A COMPARATIVE STUDY OF TWO DOSES OF INTRATHECAL CLONIDINE WITH BUPIVACAINE IN INGUINAL HERNIA SURGERIES IN A TERTIARY CARE HOSPITAL

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ABSTRACT :

Background 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.
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.
Methods: After getting the ethical committee approval the study was conducted in 90 patients undergoing elective inguinal hernia surgeries. It was a double blinded study in which patients were randomly allocated into three groups A, B and C. After getting informed consent and explaining the procedure details to the patients, the anaesthetic technique was performed.Exclusion Criteria are Patient refusal ,ASA III & IV patients,Post spinal surgeries,Spinal deformity,H/o drug allergy
Results 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. 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.

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.

Keywords: inguinal hernia , clonidine.

INTRODUCTION:

Cerebrospinal fluid discovered by Domenico cotungo in 1764 and its circulation described by F.Magendie in 1825. First spinal analgesia by J.Leonard corning in 1885. He accidentally pierced the dura while experimenting with cocaine on the spinal nerves of the dog. Later he deliberately repeated the intradural injection, called it spinal anaesthesia and suggested it might be used in surgery.

First planned spinal analgesia for surgery in man performed by August Bier on 16th august 1898, in kiel when he injected 3 ml of 0.5 % cocaine solution into a 34 year old labourer.
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. They are opioids, soda bicarbonate, ketamine, neostigmine, midazolam and the latest inclusion is clonidine.

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. Activation of post synaptic alpha 2 receptors in the substantia gelatinosa of the spinal cord is the presumed mechanism by which it produces analgesia.
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.
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.

AIM AND OBJECTIVES OF THE STUDY:

The aim of this study is 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.

MATERIALS AND METHODS:

After getting the ethical committee approval the study was conducted in 90 patients undergoing elective inguinal hernia surgeries. It was a double blinded study in which patients were randomly allocated into three groups A, B and C. After getting informed consent and explaining the procedure details to the patients, the anaesthetic technique was performed.Exclusion Criteria are Patient refusal ,ASA III & IV patients,Post spinal surgeries,Spinal deformity,H/o drug allergy

After routine preoperative assessment as for all elective surgery patients ,Patients were randomly divided into three groups.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.

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.

Statistical analysis was done using the statistical package for social sciences (SPSS).Different statistical methods were used as appropriate. Mean ± SD was determined for quantitative data and frequency for categorical variables. The independent t- test was performed on all continuous variables. The normal distribution data was checked before any t-test. The Chi-Square test was used to analyze group difference for categorical variables. A p- value < 0.05 was considered significant.

RESULTS:

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
Group C Inj.0.5% Bupivacaine 2.4cc+ Inj. Clonidine 30µg

EFFICACY OF THE THREE GROUPS

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 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

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.

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					

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		

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.

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.

MOTOR DURATION

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

POST OPERATIVE ANALGESIA (IN MINUTES)

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

Mean **S.D**	175.9 11.6	194.9 22.0	272.2 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.

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"

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. Clonidine enhances both sensory and motor blockade of local anaesthetics in peripheral nerve and central neuraxial blockade. Clonidine blocks conduction of C and A gamma fibers and increases potassium conductance in isolated neurons and intensifies the conduction of local anesthetics.By statistical analysis of three groups the age distribution was statistically not significant with a p value of 0.4232 (p> 0.05).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.

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. This finding is supported by sethi et al study where they had used inj.diclofenac as rescue analgesic and the 24 hours requirement was 1.16 in clonidine group against 2.66 in control 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. Adding 30µg of clonidine significantly results in more duration of post operative analgesia than adding 15µg of clonidine to bupivacaine.

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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