV	Group B IT	Total	
Age				0.445
11-20	6	7	13	
20-30	15	7	22	
30-40	10	11	21	
40-50	7	8	15	
50-60	5	10	15	
60-70	2	2	4	
Total	45	45	90	

Table no 1 shows age distribution in each group all students participating were in age 20 to 60. On statistical analysis comparing using unpaired t test p value was > 0.005 . hence two groups were comparable and non significant.

The demographic variables were compared between the Group-A and Group-B and it was found that there was no significant differences between the two groups with respect to age, sex, height, weight, ASA physical status and duration of surgery.

variable	Nof patients	mean	SD	Pvalue 0.3476
Group A (iv)	45	112.89	16.35	
Group B (it 0)	45	111.67	12.92	

Table no shows distribution of duration of operation in mins between two groups. On statistical comparison using unpaired t test p value was found to be > 0.05 . hence comparable and non significant

Table no 3 distribution of patient in groups according to ASA physical status I and 2

ASA	Group			p value
	Group A (IV)	Group B (IT)	Total	
I	15	17	32	0.66
II	30	28	58	
Total	45	45	90	

Table no 3 shows distribution of patient in groups according to ASA I and 2. on statistical comparison using chi square test, p value was found to be > 0.66 . hence the groups were comparable and nonsignificant

1. Table no 3 shows distribution of BMI between two group

able shows distribution of bmi between two groups. On statistical comparison, using unpaired student t test, p value was found to be more > 0.005 . hence two groups were comparable and non significant

On comparing the spinal block characteristics among the two groups it was noticed after applying unpaired t test there was significant difference in two segment regression, tmms duration of motor block and tmms for duration of sensory block with $p < 0.001$. duration of motor block and duration of sensory block was prolonged in group B

(it) than group A (IV) However sensory onset and motor onset in both groups was non significant and comparable $p > 0.001$

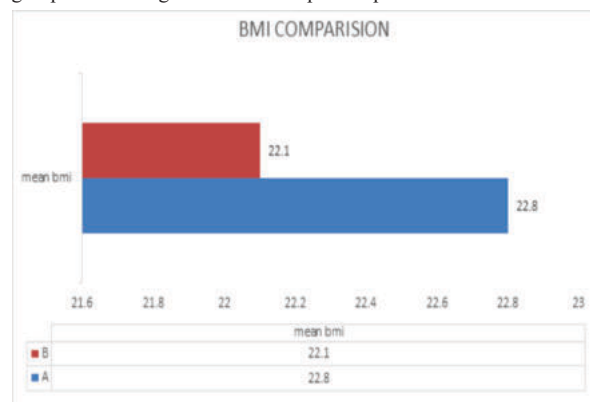


Table no comparison of subarchnoid block characteristics between two groups

variable	No of patients	Mean bmi	Standard deviation	P value
Group A iv	45	22.8	1.1	0.391
Group B it	45	22.7	1.3	

Variables	Group A (IV)	Group B(it)	P value
TMINS SENSORY ONSET AT TIO IN MINS	2.8+/-1.04	2.78+/-1.014	0.917
Tmins onset of motor block in mins	7.853+/-0.6384	7.8+/-0.4961	0.927
Tmins for two segment regression	139.58+/-0.63	171.56+/-5.763	<0.001
Tmins duration of motor blockade in mins	196.53+/-6.3	418+/-9.6	<0.001
Tmins time for sensory blockade in mins	342.69+/-5.6	450.11+/-6.11	<0.001

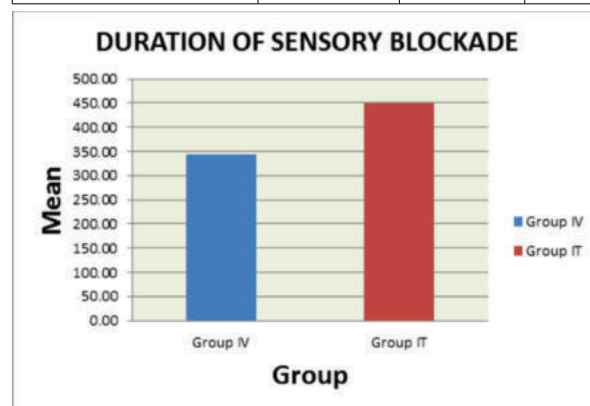


Figure shows graphical representation of sensory block

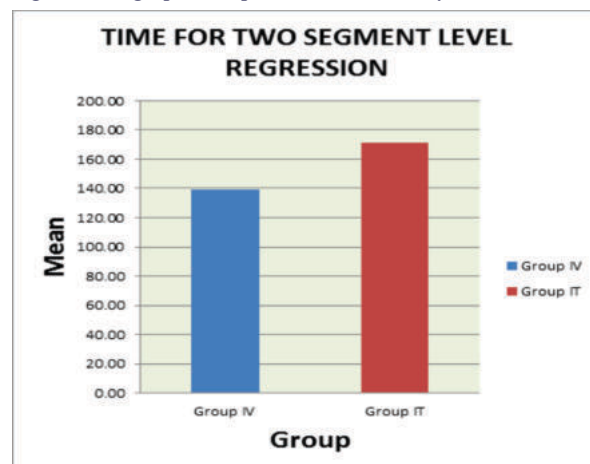
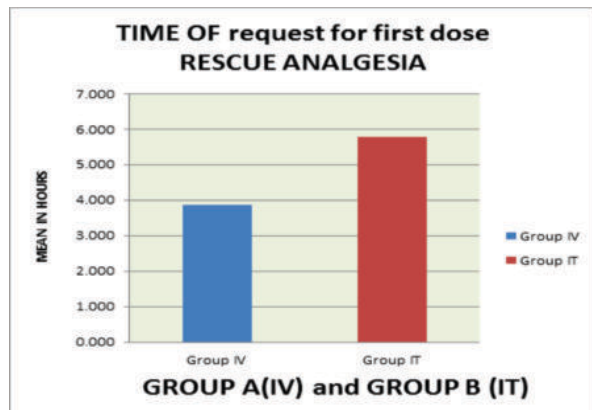


Figure shows time for two segment regression

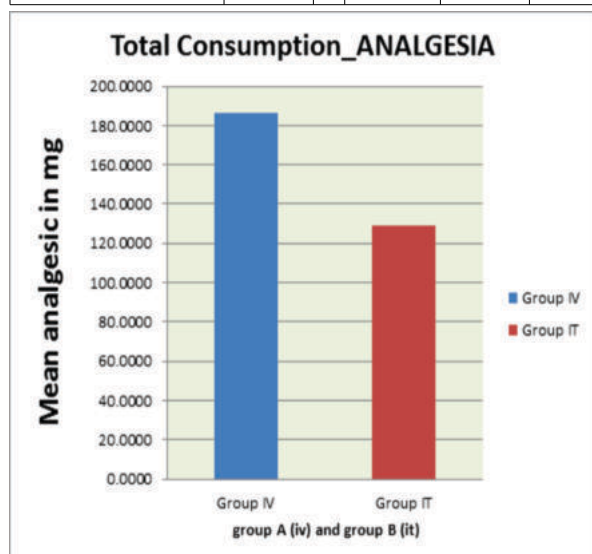
Table no comparison of time for first dose of rescue analgesia

		N	Mean	SD	p value
THOURS_TIME OF request for first dose RESCUE ANALGESIA IN HOURS	Group A IV	45	3.869	.3860	<0.001
	Group B IT	45	5.769	1.1841	

The mean time for the first dose of rescue analgesia was significantly longer in group IT as compared to I.V

**Table no; total dose of analgesic consumption over 24 hours (DICLOFENAC IN mg**

		N	Mean(mg)	SD	p value
total consumption_ analgesic (DICLOFENAC IN MG)	Group A IV	45	186.2222	16.92750	<0.001
	Group B IT	45	129.1667	32.53058	
total consumption of analgesia was significantly higher in group IV than group IT with p value >0.001					

**Figure graphical representation of total dose analgesia consumption****Comparison of systolysic bp between group A it and group B Iv**

	Group A IV	Group B IT	p value
BASELINE_SBP	117.51±6.73	118.91±6.81	0.329
5 Mins_SBP	97.49±7.92	97.13±6.73	0.819
10 Mins_SBP	94.69±6.95	94.91±5.53	0.867
15 Mins_SBP	107.44±9.63	105±10.57	0.255
30 Mins_SBP	108.93±7.57	107.29±7.67	0.309
45 Mins_SBP	110.09±7.65	111±7.82	0.578
60 Mins_SBP	112.27±8.41	112.8±9.66	0.781

90 Mins_SBP	118.96±9.53	117.31±12.34	0.481
120 Mins_SBP	124.58±7.42	124.16±8.19	0.798

No significant changes were noted between systolic bp between group AIV and group B IT as p value was more than >0.001 at 5, 10, 15, 30, 45, 60, 90, 120 mins. However we notice decrease in systolic blood pressure at 5 min and 10 mins which was due to effect of spinal anesthesia in both groups

variable	No of patients	Mean bmi	Standard deviation	P value
Group A iv	45	22.8	1.1	0.391
Group B it	45	22.7	1.3	