

Comparison of Haemodynamic and Analgesic Effects of 0.5% Hyperbaric Bupivacaine and 0.5% Hyperbaric Bupivacaine with Different Doses of Clonidine under Spinal Anaesthesia

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ABSTRACT

Background: Alpha 2 agonists such as clonidine have been used neuroaxially as local anaesthetic adjuvant to enhance perioperative analgesia. This study compared three different combinations of the clonidine with bupivacaine and bupivacaine alone.

Material and Methods: A total of 60 patients scheduled for surgery under spinal anaesthesia were randomly allocated into 4 groups (n=15 each) to receive intrathecal bupivacaine 15 mg [Control group (group 1)], bupivacaine 15 mg + clonidine 0.5 mcg/kg (group II), bupivacaine 15 mg + .75 mcg/kg clonidine (group III), bupivacaine 15 mg + 1mcg/kg clonidine (group IV). Heart rate, SBP, DBP, MAP, oxygen saturation were monitored. The level of the sensory block recorded every 5th min till 20th min with level achieved at 20th min was considered as highest dermatome level achieved, time to onset of different grades of motor block, time to complete motor block, recovery and duration of spinal analgesia were recorded. p value <0.05 considered significant.

Results: Demographic data and duration of surgery were comparable amongst the groups. On haemodynamical comparison there was highly significant fall in heart rate, systolic and diastolic in group II,III,IV as compared to I. There was no incidence of bradycardia in group I whereas there were 2, 4 and 11 cases in group II,III,IV respectively. Similarly there was no hypotension in group I whereas there were 2, 5 and 11 cases in group II,III,IV respectively. On statistical analysis the level of sensory block was comparable at 5 min and highly significant at 10, 15, 20 mins in group II,III,IV as compared to I.

The attainment of the different grades of motor block (modified bromage scale) at 5, 10, 15, 20 min interval was comparable amongst all groups. The duration of analgesia was highly significant when analysed statistically (p=0.000) in group II,III,IV as compared to I.

Conclusion: In conclusion our study demonstrates that addition of 0.75 µg/Kg of clonidine to intrathecal bupivacaine is safe as compared to 1.0 µg/Kg. By using small dose of intrathecal clonidine side effects were not increased whereas intrathecal clonidine at the usual dose of 1µg/kg is associated with bradycardia and relative hypotension. So, 0.75 µg/Kg of clonidine is the preferred dose for addition to 0.5% hyperbaric bupivacaine in patients undergoing gynaecological and lower abdominal surgeries.


Keywords: Intrathecal Clonidine, Spinal Adjuvants.

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INTRODUCTION

A number of drugs e.g. opioids, benzodiazepines, neostigmine and ketamine have been used intrathecally as an adjuvant to local anaesthetics.¹

Clonidine is of interest because it preserves cardiovascular reflexes, provides sedation, greater intra operative haemodynamic stability and a reduction in anaesthetic and postoperative analgesics requirements and also has a marked opioid sparing

effect, further intrathecal clonidine also prolongs the duration of hyperbaric bupivacaine spinal block.^{2,3} The present study was done to assess the haemodynamic response and post-operative analgesia provided by low dose (0.5, 0.75, 1.0µg/kg body weight) intrathecal clonidine admixed with 0.5% hyperbaric bupivacaine as compared to 0.5% hyperbaric bupivacaine alone in patients undergoing gynaecological and other lower abdominal surgeries.

MATERIAL AND METHODS

After institutional ethics committee approval and written informed consent 60 adult patients, ASA grade I and II scheduled for gynaecological and other lower abdominal surgeries were included in the study. Exclusion criteria included any patient on alpha blocker, contraindication to regional anaesthesia, history of significant coexisting disease like ischemic heart disease, hepatic or renal disease, hypertension, diabetes mellitus, neuropathies, rheumatoid arthritis, spinal deformity like kyphoscoliosis, history of allergy to local anaesthetics and morbidly obese patients. A detailed pre anaesthetic check-up was conducted one day prior to surgery. Patients were instructed about the use of VAS preoperatively as a tool for measuring postoperative pain. Investigations such as complete haemogram, urine routine, renal function tests, random blood sugar, chest X-Ray, ECG were done prior to surgery. Patients were allowed light meals 6 hrs before surgery. All patients were premedicated with tablet ranitidine 150 mg and tablet alprazolam 0.5 mg a night prior to surgery and 2 hr before surgery. After shifting the patient to operation theatre monitoring of ECG, NIBP, and SpO₂ was established and documented. All patients were preloaded with 20 ml/kg of Ringer lactate over 15 -20 mins. Patients were assigned to one of the 4 groups randomly. A midline lumbar puncture was performed with 25 G quincke's needle at L3 – L4 interspace with patient in lateral

decubitus position under complete aseptic precautions. After ensuring free flow of CSF patients intrathecal drugs were given as:

Group I (n=15): Patients received 15 mg of 0.5% bupivacaine heavy intrathecally.

Group II (n=15): Patients received 15 mg of 0.5% bupivacaine heavy and 0.5 µg/kg of clonidine intrathecally

Group III (n=15): Patients received 15 mg of 0.5% bupivacaine heavy and 0.75 µg/kg of clonidine intrathecally

Group IV (n=15): Patients received 15 mg of 0.5% bupivacaine heavy and 1.0 µg/kg of clonidine intrathecally

The total volume of drug was made to 3.5 ml using saline in all the groups if required. Immediately after injecting the drug the patients were turned supine for surgery.

Intraoperative monitoring

Systolic, diastolic blood pressure and pulse rate were recorded every 5 mins till 30 mins after giving sub-arachnoid block and then every 15 mins till the end of surgery. The level of the sensory block recorded every 5th min till 20th min with level achieved at 20th min was considered as highest dermatome level achieved, Time of onset of different grades of motor block using modified Bromage scale⁴ in 5 mins, 10 mins, 15 mins and 20 mins were recorded.

Grade	Criteria	Degree of block
I	Free movement of legs and feet	Nil
II	Just able to flex knees with free movement of feet	Partial
III	Unable to flex knees, but with free movement of feet	Almost complete
IV	Unable to move legs or feet	Complete

Duration of spinal analgesia as determined by the time elapsed before the first supplemental analgesic request by the patient was recorded. Onset time of analgesia was taken as time from injection of drug up to feeling of warmth. At the end of procedure patients were shifted to PACU where monitoring was continued. All patients were observed in the post anaesthesia recovery room and then in the ward. Severity of pain was measured using a 10 cm visual analogue scale (VAS) at hourly interval for first 6 hrs and 2 hourly till 24 hrs. The pain free post-operative period was observed and recorded and rescue analgesia was provided by diclofenac sodium 75 mg intramuscularly. The study was completed once the rescue analgesia was given to the patients

Statistical Analysis: The relevant data on each patient was entered into the proforma and compiled and analyzed statistically with one way ANOVA test, independent samples t-test and chi-square test. $p > 0.05$ was considered not significant, $p < 0.05$ was considered significant and $p < 0.01$ was highly significant.

RESULTS

Age, Weight, Sex, Duration of surgery were comparable amongst all the groups.

On comparison of baseline heart rate amongst all the groups p value is non-significant and decrease in heart rate was significant ($p < 0.05$) in group II as compared to group I from 15th minute to 30th minute interval, was highly significant ($p < 0.01$) in group III as compared to group I from 15th minute to 180th minute interval, rate was highly significant ($p < 0.01$) in group IV as compared to group I from 5th minute to 180th minute interval, was highly significant ($p < 0.01$) in group III as compared to group II from 25th minute to 180th minute interval, decrease in heart rate was significant ($p < 0.05$) in group IV as compared to group II from 5th minute to 45th minute interval, was highly significant ($p < 0.01$) in group IV as compared to group II from 60th to 180th minute interval and was non-significant ($p > 0.05$) in group IV as compared to group III from 5th to 180th minute interval except at 10th, 15th, 20th.

Table 1: Demographic Characteristics

	GROUP I	GROUP II	GROUP III	GROUP IV
Age	41.73±11.16	40.73± 7.27	39.27± 10.09	39.67± 11.39
Weight	55.67± 4.95	57.33± 4.58	53.33± 4.88	56.00 ±5.07
Sex(M/F)	2/13	4/11	3/12	4/11
Duration Of Surgery	130.00±40.75	130.00±40.75	121.00±44.09	127.00±47.73

Table 2: Heart Rate (HR) recorded at different time intervals after spinal anaesthesia (bpm, mean ± S.D)

Duration (min)	Mean±S.D.			
	Group I (n=15)	Group II (n=15)	Group III (n=15)	Group IV (n=15)
HRBL	85.47± 4.87	83.73± 7.67	81.6± 4.61	82.13± 3.89
HR 5	77.47± 6.65	76.27±5.60	72.27± 7.48	70±6.19
HR10	76.8± 6.58	74.13± 8.33	71.47±6.07	62.67±7.58
HR 15	76.8± 6.45	68.8± 8.97	67.07±5.18	61.07±6.22
HR 20	76.8± 4.95	69.6± 8.85	66.27±4.17	62.67±5.38
HR 25	77.33± 4.82	71.33±7.99	64.4± 3.04	64.4±3.79
HR 30	77.73± 5.06	71.87±7.46	63.47±2.20	64.8±2.36
HR 45	77.33± 5.84	72.93±7.045	63.6±2.75	64.53±1.18
HR 60	77.6± 5.62	73.87±7.07	64.67±2.15	64.93±1.03
HR 75	78.46± 5.04	77.4±5.58	65.33±1.78	65.63±0.81
HR 90	78.5 ± 5.27	78.44±4.77	65±2.17	65.09±1.04
HR 105	78.17± 4.78	79.5±3.96	64.67±1.78	65.45±1.30
HR 120	78.5± 4.91	80.25±4.83	65.45±2.21	66.36±1.50
HR 135	76.86± 6.20	80±3.83	65.71±2.13	66.28±1.79
HR 150	76.86± 6.62	79.6±5.37	65.43±2.23	66.85±1.06
HR 165	80± 1.63	78±6	67±1.41	67.2±1.10
HR 180	81.33± 1.15	78±6	69±1.41	67.5±1.91

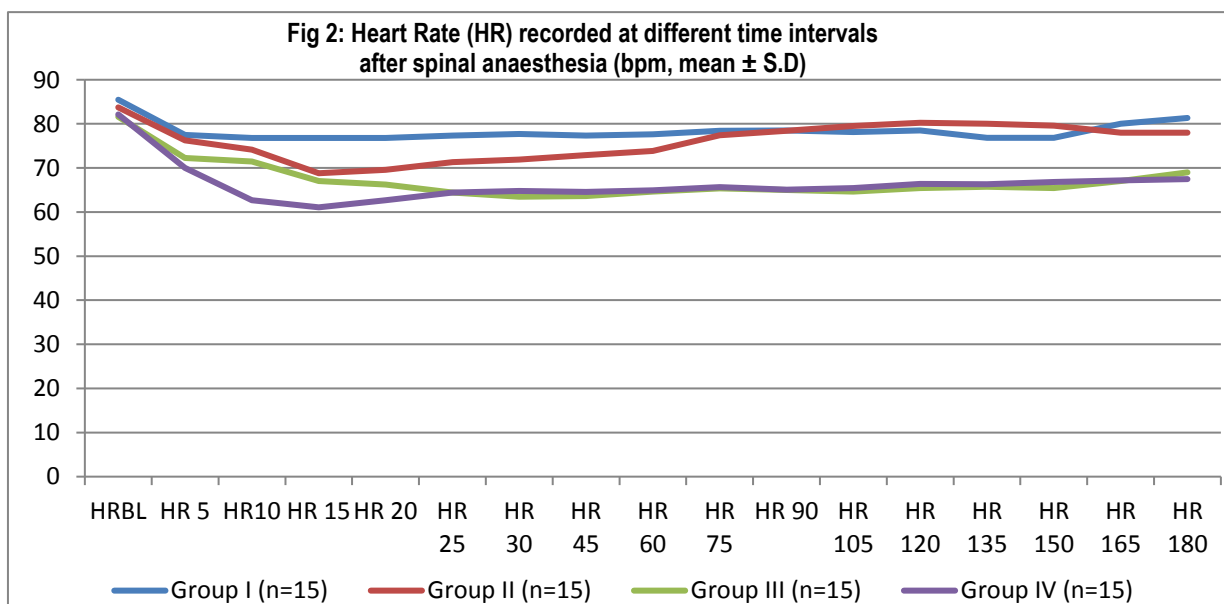
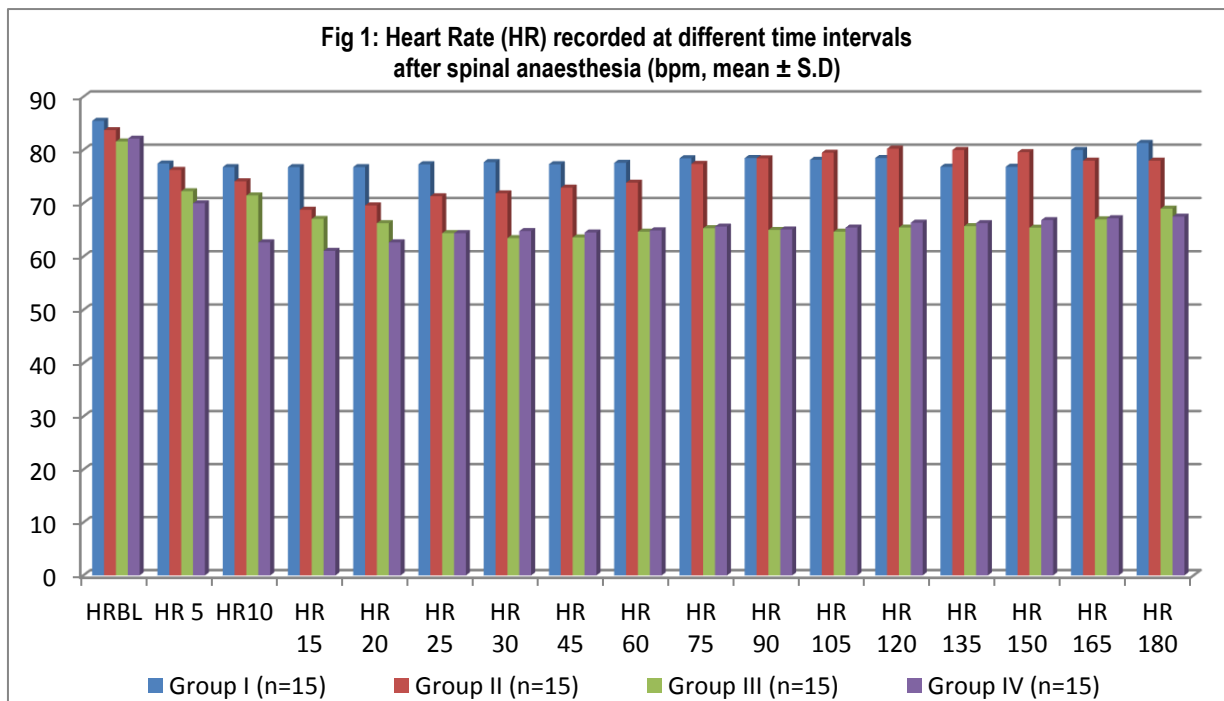


Table 3: Systolic Blood Pressure (SBP) recorded at different time intervals after spinal anaesthesia (mm of Hg, mean ± S.D)

Duration (min)	Mean ± S.D.			
	Group I (n=15)	Group II (n=15)	Group III (n=15)	Group IV (n=15)
SBP BL	123.87± 4.93	123.33± 4.88	124.267± 7.086	127.07±6.96
SBP 5	113.33± 6.17	113.33± 4.88	112± 5.61	114.27±4.77
SBP 10	109.47± 7.23	108.27± 6.36	105.6± 4.16	103.2±4.71
SBP 15	108.67± 7.32	104.53± 8.90	97.87± 6.25	98.13±6.65
SBP 20	106.93± 11.33	101.6± 8.42	94.93± 5.99	95.2±7.55
SBP 25	106.4± 9.71	97.73± 5.063	93.01± 6.31	91.73±7.74
SBP 30	106± 3.93	98.67± 4.32	93.47± 9.18	89.2±7.66
SBP 45	108.4± 1.12	99.47± 3.24	94.53± 6.61	91.73±11.85
SBP 60	112.67± 4.58	98.67± 9.93	93.10± 11.58	93.06±9.16
SBP 75	112.77± 4.94	105± 4.74	99.33± 7.10	101.09±4.84
SBP 90	113.67± 5.03	112.22± 4.06	106.17± 4.71	108.18±2.89
SBP 105	113.5± 4.60	113.75± 3.92	108.33± 4.66	109.45±1.57
SBP 120	114± 5.12	113± 4.28	108.36± 4.97	109.45±2.02
SBP 135	110.86± 1.95	113.71± 4.23	108.86± 7.73	109.43±1.51
SBP 150	112± 2.58	114.8± 4.82	109.71± 6.05	110±1.15
SBP 165	111± 1.15	112.67± 4.62	116± 11.31	111.6±3.29
SBP 180	112± 2	112.67± 4.62	116± 11.31	113±4.76

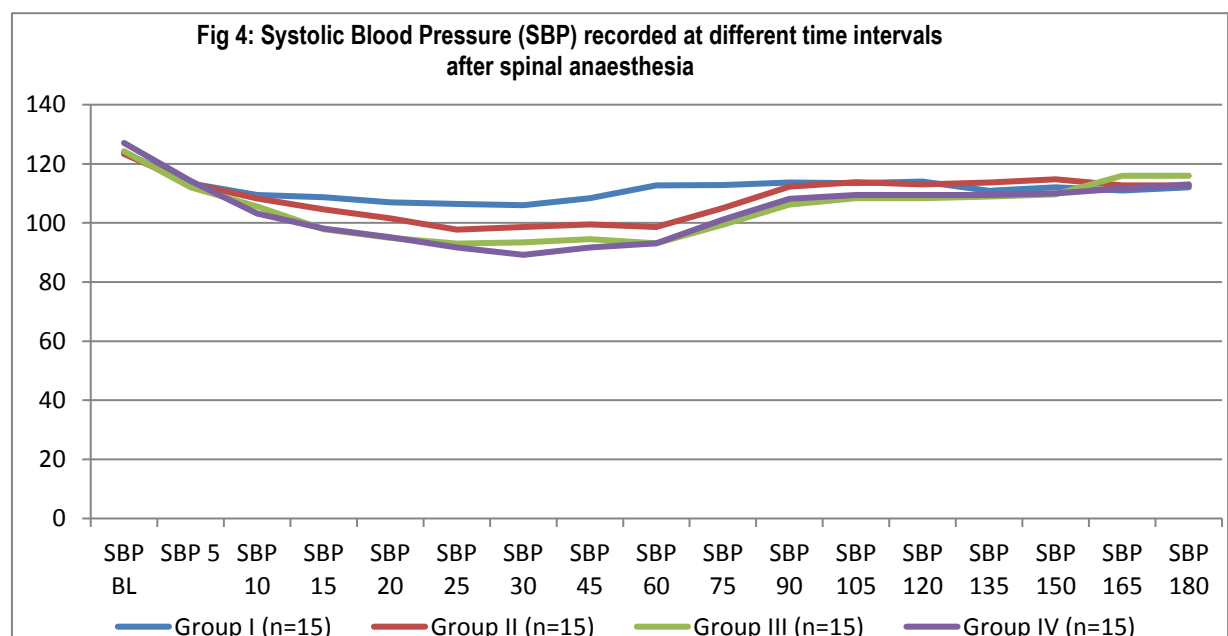
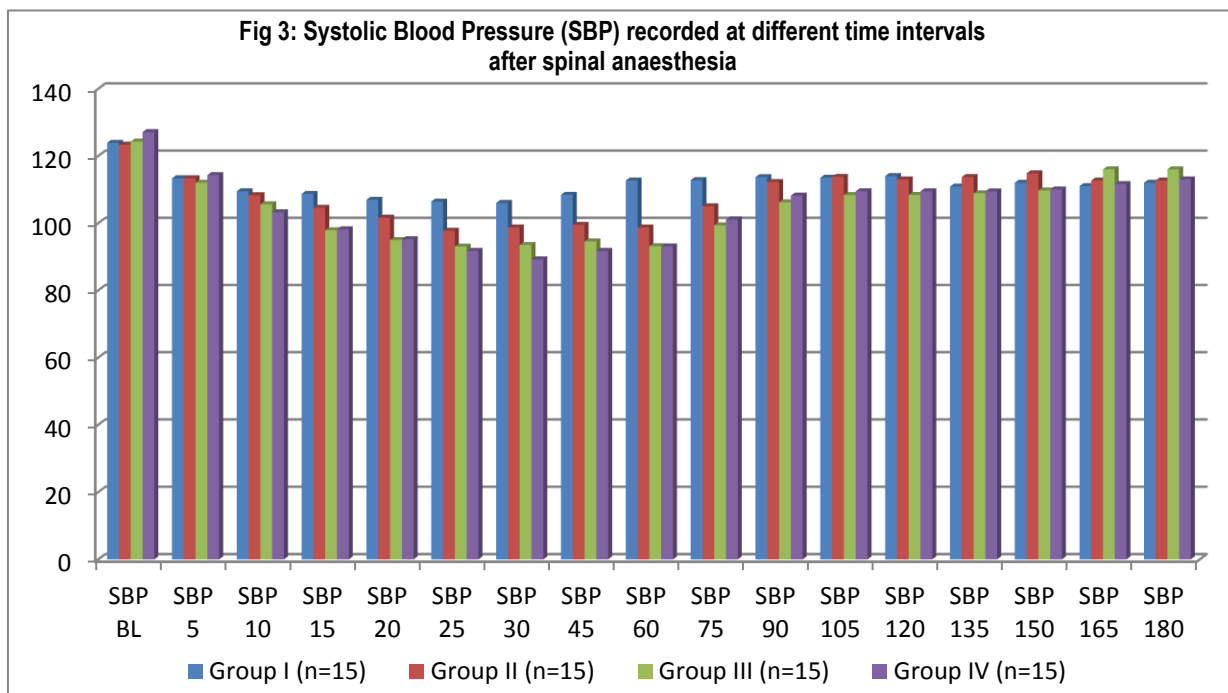
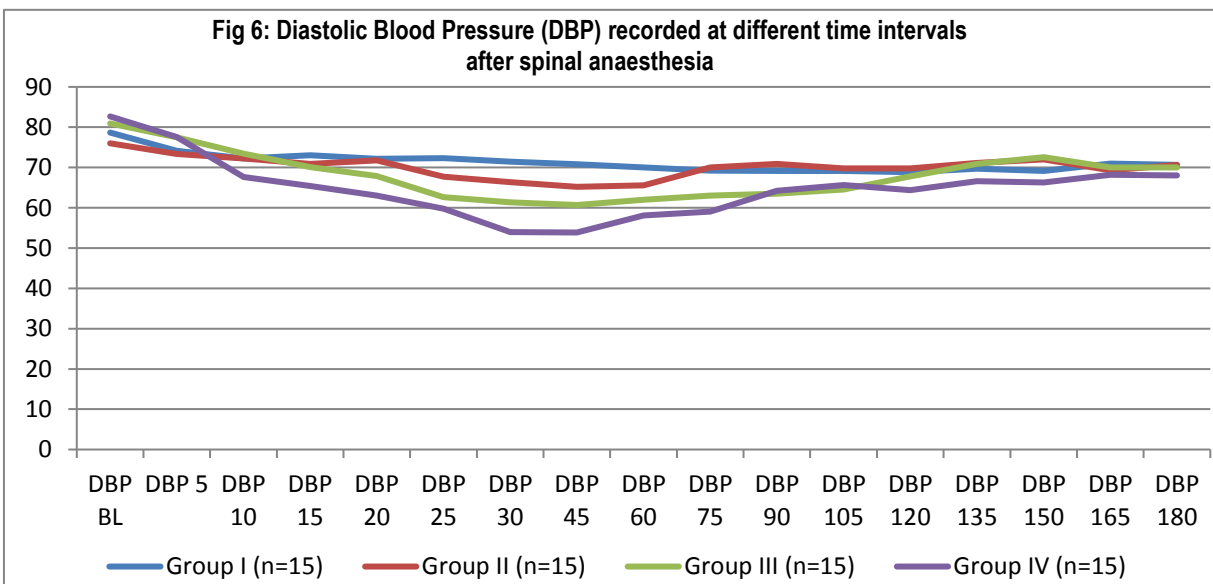
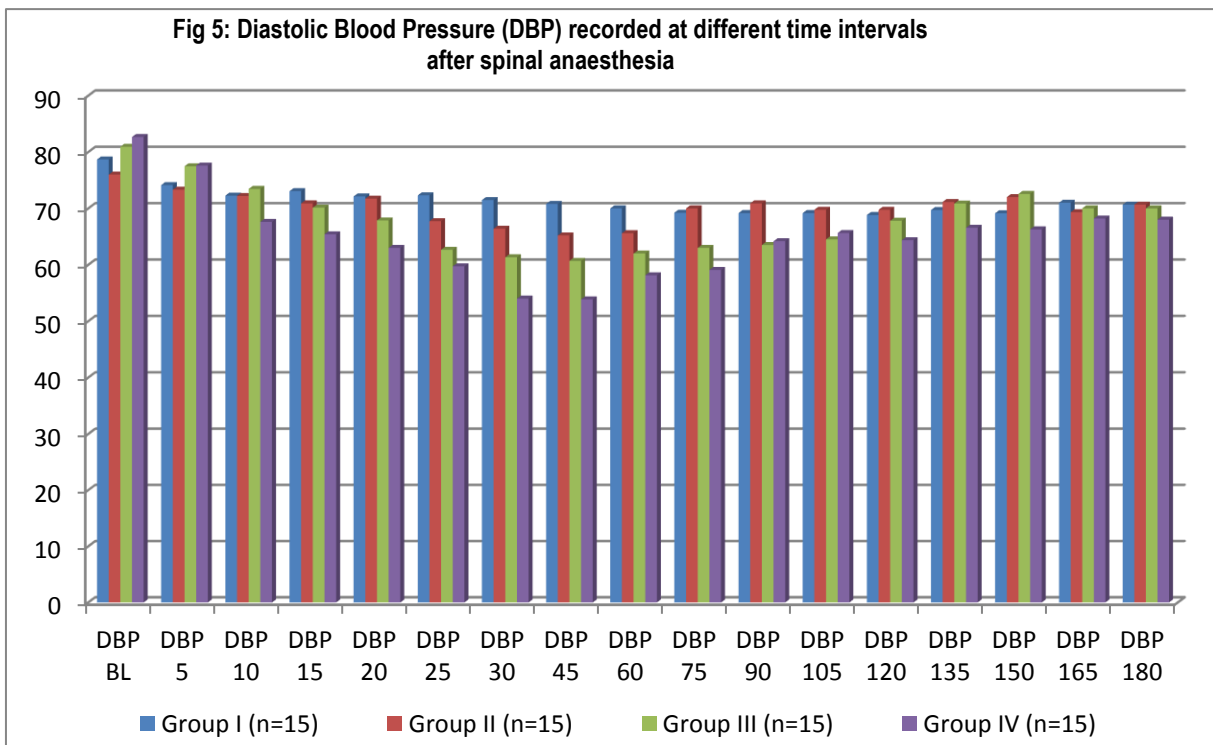


Table 4: Diastolic Blood Pressure (DBP) recorded at different time intervals after spinal anaesthesia (mm of Hg, mean \pm S.D)

Duration (min)	Mean \pm S.D.			
	Group I	Group II	Group III	Group IV
DBP BL	78.67 \pm 6.39	76 \pm 6.32	80.93 \pm 7.96	82.67 \pm 7.03
DBP 5	74.13 \pm 7.65	73.33 \pm 4.64	77.46 \pm 7.38	77.6 \pm 6.85
DBP 10	72.26 \pm 6.18	72.2 \pm 4.77	73.46 \pm 6.25	67.6 \pm 6.49
DBP 15	73.06 \pm 5.95	70.8 \pm 5.89	70.13 \pm 7.73	65.4 \pm 6.64
DBP 20	72.13 \pm 6.06	71.73 \pm 5.49	67.86 \pm 7.87	63.0 \pm 5.71
DBP 25	72.33 \pm 5.59	67.73 \pm 7.12	62.66 \pm 8.40	59.73 \pm 5.59
DBP 30	71.47 \pm 6.30	66.4 \pm 6.73	61.33 \pm 6.07	54.0 \pm 6.07
DBP 45	70.8 \pm 5.79	65.2 \pm 5.49	60.69 \pm 5.34	53.86 \pm 7.87
DBP 60	70 \pm 6.37	65.6 \pm 5.14	62 \pm 4.43	58.13 \pm 4.71
DBP 75	69.23 \pm 4.36	70 \pm 5.66	63 \pm 5.49	59.09 \pm 4.59
DBP 90	69.17 \pm 3.86	70.89 \pm 5.58	63.5 \pm 3.20	64.18 \pm 2.08
DBP 105	69.17 \pm 3.95	69.75 \pm 5.39	64.5 \pm 2.11	65.63 \pm 2.65
DBP 120	68.83 \pm 3.66	69.75 \pm 6.18	67.81 \pm 1.88	64.36 \pm 4.27
DBP 135	69.71 \pm 3.55	71.14 \pm 4.60	70.86 \pm 3.44	66.57 \pm 3.95
DBP 150	69.14 \pm 2.79	72 \pm 5.10	72.57 \pm 3.41	66.28 \pm 3.72
DBP 165	71 \pm 2.58	69.33 \pm 5.03	70 \pm 2.83	68.2 \pm 4.82
DBP 180	70.67 \pm 4.16	70.67 \pm 2.31	70 \pm 2.83	68 \pm 5.89



On comparison of baseline SBP amongst all the groups p value is non-significant whereas decrease in systolic blood pressure was highly significant ($p < 0.01$) in group II as compared to group I from 25th to 75th minute interval, was highly significant ($p < 0.01$) in group III as compared to group I from 15th to 120th minute interval, was highly significant ($p < 0.01$) in group IV as compared to group I from 10th to 120th minute interval, was significant ($p < 0.05$) in group III as compared to group I from 15th to 150th minute interval except at 90th and 105th minute interval where it was highly significant ($p < 0.01$), was significant ($p < 0.05$) in group IV as compared to group II from 10th to 150th minute interval except at 25th to 30th minute and 90th to 150th minute interval where the decrease is highly significant ($p < 0.01$), was non-significant ($p > 0.05$) in group IV as compared to group III from 5th to 180th minute interval except at 30th to 45th minute interval ($p < 0.05$).

The no. of patients with heart rate less than 60 (bradycardia) was statistically significant between group I and IV, group II and IV and group III and IV ($p < 0.05$). The no. patients having hypotension was statistically significant on comparison between group I and III, group I and IV and group II and IV.

On statistical analysis level of sensory block was comparable in all the groups at 5 mins but at 10 mins on comparing group I with group II, III and IV the difference was highly significant ($p < 0.01$).

On comparing group II with group III as well as group IV the difference was non-significant ($p > 0.05$) and comparison between group III and group IV was also non-significant ($p > 0.05$). At 15 mins on comparing group I with group II, III and IV the difference was highly significant ($p < 0.01$). On comparing group II with group III and IV the difference significant ($p < 0.05$) and comparison between group III and group IV was non-significant ($p > 0.05$). At 20 mins on comparing group I with group II, III and IV the difference was highly significant ($p < 0.01$). On comparing group II with group III and IV the difference was non-significant ($p > 0.05$) and comparison between group III and group IV was non-significant ($p > 0.05$).

At 5, 10, 15 and 20 min interval all the groups were comparable. There was no Statistical difference obtained between these groups ($p > 0.05$).

Duration of analgesia, as determined by the time elapsed before the first supplemental analgesic request by the patient, lasted for 198 ± 40.96 min, 265.16 ± 38.73 min, 334 ± 66.47 min and 351 ± 54.91 min in group I, II, III and IV respectively. It was statistically highly significant ($p < 0.01$) when group I was compared to group II, III and IV. It was also highly significant ($p < 0.01$) when group II was compared to group III and IV, but it was not significant when group III was compared to group IV ($p > 0.05$).

Table 5: Bradycardia And Hypotension

	GROUP I	GROUP II	GROUP III	GROUP IV
Bradycardia (Y/N)	0/15	2/13	4/11	11/4
Hypotension (Y/N)	0/15	2/13	5/10	11/4

Table 6: Showing Level Of Sensory Block Distribution Of Patients At 5,10,15 And 20 Minutes In Group I, II,III And IV

Time interval	Level of sensory Block	GROUPS							
		Group I		Group II		Group III		Group IV	
		No. Of cases	% within group	No. Of cases	% within group	No. Of cases	% within group	No. Of cases	% within group
5 mins	L1	2	13.33	1	6.67				
	T12	13	86.67	14	93.33	13	86.67	14	93.33
	T10					2	13.33	1	6.67
10 mins	T10	15	100	5	33.33	3	20	3	20
	T8			10	66.67	12	80	12	80
15 mins	T10	11	73.33						
	T8	3	20	12	80	3	20	4	26.67
	T7	1	6.67						
	T6			3	20	12	80	11	73.33
20 mins	T10	10	66.67						
	T8	4	26.67	7	46.67	3	20	2	13.33
	T7	1	6.66						
	T6			8	53.33	10	66.67	9	60
	T4					2	13.33	4	26.67

Table 7: Showing Level Of Motor Block Distribution Of Patients At 5 Minutes In Group I, II,III And IV (Bromage Scale)

Time interval	Level of Block	GROUPS							
		Group I		Group II		Group III		Group IV	
		No. Of cases	% within group	No. Of cases	% within group	No. Of cases	% within group	No. Of cases	% within group
5 MIN	III	3	20	2	13.33				
	IV	12	80	13	86.67	15	100	15	100
10 MIN	IV	15	100	15	100	15	100	15	100
15 MIN	IV	15	100	15	100	15	100	15	100
20 MIN	IV	15	100	15	100	15	100	15	100

Table 8: Duration Of Analgesia In Min

Group	No of patients	Mean \pm S.D.	Range
I	15	198 \pm 40.96	120-270
II	15	265 \pm 38.73	180-330
III	15	334 \pm 66.47	225-420
IV	15	351 \pm 54.91	240-420

DISCUSSION

Clonidine is known to increase both sensory and motor blockade of local anaesthetics.⁵ Intrathecal clonidine has been used as an adjuvant to local anaesthetics in various surgical procedures without any clinically significant side effects.⁶ Previous studies have described the use of clonidine in a wide range (15 μ g-150 μ g). However best regimen remains unknown.

The present study was done to assess the haemodynamic response and post-operative analgesia provided by low dose (0.5, 0.75, 1.0 μ g/kg body weight) intrathecal clonidine admixed with 0.5% hyperbaric bupivacaine as compared to 0.5% hyperbaric bupivacaine alone in patients undergoing gynaecological and other lower abdominal surgeries. Clonidine is known to exert its hemodynamic effects by acting at several sites, either in the central nervous system or in the periphery. Clonidine decreases the heart rate by a presynaptic mediated inhibition of nor- epinephrine release and by direct suppression of atrioventricular node after systemic absorption. Our findings were in consonance with the study by B.S. Sethi et al 2007 in which he observed that the decrease in mean heart rate from 45 minutes until the end of 6 hours was greater in clonidine group than in the control group ($p < 0.001$).¹

Similar results were shown by Grandhe et al 2008 in which the mean heart rate was significantly lower in clonidine group compared to control group between 105 min to 8hrs following intrathecal drug administration.⁷

It has been demonstrated that intrathecal clonidine has depressed effect on systemic blood pressure, mediated by spinal α_2 adreno receptors.

In our study the mean basal values of SBP and DBP for all the groups were statistically comparable. There was significant fall in SBP and DBP in group II, III and IV as compared to group I ($P < 0.05$). The fall in blood pressure showed a similar trend in SBP and DBP.

Similar results were shown by Kriton et al 1992 who recorded significant decrease in mean arterial pressure in the clonidine group than in the control group from 20 to 120 min. He observed that the mean arterial pressure was significantly less compared to the baseline value (89.7 \pm 16.2mmHg) between 60 and 360 min, with a maximum decrease (18.2 \pm 11.7%) recorded at 90 min. It was also observed that the diastolic arterial pressure decreased significantly after intrathecal clonidine compared to control group from 15 to 120 min.⁸

Our observations were similar to that by Dobrydnjov et al 2003. In this study it was observed that significant decrease in systolic and diastolic blood pressure occurred at 45-120 min after spinal injection in groups BC15 (6mg Of 0.5% bupivacaine +15 μ g clonidine) and BC30 (6mg Of 0.5% bupivacaine +30 μ g clonidine) than in group B (6mg Of 0.5% bupivacaine).⁹

Our findings were also in consonance with the study by B.S. Sethi et al 2007 where they recorded significant fall in mean arterial pressure in the clonidine group as compared to the control group from 45 minutes to end of 6 hours.¹

Grandhe RP et al 2008 also observed significant decrease in mean arterial pressure in groups BC1 (1.5ml of 0.5% heavy bupivacaine +clonidine 1 μ g/kg) and BC2 (1.5ml of 0.5% heavy bupivacaine +clonidine 1.5 μ g/kg) as compared to group B from 45 min to 8 h after intrathecal injection.⁷

Duration of analgesia, as determined by the time elapsed before the first supplemental analgesic request by the patient, lasted for 198 \pm 40.96 min, 265.16 \pm 38.73 min, 334 \pm 66.47 min and 351 \pm 54.91 min in group I, II, III and IV respectively. Similar results were observed by studies.^{1,7}

CONCLUSION

To conclude, three doses (0.5, 0.75, 1.0 μ g/Kg) are effective in increasing the duration of analgesia and the time to first analgesic request in the post-operative period. These doses do have an effect on systolic, diastolic blood pressure and heart rate of the patients.

The addition of clonidine to bupivacaine yields long lasting, profound pain relief, although hemodynamic effects require careful monitoring. Number of patients having bradycardia were 11 & 4 in group IV & III respectively and number of patients having hypotension were 11 & 5 in group IV & III respectively.

In conclusion our study demonstrates that addition of 0.75 μ g/Kg of clonidine to intrathecal bupivacaine is safe as compared to 1.0 μ g/Kg. By using small dose of intrathecal clonidine side effects were not increased whereas intrathecal clonidine at the usual dose of 1 μ g/kg is associated with bradycardia and relative hypotension. So, 0.75 μ g/Kg of clonidine is the preferred dose for addition to 0.5% hyperbaric bupivacaine in patients undergoing gynaecological and lower abdominal surgeries.

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