Original Research Paper

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ANALGESIC EFFICACY OF LOW DOSE INTRATHECAL NEOSTIGMINE IN COMBINATION WITH FENTANYL AND BUPIVACAINE FOR LOWER ABDOMINAL AND LOWER LIMB SURGERY-A PROSPECTIVE RANDOMIZED DOUBLE BLIND STUDY

Dr.A.Seshu	Postgraduate
Dr.V. Karuna sree	MD Assistant Professor,RMC,Kakinada
Dr.D.Hemalatha	MD DA Associate professor,Eluru
Dr.K.Aparanji*	MD DA Professor,RMC, Kakinada*Corresponding Author

ABSTRACT **BACKGROUND:** Intrathecal (IT) neostigmine has been used as an adjunct to spinal anesthesia. The purpose of this study was to determine whether a combination of low-dose neostigmine IT would enhance analgesia of a fixed dose of fentanyl IT, in patients undergoing lower abdominal and lower limb surgeries **AIM:** To evaluate the analgesic efficacy of low dose intrathecal Neostigmine in combination with Fentanyl and Bupivacaine for lower abdominal and lower limb surgeries.

OBJECTIVES:

1. To compare the onset of sensory and motor blockade.
2. To evaluate the piont of maximum sensory blockade.
3. To assess the VAS pain score,first rescue analgesia time and adverse effects.

METHODOLOGY:

After obtaining approval from institutional ethics committe and informed consent,50 patients with ASA class I and II patients posted for elective lower abdominal and lower limb surgeries were selected and randomly divided into two gruops. GROUP A: Intrathecal Bupivacaine 12.5mg(2.5ml)+Fentany 20mcg (0.4ml)+ Normal saline (0.1ml) (Total 3ml). GROUP B: Intrathecal Bupivacaine 12.5mg(2.5ml)+Fentany 20mcg (0.4ml)+ Neostigmine 1mcg (0.1ml) (Total 3ml). **RESULTS:** Statistical analysis was done with paired t-test,student t test and chi square test .The p-valve $p<0.005$ was considered statistically significant.Both the groups showed statistically significant differance in terms of sensory blockade and recovery of sensory blockade.Group B showed the early onset of sensory blockade and prolonged recovery time. **CONCLUSION :** Intrathecal neostigmine precipitated the onset of motor and sensory blockade and prolongs the block significantly when used with Bupivacaine and Fentanyl in spinal anaesthesia in a low dose.

KEYWORDS : Spinal anesthesia, Fentanyl, Neostigmine, Bupivacaine

INTRODUCTION

Background

Acute post-operative pain is most commonly seen in more than 80% of patients undergoing surgical procedures under Spinal Anaesthesia.

Now a days it has become a common practice to use different therapeutic regimens for treating intra and post operative pain and increasing regional anaesthesia period.

Intrathecal opioids along with local anaesthetics prolongs the analgesia in the postoperative period.

When neostigmine given intrathecally along with opioid and local anesthetic agent, it increases the effect of opioid analgesia along with minimizing unwanted side effects.

AIM :

The present study was done with an aim to compare the analgesic efficacy of low dose intrathecal Neostigmine in combination with Fentanyl and Bupivacaine for lower abdominal and lower limb surgery.

MATERIAL AND METHODS:

Study Design : Prospective , randomized, double blind study.

Study Population : The study was conducted from July 2022 to August 2022 in the department of Anesthesiology, G.G.H, Kakinada. After getting the approval from the institutional ethical committee, 50 patients undergoing lower abdominal and lower limb surgeries were selected.

INCLUSION CRITERIA:

Age 18-60(either sex)
ASA 1&2
Elective cases posted for lower abdominal and lower limb surgeries

EXCLUSION CRITERIA:

- Patient Refusal
- Patient with allergic history to Neostigmine,Fentanyl,bupivacaine
- Patients with bleeding disorders,pregnant womens,any history of convulsions or any existing neurological conditions
- Sample size calculations was done on the basis of previous study. The primary outcome was taken as prolonged postoperative analgesia and assuming 90% of study power and 5% alpha error ; the minimum sample size was calculated to be 23 patients per group . Therefore, 25 patients in each group were taken.
- Patients were assigned randomly into two groups in a double blind manner.

Group A : Intrathecal Bupivacaine 12.5 mg (2.5ml)+Fentanyl 20mcg (0.4ml)+ Normal saline (0.1ml) (Total 3ml).

Group B : Intrathecal Bupivacaine 12.5 mg (2.5ml)+Fentanyl 20mcg (0.4ml)+ Neostigmine 1mcg (0.1ml) (Total 3ml).

Subarachnoid block is given at the level of L2-L3 or L3-L4 space. Following the block ,the patient made supine. The intra-operative data was recorded by the anesthesiologist who performed the block.

PR, BP and SpO2 were recorded at different time intervals.

A pin prick test in the mid axillary line was used to determine sensory blockade. Modified Bromage Score was used to determine motor blockade.

Sensory and motor blockade were measured every two minutes for the first 10 minutes of the procedure and then every five minutes after that.

The VAS rating approach was used to measure patient's pain levels. And subjects were monitored for other various side effects after spinal injection which include nausea, vomiting, hypotension, desaturation , bradycardia and others.

Statistical analysis:

The sample size was chosen after reviewing many randomized control studies on the same subject. The statistical evaluation was performed using SPSS version 17.0 software.

The parameters were expressed as mean ± standard deviation and t=test was used for comparing demographic and clinical data.

Analysis of variance technique was used for comparison between the two groups for parametric data.

Chi- square test was used for non parametric data.
For comparisons, P < 0.05 was considered statistically significant .

Results :

Table 1 : Demographic profile and ASA grading of patients scheduled for study were comparable.

CHARACTERISTICS	GROUP A (n=25)	GROUP B (n=25)	P VALUE
AGE (Years)	34.06 ± 13 .44	32.89 ± 12.98	0.327
SEX (M/F)	16/9	18/7	
WEIGHT (Kg)	58.83 ± 8.07	53.16 ± 5.73	0. 382
ASA GRADING (I / II)	21/4	23/2	

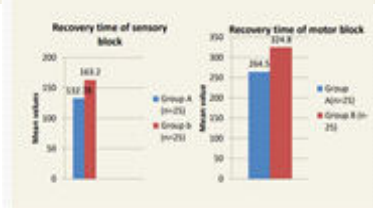
Table 2 : Sensory block onset time (in minutes)

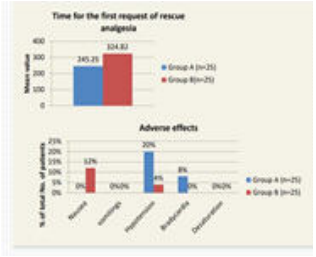
Onset time of sensory block (in minutes)	Group A (n=25)	Group B (n= 25)	P- Value
Mean ± SD	7.2 ± 0.89	3.52 ± 0.65	< 0.0001
Median	7	3	
Min-Max	6-9	2-5	

SD= Standard deviation

Table 3 : Motor block onset time

Onset time of motor block (in minutes)	Group A (n=25)	Group B (n=25)	P – Value
Mean ± SD	12.55 ± 1.92	6.84 ± 1.74	< 0.0001
Median	13	7	
Min-Max	9-15	4-10	





Discussion :

- In this study we compared the analgesic efficacy of low dose of intrathecal neostigmine in combination with fentanyl and bupivacaine and fentanyl and bupivacaine alone.
- Addition of low dose of intrathecal neostigmine is found to be producing early onset of motor and sensory blockade and prolongs the block significantly .
- The mean time for sensory block onset in group B was earlier, thus signifying that in early stages of sensory blockade, neostigmine was helpful.
- Both the groups were comparable regarding maximum sensory level when subjected to statistical analysis, (p value >0.5). No addition effect of neostigmine was seen on maximum sensory level achieved in our study .
- Neostigmine induces analgesia by inhibiting the degradation of acetylcholine. The release of nitric oxide in the spinal cord also prolongs and intensifies the analgesic effect.
- On comparing both the groups in terms of recovery time it was shown that addition of neostigmine prolonged the duration of sensory block ,similar results were shown by Jain A et al and Tekin et al in their studies.
- In this study the mean time of onset of motor block showed statistically significant differences between both the groups(P-value <0.0001) which inferred that neostigmine helped in the early onset of motor blockade . In the study of Sharma et .al the onset of motor block was 12.4 min and it was also significantly less than the control as seen our study .
- Intrathecal neostigmine induces motor block by reducing motor neuron outflow through acetyl choline, with no changes in spinal cord blood flow or histopathology. Furthermore, increased acetylcholine level in the spinal fluid can enhance the motor blockade caused by spinal bupivacaine.
- Our study showed that addition of neostigmine prolonged the duration of motor block. Jain A et,al in his study also found statistical significance between his two study groups (p-Value <0.05).
- The time for first request of rescue analgesia was significantly earlier in group A.(p-Value = 0.0001), Bhavsar M et al , showed that mean time of rescue analgesia in neostigmine, fentanyl and bupivacaine group was 476.7 min.

CONCLUSION :

Intrathecal neostigmine produced the early onset of sensory and motor blockade and prolonged the sensory and motor block significantly when used with fentanyl and bupivacaine in spinal anesthesia in a low dose.

The duration of analgesia was significantly prolonged among the neostigmine added groups as indicated by the time of first rescue analgesia.

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