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A Comparative Study Between Dexmedetomidine As An Adjunct To Bupivacine In Comparison To Bupivacine Alone In Haemodynamic Stability

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Abstract: *Spinal anaesthesia is one of the most common procedure used in clinical anaesthesia practice. It has the advantage that profound nerve block can be produced in a large part of the body by the relatively simple injection of a small amount of local anaesthetic.Hypotension is one of the most common event encountered with the procedure Hypotension and bradycardia during spinal anesthesia are common and may relate to severe adverse events such as cardiac arrest or death. Preventive measures include fluid preload, lateral tilt, and use of vasopressors. Search is still on for the pharmacological agents that can provide hemodynamic stability with neuraxial blockade.*

I. Objective

The prolongation of spinal anesthesia by using opioids and α2 agonist like Clonidine through the oral,intravenous and spinal route has been known. The new α2 agonist, dexmedetomidine has also been proved to prolong the spinal anesthesia through the intrathecal route.The aim of the study is to compare dexmedetomidine as an adjunct to bupivacaine in comparison to bupivacine alone & its effect on various haemodynamic factors.

Methods

Fourty six patients of ASA grade I and II between 18-58yrs of age of either sex, admitted in RIMS,RANCHI (Jharkhand), scheduled for elective lower abdominal & lower limb surgical procedure were included The study protocol was approved by Institutional Ethical Committee and written informed consent was obtained from all patients.

The pre-anaesthetic check-up included a detailed medical and surgical history, and any previous anaesthetic exposure with its outcome. General examination includes general condition, built, weight, pulse rate, blood pressure, respiratory rate, and presence of cyanosis, anaemia, clubbing, jaundice or edema. A careful thorough systemic examination was done to rule out any cardiovascular, respiratory, gastrointestinal and neurological or any other systemic illness.Routine biochemistry investigation included haemoglobin, total leucocyte count, differential leucocyte count, blood sugar, blood urea, and serum creatinine, were done in all patients. ECG and X-Ray Chest were done in patients where indicated and in those over 40 years of age along with other relevant investigation.

After taking detailed history and thorough clinical examination, the patients were excluded from the study on the basis of below mentioned criteria:

Patients with systemic hypertension, hepatic dysfunction, renal dysfunction, endocrine dysfunction, cardiac dysfunction, morbid obesity (body weight more than 20% of the ideal body weight),Other exclusion criteria were patients with known drug hypersensitivity, those on antihypertensive medication or antidepressant drugs and those who refused to give consent.

- ***Inclusions***
  - ASA I & II
  - 18-58 yrs of age of either sex
  - Scheduled for elective lower abdominal & lower limb surgical procedure
- ***Exclusions***
  - Contraindications to spinal anesthesia
  - Allergy to local anesthetics
  - Systemic hypertension
  - Hepatic, renal, endocrine, cardiac dysfunction
  - Morbid obesity (body weight more than 20% of the ideal body weight
  - Patients on antihypertensive medication or antidepressant drugs
  - Patients who refused to give consent.

Patients using 2-adrenergic receptors antagonists, calcium channel blockers, angiotensin converting enzyme inhibitors, or noted to have dysrhythmias on the electrocardiogram(ECG), a body weight of more than 120 kg, or height less than 150 cm were excluded from the study. Standard monitoring was used, including non-invasive arterial blood pressure, ECG, heart rate (HR) and pulseoximetry (Spo2).

The total 46 patients were randomly divided into two groups of 23 patients each according to a computer generated random table. Group B (n=80) patients received 15mg of bupivacaine & 1 ml of NS and Group D (n=80) patients received bupivacane 15mg & 10 µg. Group allocation was done by an assistant who was unaware of the study protocol and was not involved in the study.

- The total 46 patients were randomly divided into two groups of 23 patients each.
    - **Group B – inj 0.5 % hyperbaric bupivacaine 15mg + 1ml of NS**
    - **Group D – inj 0.5 % hyperbaric bupivacaine 15mg + 1 ml of Dexmedetomidine (10µg), diluted with NS**

Total volume of Drug was 4 ml in both the groups.

Anaesthetic technique

Patients were premedicated with tab. alprazolam 0.25 mg and tab. Ranitidine 150 mg the night before the surgery. All patients were kept fasting for 8 hours prior to surgery.

On arrival to operation theatre routine monitoring was started and base line vital parameters of heart rate, systemic arterial pressure including systolic, diastolic and mean arterial pressure, arterial oxygen saturation (SpO2), and ECG were recorded. An intravenous line was secured and Ringer lactate was given at rate of 6-8 ml/kg. All patients received premedication of intravenous Inj. Midazolam (0.02mg/kg) and inj. glycopyrrolate (0.01mg/kg)..

After preparation with the patient in sitting position spinal anaesthesia was performed at L3-L4 level through a midline approach with quincke needle. Study group B patients were given bupivacaine 15mg & 1ml of NS (total volume 4 ml) and group D bupivacaine 15mg & 10 µg dexmedetomidine(total volume 4 ml). Study medication was prepared by an anaesthesiologist who was blinded to the randomization schedule.the anaesthesiologist performing block recorded baseline vitals preoperatively,every 3 min for first 15 min,then every 5 min until patient discharged from PACU.sensory dermatome was assessed by pinprick & motor by modified bromage score

II. Bromage Scale For Motor Blockade

I	Free movement of hips, legs and feet
II	Just able to flex knees with free movement of feet
III	Unable to flex knees, but with free movement of feet
IV	Unable to move hips or legs or feet

The Hemodynamic changes observed as abnormal findings during the study were defined as follows :

- Hypotension was defined as SBP < 20% of baseline value or < 90 mm Hg, whichever was lower.
- Hypertension was defined as SBP > 20% of baseline value or > 140 mm Hg whichever was higher.
- Tachycardia was defined as heart rate >100/minute.
- Bradycardia was defined as heart rate < 50/minute

After completion of surgery patients transferred to post anaesthesia care unit and monitored for any hemodynamic changes or any other adverse effects.

III. Results

- The data recorded in tabulated manner and was analyzed using Microsoft Excel and SPSS software version 16.0 for windows.
- Statistical analysis done using independent student ‘t’ test for parametric data and Chi square test for nonparametric variables.
- A ‘p’ value of less than 0.05 was considered statistically significant.

Out of 46 patients one patient from group B & two from group D were considered as failure.43 patients completed study protocol and included in data.the onset of block & duration is given in Table 1.The various vitals monitoring before during and after procedure are arranged in table2.

Table 1.

	Group b(n=21)	Group D(n=22)
Gender		
Male	12	14
Female	9	8
Surgery		
Abdominal & vaginal hystrectomy	8	6
Appendicitis	5	8
Hernia	7	2
Turp	1	4
Skin grafting	0	2

Demographic parameters

	Group D (n= 23)	Group B (n= 23)	p value
Age (yrs)	32.54±10.73	34.07±12.03	0.39
Sex (M/F)	10/13	11 / 12	0.273
Ht (cm)	149.73 ± 4.76	149.03 ± 5.77	0.61
Wt (Kg)	55.8 ±8.41	53.6 ±9.44	0.28
ASA grade I/II	19 / 4	21 / 2	0.198

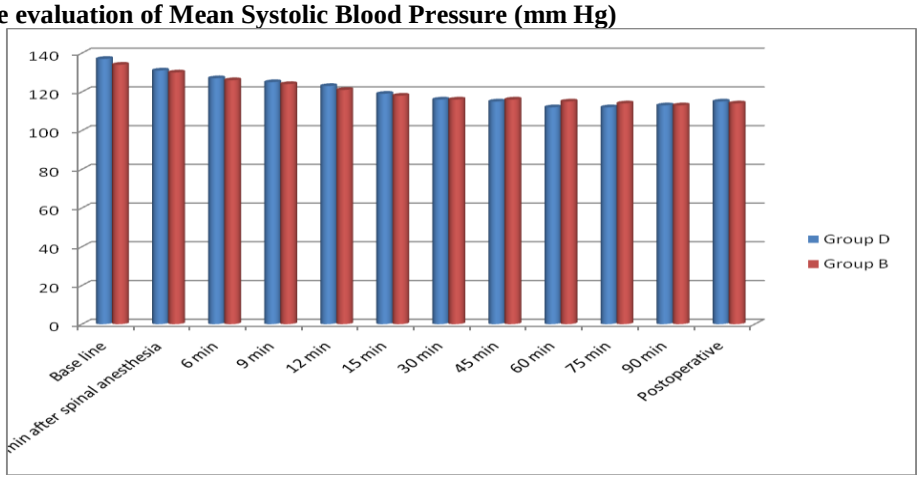
Various surgical interventions done in patients in both groups

Surgery	Group D	Group B
Appendectomy	4	2
Hernia	8	9
Hysterectomy	7	7
DHS fixation	2	3
Skin grafting	0	1
Turp	2	1

Comparative evaluation of Mean Systolic Blood Pressure (mm Hg)

Time interval in min	Group D	Group B	Pvalue
Base line	137.19± 13.18	134.79 ± 14.62	0.14
3 min after spinal anesthesia	131.06 ± 13.09	130.56 ± 13.07	0.40
6 min	127.80 ± 13.74	126.34 ± 12.25	0.24
9 min	125.98 ± 15.79	124.66 ± 19.44	0.33
12 min	123.22 ± 14.78	121.52 ± 13.49	0.22
15 min	119.32 ±15.72	118.92 ± 12.60	0.09
30 min	116.21 ± 12.40	116.43 ± 12.20	0.40
45 min	115.68 ± 10.94	116.10 ± 10.45	0.08
60 min	112.80 ± 10.40	115.16 ± 10.70	0.16
75 min	112.78 ± 10.01	114.39 ± 10.35	0.40
90 min	113.65 ± 7.71	113.34 ± 8.14	0.30
Postop erative	115 ± 7.64	114.39 ± 7.34	0.45

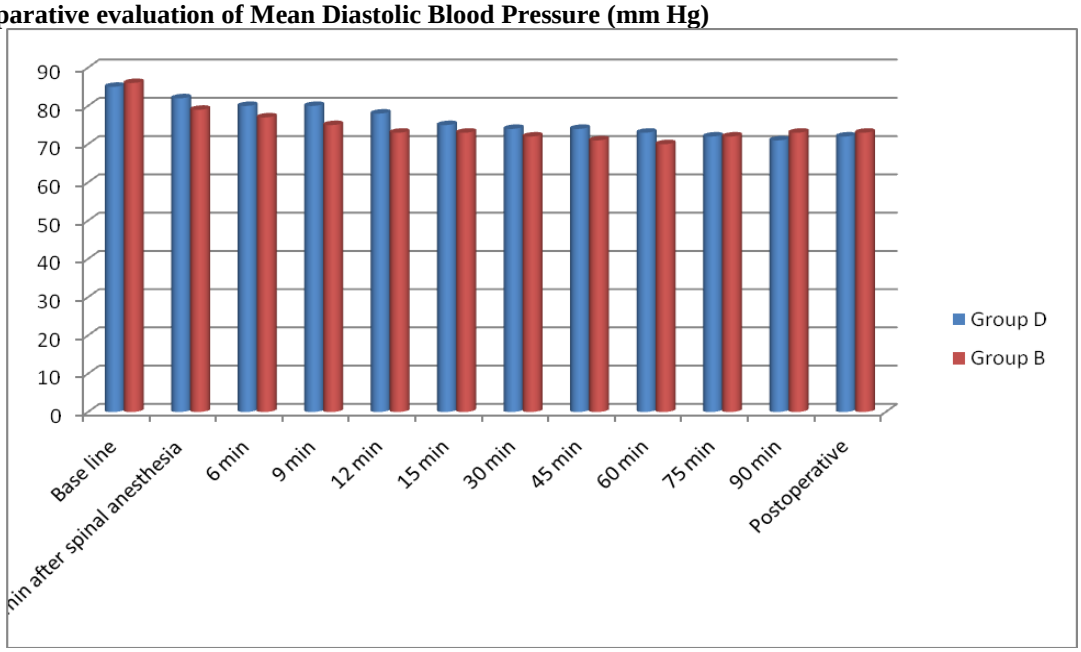
Comparative evaluation of Mean Systolic Blood Pressure (mm Hg)



Comparative evaluation of Mean Diastolic Blood Pressure (mm Hg)

Time interval in min	Group D	Group B	P-value
Base line	85.85 ± 9.07	86.08 ± 9.99	0.43
3 min after spinal anesthesia	82.59 ± 7.86	79.61 ± 9.40	0.01*
6 min	80.93 ± 7.78	77.26± 10.33	0.006**
9 min	80.21 ± 8.18	75.38± 9.68	0.0005**
12 min	78.52 ± 8.21	73.61 ± 9.15	0.0003**
15 min	75.69 ± 10.89	73.28 ± 8.38	0.04 *
30 min	74.57 ± 8.29	72.43 ± 8.47	0.05*
45 min	74.52 ± 8.59	71.33 ± 8.32	0.01*
60 min	73.44 ±7.59	70.53 ± 6.98	0.007**
75 min	72.88 ± 6.95	72.67 ± 6.96	0.42
90 min	71.86 ± 6.77	73.05 ± 6.37	0.13
Postoperative	72.48 ± 6.52	73.64 ± 6.47	0.13

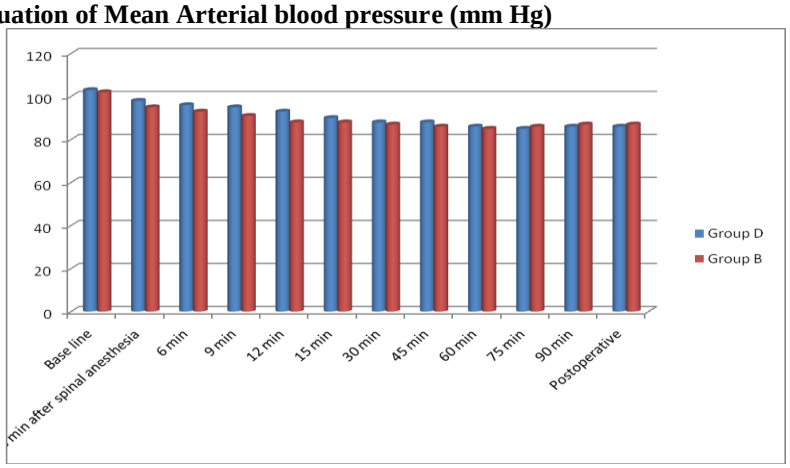
Comparative evaluation of Mean Diastolic Blood Pressure (mm Hg)



Comparative evaluation of Mean Arterial blood pressure (mm Hg)

Time interval in min	Group D	Group B	P -value
Base line	103.02 ± 9.49	102.11 ± 10.55	0.28
3 min after spinal anesthesia	98.86 ± 8.88	95.82 ± 9.59	0.024*
6 min	96.56 ± 9.25	93.23 ± 9.63	0.01*
9 min	95.47 ± 9.86	91.30 ± 9.93	0.07
12 min	93.40 ± 9.72	88.58 ± 9.52	0.001**
15 min	90.26 ± 12.00	88.14 ± 8.75	0.10
30 min	88.51 ± 9.05	87.62 ± 9.10	0.27
45 min	88.30 ± 8.74	86.93 ± 8.68	0.16
60 min	86.42± 7.89	85.25 ± 7.18	0.47
75 min	85.81 ± 5.97	86.33 ± 7.49	0.25
Postoperative	86.5 ± 5.61	87.17 ±5.55	0.22

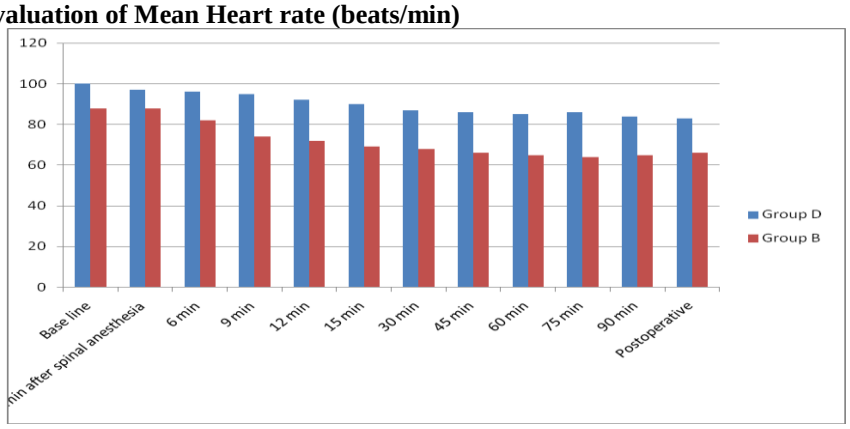
Comparative evaluation of Mean Arterial blood pressure (mm Hg)



Comparative evaluation of Mean Heart rate (beats/min)

Time interval in min	**Group D**	**Group B**	**P -value**
Base line	100.55 ± 11.47	88.03 ± 11.57	1.0
1 min after spinal anesthesia	97.98 ± 10.05	88.08 ± 11.06	1.0
3 min	96.60 ± 9.17	82.87 ± 11.74	0.17
5 min	95.06 ± 10.02	74.67 ± 10.51	0.0**
10 min	92.68 ± 9.53	72.29 ± 10.69	0.0**
15 min	90.23 ± 12.08	69.21 ± 9.41	0.0**
30 min	87.68 ± 8.91	68.61 ± 10.02	0.0**
45 min	86.98 ± 8.79	66.70 ± 9.09	0.0**
60 min	85.48 ± 8.30	65.92 ± 8.06	0.0**
75 min	86 ± 8.59	64.91 ± 7.41	0.0**
90 min	84.05 ± 6.07	65.34 ±7.06	0.0**
Postoperative	83.67±5.44	66.38 ± 5.94	0.0**

Comparative evaluation of Mean Heart rate (beats/min)



Intra-operative and postoperative adverse events

	Group D	**Group B**
Adverse Events	No. of patient	No. of patient
Hypotension	2	8
Bradycardia	1	3
Shivering	1	5
Headache	0	0
Nausea	0	2

IV. Conclusion

- Dexmedetomidine when used as an adjunct to bupivacaine in spinal anaesthesia helped in keeping the patient hemodynamically stable throughout the surgery.
- Intrathecal dexmedetomidine did not potentiate the effect of bupivacaine on blood pressure. This may be explained by the mechanism local anaesthetics affect blood pressure. Local anaesthetics reduce blood pressure by decreasing sympathetic outflow. Sympathetic blockade produced by intrathecal dexmedetomidine does not decrease blood pressure further presumably because the blockade produced by bupivacaine is nearly maximum.
- The intrathecal use of dexmedetomidine is off label. Highest dose of intrathecal dexmedetomidine used in animal studies was 100 µg .Konakci and colleagues reported white matter injury in rats when high dose epidural dexmedetomidine (6 µg/kg) was used alone; however,
- subsequently Brummett and co-workers demonstrated no injury and a protective effect when doses of 26-40 µg/kg were used perineurally.
- In humans the largest epidural dose used was 2µg/kg (and the largest intrathecal dose used was 10 µg .
- Although no major neurological complications have been reported so far, larger studies are required to rule out any short term or long term adverse effects.

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