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IP International Journal of Ocular Oncology and Oculoplasty

Journal homepage: <https://ijooo.org/>

Original Research Article

Evaluation of effects of intrathecal clonidine as adjuvant to 0.5% bupivacaine (heavy) in lower abdominal surgeries

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ARTICLE INFO

Article history:

Received 20-01-2021

Accepted 24-04-2021

Available online 24-11-2021

Keywords:

Effect
Clonidine
Bupivacaine
Surgery
Anesthesia
Technique

ABSTRACT

Background: Various agents have been tried for spinal anesthesia including opioids as an adjuvant to bupivacaine. But due to complications or shorter duration of action of opioids, intrathecal clonidine as an adjuvant to bupivacaine has been found to be a promising candidate.

Objective: To evaluate effects of intrathecal clonidine as adjuvant to 0.5% bupivacaine (heavy) in lower abdominal surgeries

Materials and Methods: Comparative prospective study was carried out among 60 patients who underwent surgeries of the lower abdomen. Group 1 patients (N=30) were given bupivacaine and clonidine. Group 2 patients (N=30) were given bupivacaine and saline. Hemodynamic parameters at regular intervals, oxygen saturation, onset of analgesia, intensity of motor blockade, highest level of analgesia at 10 minutes, duration of sensory blockade, duration of analgesia and motor blockade were recorded.

Results: Baseline parameters like age, height and weight were comparable in two groups ($p > 0.05$). Time of onset of analgesia and onset of motor blockade was significantly lower in clonidine group compared to saline group. Two segment regression; duration of motor blockade and duration of analgesia were significantly more in clonidine group compared to saline group ($p < 0.01$). Mean heart rate, Mean systolic blood pressure, Mean diastolic blood pressure, and Mean of mean arterial pressures were comparable between both the groups ($P > 0.05$).

Conclusion: Thus, addition of clonidine in the dose of $75\mu\text{g}$ to 0.5% bupivacaine (heavy) in the dose of 3ml given intrathecally to patients undergoing surgeries of the lower abdomen was effective in prolonging the motor blockade duration as well as duration of analgesia, and also found to be associated with few complications

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1. Introduction

Lower abdominal surgeries are generally performed under regional anesthesia. There are many advantages of regional anesthesia. It avoids the side effects associated with general anesthesia and keeps the patient awake. Apart from this, anesthesia onset is fast in regional anesthesia and it is

simple. Thus, it enables surgeons to start the surgery at the earliest. Commonly used regional anesthesia technique is spinal anesthesia which is commonly used in surgeries of the lower abdomen. In 1885, J Leonard Corning was the first to produce spinal anesthesia that used cocaine for it. In 1898, August Bier was the first to use it deliberately. Another advantage of this technique is reduced risk of toxicity of the drugs as dose required is small. Occurrence of

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post dural puncture headache now a days has been reduced due to advanced techniques of use of small gauge spinal needles with non-cutting pencil point tips.¹

Lignocaine is the commonly used anesthetic agent for decades due to its rapid onset of action and good muscular relaxant but bears disadvantages like action is short term and can lead to few complications.^{2,3} It has been documented that bupivacaine is more effective than lignocaine due to the fact that its action lasts for a longer time but onset of action is slow and it is not as good as lignocaine in terms of muscle relaxation. In today's world, hyperbaric bupivacaine 0.5% is the anesthetic agent of choice for spinal anesthesia. It can not produce post surgical analgesia for longer time. Hence it needs an adjuvant to achieve this goal.⁴

In 1976, Yaksh and Rudy demonstrated for the first time that opioids can be used to produce analgesia at spinal cord level.⁵ This led to the use of new agents of opioids and the first to be used was morphine which was given intrathecally to enhance the neuraxial blocks. They give the advantage of prolonged analgesia and at the same time do not affect the motor power, sensations and do not bring about changes in the autonomic system.⁶ But they can cause respiratory depression which is difficult to predict,^{7,8} itching, retention of urine, post-operative nausea and vomiting.⁹

Local anesthetic effects can be potentiated by clonidine.¹⁰ It prolongs both the sensory as well as motor blockade and also reduces the needed dose of the local anesthetic agent. For prolonging the duration of the spinal anesthesia, clonidine orally was used along with lidocaine,¹¹ Tetracaine,¹² and bupivacaine.¹³ But intrathecal clonidine is more effective than oral form to prolong analgesia as well as motor blockade and also decreased the consumption of the morphine after surgery.¹³

Clonidine alone can produce prolonged analgesia post surgery and sedation¹⁴ but not found to be adequate for surgical anesthesia even in large doses. Hence, it has to be used as an adjuvant to local anaesthetics.¹⁵ It provides a good alternative to opioids not only to prolong the post surgical analgesia but also to reduce the side effects. Effectiveness of parenteral form of clonidine needs to be studied.

Therefore, present study was designed to evaluate the effects of clonidine as an adjuvant to 0.5% bupivacaine (heavy), given intrathecally for prolonging the duration of analgesia and to evaluate the effects like onset and duration of sensory and motor blockade of intrathecal clonidine as adjuvant to 0.5% bupivacaine (heavy) in lower abdominal surgeries.

2. Materials and Methods

2.1. Study design

Hospital based comparative prospective study

2.2. Study duration

October 2012 to December 2013

2.3. Settings

Present clinical study was conducted at MEDWIN Hospital, Nampally, Hyderabad,

2.4. Ethical considerations

Institution Ethics Committee permission was obtained. All study participants were explained about the study protocol and written informed consent was taken. All patients were followed for required duration and they were managed appropriately.

2.5. Study population

Present study was carried out among 60 willing patients who were undergoing surgery for the lower abdomen and selected as per the inclusion and exclusion criteria of the study.

2.6. Inclusion criteria

1. Age between 20-50 years of either gender.
2. American Society of Anaesthesiologist (ASA) grades I and II.

2.7. Exclusion criteria

1. Patient with neurological disorders.
2. Patients with allergy to study drug.
3. Patients with coagulation disorders.
4. Patients with local infections at site of injection.
5. Patients with spine deformities.

2.8. Sample size

Sample size was calculated based on the power analysis performed in a pilot study with an $\alpha=0.05$ and $\beta=0.90$. A sample size of 30 patients per study group was needed to detect a change of 10% in onset of motor blockade, onset of analgesia and the duration of analgesia from the control group.

2.9. Methods

Detailed history and clinical examination was carried out. Informed consent was taken. Nil by mouth status was ascertained before surgery. Patients were given tablet alprazolam in the dose of 0.01 mg/kg body weight in the night before the day of surgery. Re-assessment of all the patients was done before surgery. Half an hour before surgery, they were given Ringer Lactate solution in the dose of 15 ml/kg. Baseline parameters were recorded.

30 patients were randomly distributed in two groups. Group 1 patients (N=30) were given bupivacaine and clonidine. Group 2 patients (N=30) were given bupivacaine and saline.

Left later position was given to the patients and L3-L4 intervertebral space was used for lumbar puncture taking aseptic precautions. Cerebrospinal fluid free flow was ensured. 3ml of 0.5% heavy bupivacaine along with 0.5ml of clonidine was given to group 1 patients and group 2 patients were given 0.5ml of 0.9% saline instead of bupivacaine. After giving these injections, patients were made to lie down in supine position.

Hemodynamic parameters at regular intervals, oxygen saturation, onset of analgesia, intensity of motor blockade, highest level of analgesia at 10 minutes, duration of sensory blockade, duration of analgesia and motor blockade were recorded.

2.10. Statistical analysis

The mean and standard deviation for each parameter studied was calculated. Student's t test was used to compare the two groups and p value of less than 0.05 was taken as statistically significant.

3. Results

Table 1 shows comparison of baseline parameters in both groups. The baseline parameters like age, height and weight were comparable in two groups ($p > 0.05$)

Table 2 shows comparison of anesthetic parameters in both groups. The time of onset of analgesia and onset of motor blockade (min) was significantly lower in clonidine group compared to saline group. Two segment regression (min); duration of motor blockade (min) and duration of analgesia (min) were significantly more in clonidine group compared to saline group ($p < 0.01$)

Table 3 shows comparison of maximum height of sensory blockade and occurrence of post-operative complications in two groups. Maximum height of sensory blockade at T4, T6, T8, T10 were similar in two groups ($p > 0.05$). Occurrence of complications was also comparable in two groups ($p > 0.05$)

Table 4 shows comparison of heart rates (Mean±SD) in both groups (N=60). Mean heart rates were comparable between both the groups ($p > 0.05$).

Table 5 shows comparison of systolic blood pressures (Mean±SD) in both groups (N=60). Mean systolic blood pressures are comparable between both the groups ($p > 0.05$).

Table 6 shows comparison of diastolic blood pressures (Mean±SD) in both groups (N=60). Mean diastolic blood pressures are comparable between both the groups ($P > 0.05$).

Table 7 shows comparison of mean arterial pressures (Mean±SD) in both groups (N=60). Mean of mean arterial

pressures are comparable between both the groups ($P > 0.05$).

4. Discussion

In the present study, mean age in the clonidine and control groups was 40.1 ± 7.81 and 39.6 ± 7.95 years respectively. Mean age among the groups was comparable. The mean age of patients in clonidine and control groups of the present study is in accordance with those of Sethi BS et al¹⁶ (2007) (44.87 ± 4.38 and 44.47 ± 4.83), Grandhe PR et al¹⁷ (2008) (36.5 ± 9.7 and 34.5 ± 0.4), Shah ZA et al¹⁸ (2012) (46.90 ± 11.73 and 45.93 ± 13.80).

In the present study, mean weight in the clonidine and control groups was 56.6 ± 8.98 and 57.27 ± 8.94 kilograms respectively. Mean weight among the groups was comparable. The mean weight of the patients in clonidine and control groups of present study is in accordance with those of Sethi BS et al¹⁶ (2007) (57.93 ± 4.75 and 56.53 ± 5.31), Grandhe PR et al¹⁷ (2008) (62.7 ± 18 and 54.6 ± 15.7), Bhure A et al¹⁹ (2011) (54.43 ± 3.44 and 54.6 ± 3.29).

In the present study, mean height in the clonidine and control groups was 159.2 ± 3.16 and 159.5 ± 3.01 centimetres respectively. Mean height among the groups was comparable. Mean height of patients in clonidine and control groups of present study is in accordance with the studies of Benhamou D et al²⁰ (1998) (161 ± 6 and 162 ± 7), Sethi BS et al¹⁶ (2007) (155.47 ± 2.54 and 156.27 ± 3.07), Bhure A et al¹⁹ (2011) (152.83 ± 2.06 and 153.7 ± 2.43).

In the present study, total male patients in clonidine and control groups were 25 and 26 respectively, while female patients in clonidine and control groups were 5 and 4 respectively. Male to female ratio of clonidine and control group in present study is in accordance with the studies of Grandhe PR et al¹⁷ (2008) and Shah ZA et al¹⁸ (2012).

In the present study the maximum height of sensory blockade in clonidine group was (T6-T8) compared to (T6-T8) level in control group, which were comparable. The maximum height of sensory blockade of present study is in accordance with Kaabachi O et al²¹ (2007) (T6-T10) in clonidine and (T6-T10) control group respectively, Grandhe PR et al¹⁷ (2008) (T4-T7) in clonidine and (T4-T7) in control group respectively, and with Saxena H et al²² (2010) (T6-T8) in both clonidine and control groups.

In present study, mean duration of two segment regression in clonidine and control groups was 210.5 ± 6.86 and 125 ± 5.08 minutes respectively and it is prolonged in clonidine group which is statistically significant ($P < 0.05$). Mean duration of two segment regression in present study is in accordance with Kaabachi O et al²¹ (2007) (136 ± 56 and 107 ± 42), Sethi BS et al¹⁶ (2007) (218 and 136) and Shah ZA et al¹⁸ (2012) (190 ± 39.65 and 121.96 ± 27.8 minutes in clonidine and control groups respectively). Thus it is seen that duration of two segment regression is prolonged in clonidine group as compared to control group.

Table 1: Comparison of baseline parameters in both groups

Baseline parameters	Group 1 (N=30)	Group 2 (N=30)	T value	P value
Age (years)	40.1±7.81	39.60±7.95	0.251	0.802
Height (cm)	159.2±3.16	159.5±3.01	0.376	0.707
Weight (kg)	56.6±8.98	57.27±8.94	0.289	0.773

Table 2: Comparison of anesthetic parameters in both groups

Anesthetic parameters	Group 1 (N=30)	Group 2 (N=30)	T value	P value
Time of onset of analgesia (min)	2.25±0.18	2.5±0.19	5.232	< 0.01
onset of motor blockade (min)	8.51±0.175	9.32±0.14	17.175	< 0.01
two segment regression (min)	210.50±6.86	125±5.08	54.86	< 0.01
duration of motor blockade (min)	220±9.55	155.2±6.22	34.142	< 0.01
duration of analgesia (min)	650±9.22	230.2±26.05	82.208	< 0.01

Table 3: Comparison of maximum height of sensory blockade and occurrence of post-operative complications in two groups

Parameter		Group 1 (N=30)	Group 2 (N=30)	Chi square	P value
Maximum height of sensory blockade (segments)	T4	2	1	0.351	0.554
	T6	12	13	0.0685	0.793
	T8	13	14	0.0673	0.795
	T10	3	2	0.218	0.640
Complications	Nausea	4	2	0.185	0.667
	Sedation	2	0	0.517	0.472
	Dry mouth	3	1	0.268	0.605

Table 4: Comparison of heart rates (Mean±SD) in both groups (N=60).

Time in minutes	Group 1 (n=30)	Group 2 (n=30)	p-value
Baseline	85±10.5	83.60±3.529	P>0.05
SAB	83.60±3.529	85.00±10.14	P>0.05
2	85.00±10.83	84.20±12.48	P>0.05
4	84.80±6.63	84.00±11.38	P>0.05
6	84.60±8.02	83.40±8.25	P>0.05
8	84.20±5.97	83.10±8.18	P>0.05
10	83.40±6.63	83.00±10.52	P>0.05
20	83.00±11.88	82.20±9.75	P>0.05
30	82.90±10.83	82.00±7.13	P>0.05
60	82.50±8.02	82.40±10.73	P>0.05
90	82.70±10.27	82.50±10.14	P>0.05
120	82.80±10.83	82.70±12.48	P>0.05
150	82.90±5.97	83.00±11.38	P>0.05
180	83.00±6.63	83.10±8.25	P>0.05
240	83.20±8.07	83.50±12.48	P>0.05
300	83.50±8.02	83.60±11.38	P>0.05
360	83.80±10.83	83.90±8.25	P>0.05
420	84.00±7.59	84.00±8.55	P>0.05
480	84.20±8.42	84.10±6.73	P>0.05
540	84.60±7.51	84.30±7.89	P>0.05
600	84.80±7.91	84.50±5.8	P>0.05
660	84.00±7.59	84.00±8.55	P>0.05

P-value <0.05 is taken as significant.

Table 5: Comparison of systolic blood pressures (Mean±SD) in both groups (N=60)

Time in minutes	Group 1 (n=30)	Group 2 (n=30)	p-value
Baseline	125±6.82	124.97±10.90	P>0.05
SAB	125.36±11.47	125.7±12.36	P>0.05
2	120.23±9.02	119.21±8.78	P>0.05
4	118.45±7.8	118.94±8.11	P>0.05
6	118.39±9.92	118.7±10.14	P>0.05
8	118±8.61	118±13.46	P>0.05
10	117.85±8.93	117.32±10.64	P>0.05
20	117.3±6.88	117.26±7.82	P>0.05
30	116.28±10.90	116±9.02	P>0.05
60	115.32±12.36	115.38±9.92	P>0.05
90	114.1±8.78	115.16±8.76	P>0.05
120	114.86±11.47	114.66±12.56	P>0.05
150	116.66±9.02	116.83±13.54	P>0.05
180	118.43±7.8	119±12.65	P>0.05
240	118.96±9.92	119.93±45.76	P>0.05
300	120.9±8.61	120.66±34.76	P>0.05
360	122.2±9.88	122.56±12.78	P>0.05
420	124±8.76	122.46±13.89	P>0.05
480	124.2±6.88	123.09±14.65	P>0.05
540	125.21±4.87	123.32±12.78	P>0.05
600	125.54±6.78	123.75±13.67	P>0.05
660	124±8.76	122.46±13.89	P>0.05

P-value <0.05 is taken as significant.

Table 6: Comparison of diastolic blood pressures (Mean±SD) in both groups (N=60)

Time in minutes	Group 1 (n=30)	Group 2 (n=30)	p-value
Baseline	78.10±11.88	79.2±8.63	P>0.05
SAB	77.86±10.77	77.03±8.41	P>0.05
2	77.58±7.52	77.00±7.15	P>0.05
4	77.38±7.80	76.89±7.14	P>0.05
6	76.98±8.86	76.45±6.63	P>0.05
8	76.73±7.98	76.00±9.33	P>0.05
10	76.34±7.55	75.78±6.09	P>0.05
20	75.96±8.71	75.46±6.86	P>0.05
30	74.94±8.63	75.10±11.88	P>0.05
60	73.93±8.41	74.45±10.77	P>0.05
90	73.93±7.15	73.26±7.52	P>0.05
120	72.80±7.14	72.60±7.80	P>0.05
150	72.86±6.63	72.00±8.86	P>0.05
180	73.33±9.33	73.46±7.98	P>0.05
240	75.56±6.09	75.40±7.55	P>0.05
300	76.66±6.86	76.10±8.71	P>0.05
360	76.86±6.21	76.63±8.86	P>0.05
420	76.98± 6.78	77.74 ±8.78	P>0.05
480	77.45± 7.87	77.89 ±9.3	P>0.05
540	77.96± 8.78	77.98 ±8.67	P>0.05
600	78± 8.98	78.00 ±8.56	P>0.05
660	76.98± 6.78	77.74 ±8.78	P>0.05

P-value <0.05 is taken as significant.

Table 7: Comparison of mean arterial pressures (Mean±SD) in both groups (N=60)

Time in minutes	Group 1 (n=30)	Group 2 (n=30)	p-value
Baseline	93.73±6.56	94.45±6.14	P>0.05
SAB	93.69±5.87	93.25±5.45	P>0.05
2	91.79±7.67	91.07±7.54	P>0.05
4	91.07±3.55	90.9±4.21	P>0.05
6	90.78±8.34	90.53±8.11	P>0.05
8	90.48±6.75	90±6.66	P>0.05
10	90.17±7.56	89.62±7.11	P>0.05
20	89.74±6.12	89.39±6.55	P>0.05
30	88.72±5.74	88.73±7.61	P>0.05
60	87.72±5.89	88.09±7.84	P>0.05
90	87.32±3.98	87.22±8.10	P>0.05
120	86.82±5.76	86.62±7.25	P>0.05
150	87.46±7.23	86.94±6.25	P>0.05
180	88.36±8.10	88.64±5.33	P>0.05
240	90.02±5.77	90.24±6.11	P>0.05
300	91.4±6.56	90.95±5.78	P>0.05
360	91.97±6.77	91.94±4.99	P>0.05
420	92.65±5.13	92.64±6.87	P>0.05
480	93.03±4.76	92.95±4.61	P>0.05
540	93.71±8.56	93.09±7.12	P>0.05
600	93.84±8.11	93.25±5.66	P>0.05
660	92.65±5.13	92.64±6.87	P>0.05

P-value <0.05 is taken as significant.

In present study, mean duration of motor blockade in clonidine and control groups was 220±9.55 and 155.2±6.22 minutes respectively and it is prolonged in clonidine group which is statistically significant (P<0.05). The mean duration of motor blockade in present study is in accordance with Sethi BS et al¹⁶ (2007) (205 and 161) and Shah ZA et al¹⁸ (2012) (219.4±86.27 and 159.7±66.74 minutes in clonidine and control groups respectively). Thus it is seen that mean duration of motor blockade is prolonged in clonidine group as compared to control group.

In present study, mean duration of analgesia in clonidine and control groups was 650.5±9.22 and 230.2±26.05 minutes respectively and it is prolonged in clonidine group which is statistically significant (P<0.05). The mean duration of analgesia in present study is in accordance with Kaabachi O et al²¹ (2007) (461±147 and 330±138), Sethi BS et al¹⁶ (2007) (614 and 223) and Shah ZA et al¹⁸ (2012) (714.93±235.8 and 214.1±157.1 minutes in clonidine and control group respectively). Thus it is seen that mean duration of analgesia is prolonged in clonidine group as compared to control group.

In the present study the changes in mean values of heart rate in both the groups after administration of study drug were not statistically significant. In both groups there was an initial slight fall in blood pressure which is in accordance with the expected sympathetic block produced by spinal anaesthesia. ECG monitoring through out the study did not show any abnormalities. The findings of present study are in accordance to the study conducted

by, Benhamou D et al²⁰ (1998) stated that comparison of serial measurements of blood pressure and heart rate during and after surgery did not reveal any significant difference among groups.²⁰ Strebel S et al²³ (2004) stated that relative haemodynamic stability was maintained in all groups. Shah ZA et al¹⁸ (2012) stated that haemodynamic parameters were comparable and statistically insignificant (p>0.05) and Saxena H et al²² (2010) stated that the haemodynamic parameters were similar in all the groups at any point of time with no statistical variation.

In the present study occurrence of complications like nausea were four (13.33%) cases in the clonidine group and two (6.66%) cases in control group, dry mouth was three (9.99%) cases in the clonidine group and one (3.33%) case in control group and sedation was two (6.66%) cases in the clonidine group. Respiratory depression and bradycardia was not found in any case of clonidine and control groups. Present study findings are in accordance with that of Kaabachi O et al²¹ (2007) in which four patients of clonidine group, two patients of control group developed nausea, one patient of clonidine group developed sedation and Shah ZA et al¹⁸ (2012) in which three patients in clonidine group, two patients in control group developed nausea, three patients in clonidine group, two patients in control group developed dry mouth and two patients of clonidine group developed sedation.

5. Conclusion

Thus, addition of clonidine in the dose of 75µg to 0.5% bupivacaine (heavy) in the dose of 3ml given intrathecally to patients undergoing surgeries of the lower abdomen was effective in prolonging the motor blockade duration as well as duration of analgesia, and also found to be associated with few complications.

6. Conflict of Interest

The authors declare that there are no conflicts of interest in this paper.

7. Source of Funding

None.

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Cite this article: Gaddam R, Bikumalla L, Aleti V, Appagalla S, Pasupuleti S. Evaluation of effects of intrathecal clonidine as adjuvant to 0.5% bupivacaine (heavy) in lower abdominal surgeries. *IP Int J Ocul Oncol Oculoplasty* 2021;11(3):412-418.