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A Comparative Study Of Two Doses Of Intrathecal Clonidine With Bupivacaine In Inguinal Hernia Surgeries

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Abstract

Back ground : Initially opioids have been the standard choice as spinal adjuvants. But since there occurs many side effects and complications like early and late depression of ventilation , pruritus, nausea, vomiting, urinary retention, central nervous system excitation, viral re- activation, sexual dysfunction, delayed gastric emptying, ocular dysfunction, there is an active search for an alternative ideal adjuvant which is devoid of these side effects and complications.Preservative free clonidine when administered into epidural or subarachnoid space produce dose dependent analgesia and unlike opioids does not produce any of its side effects.

Aim Of The Study : To evaluate the duration of post operative analgesia provided by two varying doses of clonidine with bupivacaine against bupivacaine alone in subarachnoid blockade in inguinal hernia surgeries.

Methods: After getting the ethical committee approval the study was conducted in 90 patients undergoing elective inguinal hernia surgeries in the year 2022 at Government Stanley Medical College, Chennai , Tamil nadu, India . It was a double blinded study in which patients were randomly allocated into three groups A, B and C. In this randomized double blinded study conducted in 90 patients, the subjects were allocated in to three groups.Group A- Inj. 0.5% Bupivacaine 2.4cc + 0.2 cc normal saline.Group B- Inj. 0.5% Bupivacaine 2.4cc+ 15 µg clonidine +0.1 cc normal saline Group C-Inj.0.5% Bupivacaine 2.4cc+ Inj. Clonidine 30µg After getting informed consent and explaining the procedure details to the patients, the anaesthetic technique was performed. Patients were put in right lateral position and with strict aseptic precaution lumbar puncture was done with quincke standard 23 guage spinal needle.After ensuing free flow of CSF, the drug was injected as per the group assigned.The assigned amount of clonidine and normal saline were taken in 1 ml sterile tuberculine syringe.After injection patient were put up in supine position. After attaining adequate peak level of sensory block, the surgeon was asked to proceed.

Results : In group A 80% belongs to ASA I and 20% ASA II.In group B 76.7% belongs to ASA I and 23.3% ASA II, In group C 70% belongs to ASAI and 30% ASA II. In group A the initial mean pulse rate was 88.3 with standard deviation of 9.5 per minute, reaching a minimum of 75.4 with standard deviation of 5.6 per minute. In group B the initial mean pulse rate was 85.6 with standard deviation of 9.8 per minute, reaching a minimum of 73.1 with standard deviation of 5.4 per minute. In group C the initial mean pulse rate was 84.9 with standard deviation of 11.3 per minute, reaching a minimum of 67.6 with standard deviation of 6.1 per minute. The average was 89.4 with standard deviation of 5.6 mmHg. The percentage fall of 7.1 with standard deviation of 7.9 was noted.The average was 89.8 with standard deviation of 4.9 mmHg. The percentage fall of 7.8 with

standard deviation of 6.8 was noted. The average was 83.5 with standard deviation of 4.3 mmHg. The percentage fall of 12.1 with standard deviation of 10 was noted. In group A sedation was observed in no patients.In group B grade I sedation score was observed in 4 patients In group C grade I sedation score was observed in 18 patients . In group A the mean respiratory rate was 14.9 with standard deviation of 1.2 and saturation of 99.7.In group B the mean respiratory rate was 14.8 with standard deviation of 1.1and saturation of 99.5In group C the mean respiratory rate was 14.7with standard deviation of 0.8 and saturation of 99.6. In group Athe maximum sensory level of T8 , T9, T10, T11 was observed in 3, 13, 12,2 patients respectively .In group B the maximum sensory level of T8 , T9, T10, T11 was observed in 3,5, 15,7 patients respectively.In group C the maximum sensory level of T8 , T9, T10, T11 was observed in 7,9,11,3 patients respectively. In group A the onset of maximum sensory level occurs in 7.9 minutes with standard deviation of 0.88.In group B the onset of maximum sensory level occurs in 8.17 minutes with standard deviation of 0.99.In group C the onset of maximum sensory level occurs in 8.83minutes with standard deviation of 1.05. In group A the motor onset have occurred in 8.63 minutes with standard deviation of 1.03.In group B the motor onset have occurred in 9.07 minutes with standard deviation of 0.83.In group C the motor onset have occurred in 9.33 minutes with standard deviation of 0.84. In group A mean motor duration was 110.9 minutes with standard deviation of 9.9.In group B mean motor duration was 125.2 minutes with standard deviation of 9.5.In group C mean motor duration was 142.7 minutes with standard deviation of 8.5. In group A the mean duration of post operative analgesia was 175.9 minutes with standard deviation of 11.6,In group B the mean duration of post operative analgesia was 194.9 minutes with standard deviation of 22.In group C the mean duration of post operative analgesia was 272.2 minutes with standard deviation of 33.2. Shivering have occurred in 4 patients in group A and 3 patients in group B and 3 patients in group C. Dry mouth have not been observed in any of the cases of in the three groups.Nausea or vomiting have not been observed in any of the patients the three groups.

Conculsion : This study shows that adding clonidine 15µg and 30µg to bupivacaine significantly prolongs the duration of post operative analgesia when compared to bupivacaine alone in inguinal hernia surgeries. Adding 30µg of clonidine significantly results in more duration of post operative analgesia than adding 15µg of clonidine to bupivacaine without any side effects.

Keywords: Intrathecal Clonidine, Bupivacaine, Inguinal Hernia Surgeries, Sensory block , motor block

Introduction

For inguinal hernia surgeries, the standard anaesthetic technique is subarachnoid block. Adrenaline being the first spinal adjuvant used to increase the duration and to reduce the toxicity of spinal anaesthesia in 1903. From then many drugs have been tried in search for an ideal adjuvant.[1] They are opioids, soda bicarbonate, ketamine, neostigmine, midazolam and the latest inclusion is clonidine.Initially opioids have been the standard choice as spinal adjuvants. [2]But since there occurs many side effects and complications like early and late depression of ventilation , pruritus, nausea, vomiting, urinary retention, central nervous system excitation, viral re activation, sexual dysfunction, delayed gastric emptying, ocular dysfunction, there is an active search for an alternative ideal adjuvant which is devoid of these side effects and complications.[3]Preservative free clonidine when administered into epidural or subarachnoid space produce dose dependent analgesia and unlike opioids does not produce any of its side effects. Activation of post synapticalpha 2 receptors in the substantia gelatinosa of the spinal cord is the presumed mechanism by which it produces analgesia.[4]Clonidine at appropriate doses when used as an adjuvant with bupivacaine in subarachnoid block seems to prolong the duration of surgical anaesthesia and postoperative analgesia without any of its side effects like dry mouth, hypotension, bradycardia, which is not usual in these doses with added advantages like sedation, anti-shivering.[5]This study has been taken in search for a minimal dose of clonidine as an adjuvant with bupivacaine which produces maximum post operative analgesia without or with minimal incidence of its side effects.

Volume 6, Issue 1; January-February 2023; Page No 722-733

Methods : After getting the ethical committee approval the study was conducted in 90 patients undergoing elective inguinal hernia surgeries in the year 2022 at Government Stanley Medical College, Chennai , Tamil nadu, India . It was a double blinded study in which patients were randomly allocated into three groups A, B and C. In this randomized double blinded study conducted in 90 patients, the subjects were allocated in to three groups.Group A- Inj. 0.5% Bupivacaine 2.4cc + 0.2 cc normal saline.Group B- Inj. 0.5% Bupivacaine 2.4cc+ 15 µg clonidine +0.1 cc normal saline Group C-Inj.0.5% Bupivacaine 2.4cc+ Inj. Clonidine 30µg After getting informed consent and explaining the procedure details to the patients, the anaesthetic technique was performed. Patients were put in right lateral position and with strict aseptic precaution lumbar puncture was done with quincke standard 23 guage spinal needle.After ensuing free flow of CSF, the drug was injected as per the group assigned.The assigned amount of clonidine and normal saline were taken in 1 ml sterile tuberculine syringe.After injection patient were put up in supine position. After attaining adequate peak level of sensory block, the surgeon was asked to proceed.Exclusion Criteria: Patient refusal,ASA III & IV patients,Post spinal surgeries,Spinal deformity,H/o drug allergy.On preoperative visit the patients were explained about the procedure details. Then preoperative baseline parameters like pulse rate, blood pressure, respiratory rate were recorded. Intravenous line started with 18 gauge intra venous cannula and preloaded with ringer's lactate 15 ml/kg 15min prior to subarachnoid blockade.

Statistical Analysis

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2008).Using this software range, frequencies, percentages, means, standard deviations, chi square and 'p' values were calculated. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

Observation And Results

Table 1 : Age distribution

Age group	Cases in					
	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Upto 40 years	2	6.7	3	10	1	3.3
41-50years	10	33.3	12	40	11	36.7
51-60 years	14	46.7	12	40	12	40
>60years	4	13.3	3	10	6	20
Total	30	100	30	100	30	100
Range Mean S.D.	39-64 yrs 52.4 7		39-66 yrs 50.3 7.5		39-69 52.9 8.5	
'p'	0.4232 Not significant					

Volume 6, Issue 1; January-February 2023; Page No 722-733

Age distribution in the group A ranges from 39 to 64 years with mean age of 52.4 years and standard deviation of 7.In group B the age distribution ranges from 39-66 years with mean age of 50.3 years and standard deviation of 7.5. In group C the age distribution ranges from 39 to 69 years with mean of 52.9 and standard deviation of 8.5.The p value for three groups are not significant, so the three groups are comparable.

Table 2: ASA status

ASA	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
I	24	80	23	76.7	21	70
II	6	20	7	23.3	9	30
Total	30	100	30	100	30	100

In group A 80% belongs to ASA I and 20% ASA II,In group B 76.7% belongs to ASA I and 23.3% ASA II In group C 70% belongs to ASAI and 30% ASA II

Table 3 : Pulse rate

Pulse rate	Group-A		Group-B		Group-C	
	Mean	S.D	mean	S.D	Mean	S.D
Initial PR	88.3	9.5	85.6	9.8	84.9	11.3
Minimum PR	75.4	5.6	73.1	5.4	67.6	6.1
Average PR	82.5	5.9	80.8	6.3	73.6	5.3
Fall in PR	12.8	6.6	12.5	5.9	17.4	9.3
% fall in PR	14.1	6.1	14.2	5.4	19.6	8.6
'p' for 3 groups	0.0159 significant					
A&B	0.9058 not significant					
B&C	0.012 significant					
A&C	0.0141 significant					

In group A the initial mean pulse rate was 88.3 with standard deviation of 9.5 per minute, reaching a minimum of 75.4 with standard deviation of 5.6 per minute. The mean average pulse rate was 82.5 with standard deviation of 5.9 per minute and the percentage of fall in pulse rate was 14.1 with standard deviation of 6.1.In group B the initial mean pulse rate was 85.6 with standard deviation of 9.8 per minute, reaching a minimum of 73.1 with standard deviation of 5.4 per minute. The mean average pulse rate was 80.8 with standard deviation of 6.3 per minute and the percentage of fall in pulse rate was 14.2 with standard deviation of 5.4.In group C the initial mean pulse rate was 84.9 with standard deviation of 11.3 per minute, reaching a minimum of 67.6 with

Volume 6, Issue 1; January-February 2023; Page No 722-733

standard deviation of 6.1 per minute. The mean average pulse rate was 73.6 with standard deviation of 5.3 per minute and the percentage of fall in pulse rate was 19.6 with standard deviation of 8.6.

Table 4: Mean Arterial Pressure

MAP	Group A		Group B		Group C	
	Mean	S.D	Mean	S.D	mean	S.D
Initial MAP	89.7	6.7	90.5	7.5	90.1	8.4
Minimum MAP	83.1	7.6	83.2	6.7	78.6	6.5
Average MAP	89.4	5.6	89.8	4.9	83.5	4.3
Fall in MAP	6.6	8.0	7.3	6.4	11.5	10.1
% fall in MAP	7.1	7.9	7.8	6.8	12.1	10
'p' for 3 groups	0.151 not significant					
A&B	0.2572 not significant					
B&C	0.0422 significant					
A&C	0.0347 significant					

In group A the initial mean arterial blood pressure was 89.7 with standard deviation of 6.7 mm Hg, reaching a mean minimum of 83.1with standard deviation of 7.6 mm Hg. The average was 89.4 with standard deviation of 5.6 mmHg. The percentage fall of 7.1 with standard deviation of 7.9 was noted.In group B the initial mean arterial blood pressure was 90.5with standard deviation of 7.5 mm Hg, reaching a mean minimum of 83.2with standard deviation of 6.7 mm Hg. The average was 89.8 with standard deviation of 4.9 mmHg. The percentage fall of 7.8 with standard deviation of 6.8 was noted.In group C the initial mean arterial blood pressure was 90.1 with standard deviation of 8.4mm Hg, reaching a mean minimum of 78.6with standard deviation of 6.5mm Hg. The average was 83.5 with standard deviation of 4.3 mmHg. The percentage fall of 12.1 with standard deviation of 10 was noted.

Table 5 : Medications

Medications	Group A		Group B		Group C	
	No.	%	No.	%	No.	%
Inj.ephedrine Given	3	10	2	6.7	4	13.3
Not given	27	90	28	93.3	26	86.7
Inj. Atropine Given	0	-	0	-	1	3.3

Volume 6, Issue 1; January-February 2023; Page No 722-733

Not given	30	100	30	100	29	96.7

In group A 3 patients received inj. Ephedrine and no patients received inj. Atropine.In group B 2 patients received inj. Ephedrine and no patients received inj. Atropine.In group C 4 patients received inj. Ephedrine and one patient received inj. Atropine.

Table 6: Sedation score

Sedation score	**Group A**		**Group B**		**Group C**	
	No.	**%**	**No.**	**%**	**No.**	**%**
0	30	100	26	86.7	12	40
1	-	-	4	13.3	18	60
2	-	-	-	-	-	-
Mean	0		0.13		0.6	
S.D	-		0.35		0.4983	
'p' for 3 groups	0.0001 significant					
A&B	0.0280 significant					
B&C	0.0001 significant					
A&C	0.0001 significant					

In group A sedation was observed in no patients.In group B grade I sedation score was observed in 4 patients In group C grade I sedation score was observed in 18 patients.

Table 7: Respiratory rate & SpO2

	Respiratory rate			**SpO2**		
	Group A	**Group B**	**Group C**	**Group A**	**Group B**	**Group C**
Mean	14.9	14.8	14.7	99.7	99.5	99.6
S.D	1.2	1.1	0.8	0.55	0.68	0.67
"p" for 3 groups	0.5525 not significant			0.7827 not significant		
A&B	0.6894 not significant			0.4971 not significant		

Volume 6, Issue 1; January-February 2023; Page No 722-733

B&C	0.5151 not significant	0.6309 not significant
A&C	0.2736 not significant	0.8683 not significant

In group A the mean respiratory rate was 14.9 with standard deviation of 1.2 and saturation of 99.7.In group B the mean respiratory rate was 14.8 with standard deviation of 1.1and saturation of 99.5.In group C the mean respiratory rate was 14.7with standard deviation of 0.8 and saturation of 99.6.

Table 8 : Maximum sensory level

Max. SL	Group A		Group B		Group C	
	No.	**%**	**No.**	**%**	**No.**	**%**
T8	3	10	3	10	7	23.3
T9	13	43.3	5	16.7	9	30
T10	12	40	15	50	11	36.7
T11	2	6.7	7	23.3	3	10
Total	30	100	30	100	30	100

In group A the maximum sensory level of T8 , T9, T10, T11 was observed in 3, 13, 12,2 patients respectively.In group B the maximum sensory level of T8 , T9, T10, T11 was observed in 3,5, 15,7 patients respectively. In group C the maximum sensory level of T8 , T9, T10, T11 was observed in 7,9,11,3 patients respectively.

Table 9:Onset of max. sensory level

Onset SL	Group A	Group B	Group C
Mean	7.9	8.17	8.83
S.D	0.88	0.99	1.05
'p' 3 groups	0.0028 significant		
A&B	0.286 not significant		
B&C	0.0223 significant		
A&C	0.0008 significant		

Volume 6, Issue 1; January-February 2023; Page No 722-733

In group A the onset of maximum sensory level occurs in 7.9 minutes with standard deviation of 0.88.In group B the onset of maximum sensory level occurs in 8.17 minutes with standard deviation of 0.99.In group C the onset of maximum sensory level occurs in 8.83minutes with standard deviation of 1.05.

Table 10 : Two segment regression

2 segment regression	**Group A**	**Group B**	**Group C**
Mean **S.D**	86.5 7.2	102.1 12.5	122.6 5.9
'p' 3 groups	0.0001 significant		
A&B	0.0001 significant		
B&C	0.0001 significant		
A&C	0.0001 significant		

In group A the two segment regression occurred in 86.5 minutes with standard deviation of 7.2.In group B the two segment regression occurred in 102.1 minutes with standard deviation of 12.5.In group C the two segment regression occurred in 122.6 minutes with standard deviation of 5.9.

Table 11 : Motor onset

Motor onset	**Group A**	**Group B**	**Group C**
Mean S.D	8.63 1.03	9.07 0.83	9.33 0.84
'p' 3 groups	0.029 significant		
A&B	0.0902 not significant		
B&C	0.2907 not significant		
A&C	0.0106 significant		

In group A the motor onset have occurred in 8.63 minutes with standard deviation of 1.03.In group B the motor onset have occurred in 9.07 minutes with standard deviation of 0.83.In group C the motor onset have occurred in 9.33 minutes with standard deviation of 0.84**.**

Volume 6, Issue 1; January-February 2023; Page No 722-733

Table 12 : Motor duration

Motor duration	Group A	Group B	Group C
Mean	110.9	125.2	142.7
S.D	9.9	9.5	8.5
'p' 3 groups	0.0001 significant		
A&B	0.0001 significant		
B&C	0.0001 significant		
A&C	0.0001 significant		

In group A mean motor duration was 110.9 minutes with standard deviation of 9.9.In group B mean motor duration was 125.2 minutes with standard deviation of 9.5.In group C mean motor duration was 142.7 minutes with standard deviation of 8.5.

Table 13: Duration of surgery (in minutes)

Duration of surgery(min)	Group A	Group B	Group C
Mean	95.7	95.8	97.6
S.D	14.8	9.7	10.7
'p' 3 groups	0.7104 not significant		
A&B	0.8355 not significant		
B&C	0.4812 not significant		
A&C	0.4814 not significant		

The mean duration of surgery was 95.7, 95.8, 97.6 minutes with standard deviation of 14.8, 9.7, 10.7 in group A, group B, group C respectively

Table 14 : Post operative analgesia (in minutes)

Post op analgesia(min)	Group A	Group B	Group C

Volume 6, Issue 1; January-February 2023; Page No 722-733

Mean	175.9	194.9	272.2
S.D	11.6	22.0	33.2
'p' 3 groups	0.0001 significant		
A&B	0.0001 significant		
B&C	0.0001 significant		
A&C	0.0001 significant		

The post operative period till the patient demands systemic analgesic (ie. VAS score > 5) from the initiation of subarachnoid blockade.In group A the mean duration of post operative analgesia was 175.9 minutes with standard deviation of 11.6.In group B the mean duration of post operative analgesia was 194.9 minutes with standard deviation of 22.In group C the mean duration of post operative analgesia was 272.2 minutes with standard deviation of 33.2

Table 15 : Complications

Complications	**Group A**		**Group B**		**Group C**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Shivering	4	13.3	3	10	3	10
'p' A&B	0.5 not significant					
B&C	0.8 not significant					
A&C	0.5 not significant					

Shivering have occurred in 4 patients in group A and 3 patients in group B and 3 patients in group C. Dry mouth have not been observed in any of the cases of in the three groups.Nausea or vomiting have not been observed in any of the patients the three groups.

Discussion

The pain we perceive after a burn, bite (or) pinch is readily identifiable but difficult to define because it is differently perceived at different threshold.Pain is defined as psychical adjunct of protective reflex – by Sherington in 1906.The international association of society for pain (IASP) defined it as "An unpleasant sensory and emotional experience associated with actual (or) potential tissue damage (or) described in terms of such damage"[6]Clonidine assumes greater importance as anaesthetic adjuvant and analgesic. Its primary effect is sympatholytic. It reduces peripheral norepinephrine release by stimulation of prejunctional inhibitory alpha-2 adrenoreceptors. It inhibits central neural transmission in the dorsal horn by presynaptic and postsynaptic mechanism and directly in spinal preganglionic sympathetic neurons.[7] Clonidine enhances both sensory and motor blockade of local anaesthetics in peripheral nerve and central neuraxial blockade. Clonidine

Volume 6, Issue 1; January-February 2023; Page No 722-733

blocks conduction of C and A gamma fibers and increases potassium conductance in isolated neurons and intensifies the conduction of local anesthetics. [8]

By statistical analysis of three groups the age distribution was statistically not significant with a p value of 0.4232 (p> 0.05).[9] When comparing the height and weight of the patients in three groups it was statistically not significant with a p value of 0.7984 (p >0.05), 0.3413 (p>0.05) for height and weight respectively. All the three groups were comparable in relation to Age , height and Weight.[10] Duration of surgery was also comparable in all the three groups with a p value of 0.7104 (p> 0.05)Post-operative analgesia was significantly prolonged in both the group B & C, but significantly much more in group C(30µg clonidine) .In group C , it was 272.2±33.2 minutes, while in group B it was 194.9±22 minutes, when compared to 175.9±11.6 minutes in group A. This is supported by sethi et al study where they have used 1µg per kg dose of clonidine with 12.5 mg of 0.5% bupivacaine and found that this dose prolongs the duration of post operative analgesia by 614 minutes in clonidine group .24 hours inj. Tramadol (100 mg) requirement is significantly reduced in group C cases. The mean number of dose requirement was 1.67 in group C, 2.57 in group B , when compared to 2.77 in group A. [11]requirement was 1.16 in clonidine group against 2.66 in control group. Intra operative sedation was observed in group C but not of grade II or III or IV of brain and ready sedation score causing either respiratory depression or desaturation. The fall in pulse rate was significant in three groups , but not less than 60 per min in group B or group C(except in one case) requiring inj. Atropine to treat it.[12] The fall in mean arterial pressure was not significant in three groups and the requirement of inj. Ephedrine is similar in all groups . But in sethi et al study there was significant fall in mean arterial pressure though not requiring vasopressor treatment. Thus doses of 30µg and 15µg clonidine does not produce any change in mean arterial pressure values and is hemodynamically stable.[13]The two segment regression time was significantly prolonged in both the groups B and C, but more with group C. It was 122.6±5.9 minutes in group C ,102.1±12.5 minutes in group B and 86.5±7.2 minutes in group A. In sethi et al study also there was prolongation in two segment regression time of 218 minutes in clonidine 1µg per kg group.[14] The duration of motor blockade was significantly prolonged in both the groups B&C, but more with group C. The mean duration was 142.7 ±8.5 minutes in group C, 125.2±9.5 minutes in group B, and 110.9±9.9 minutes in group A . In sethi et al study the duration of motor blockade was 205 minutes in clonidine group.[15]The onset of maximum sensory blockade and the onset of motor blockade was significantly prolonged in group C when compared to other two groups. The onset of maximum sensory level was 8.83± 1.05, 8.17±0.99, 7.9±0.88 minutes in group C,B and A respectively. The duration of motor onset to achieve grade IV bromage scale was 9.33±0.84, 9.07±0.83, 8.63±1.03 minutes in group A,B and C respectively. [16] The side effects of clonidine like dry mouth was not observed in any of the cases of group B & C . While in sethi et al study they observed significant incidence of dry mouth with the dose of 1µg per kg clonidine group.The study shows that adding clonidine 15µg and 30µg to bupivacaine significantly prolongs the duration of post operative analgesia when compared to bupivacaine alone without any side effects like dry mouth or hemodynamic instability. [17,18]Adding 30µg of clonidine significantly results in more duration of post operative analgesia than adding 15µg of clonidine to bupivacaine.[19,20]

Conclusion

This study shows that adding clonidine 15µg and 30µg to bupivacaine significantly prolongs the duration of post operative analgesia when compared to bupivacaine alone in inguinal hernia surgeries. Adding 30µg of clonidine significantly results in more duration of post operative analgesia than adding 15µg of clonidine to bupivacaine without any side effects.

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Volume 6, Issue 1; January-February 2023; Page No 722-733

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Volume 6, Issue 1; January-February 2023; Page No 722-733