Original Research Paper

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POST OPERATIVE ANALGESIC REQUIREMENT AND ADVERSE EFFECTS OF INTRATHECALLY ADMINISTERED ADJUVANTS MIDAZOLAM AND CLONIDINE WITH BUPIVACAINE

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ABSTRACT We conducted a double blinded randomized control study in 60 patients belonging to ASA I and II undergoing elective lower abdominal surgeries. Patients of both sexes ranging between 22 to 65 years of age were included. Our aim was to evaluate the effects of intrathecal midazolam 2mg and clonidine 30 mcg as adjuvant to bupivacaine for hemodynamic stability and postoperative analgesia. Patients were divided randomly using closed cover technique into two groups of 25 each.Group BM received 3ml of 0.5% heavy bupivacaine 0.4ml midazolam (preservative free) and 0.1ml of normal saline. Group BC received 3ml of 0.5% heavy bupivacaine, 0.2ml clonidine and 0.3 ml of normal saline. The total volume of the injected solution was 3.5ml in both groups. adverse effects and post-operative analgesic requirement were noted in both groups. The data collected were analyzed by Chi square test and students't' tests. In both groups, no significant changes were observed in respiratory rate, O2 saturation and sedation in our study. Intrathecal Midazolam as an adjuvant to bupivacaine comparing to Clonidine resulted in reduced post-operative analgesic requirement and reduced adverse effects

KEYWORDS : Anesthesia,Midazolam,Bupivacine,Clonidine,post-operative analgesia , adverse effects

INTRODUCTION:

Spinal anaesthesia with local anaesthetic agents is extensively used for lower abdominal surgeries. It provides the excellent pain relief as compared to intravenous or epidural route. There are many advantages for spinal anesthesia over general anaesthesia which makes it the anesthesia of choice in current surgical practice. Many clinical studies support the fact that Postoperative morbidity and mortality may be reduced when neuraxial blockade is used either alone or in combination with general anaesthesia. Since it decreases the stay, it is cost effective for both patient and hospital. It is suitable for patients with respiratory diseases and helps preventing intubation related problem like laryngospasm. It is also helpful in maintaining the airway patency and reduced blood loss. Early return of gastro intestinal function following surgery can be considered as an added advantage. Other advantage may be reduced hypercoagulable state associated with surgery, increased tissue blood flow due to sympathectomy, decreased splinting which improves oxygenation, enhanced peristalsis, and reduced stress response to surgery due to suppression of neuroendocrine system.Apart from the theoretical risk of infection to the brain, difficulty in finding the space in old age and bony abnormalities can pose a challenge to the anesthesiologist. The serious complication associated with spinal anaesthesia includes bradycardia, hypotension, prolonged motor block and high spinal. It is related to the sympatholytic effect of local anaesthetic agents. If the level of the block is higher, the sympatholytic effect will be more and leads to more serious complications. Though these effects cannot be abolished completely, they can be considerably minimized by using either low dose or low concentration of local anesthetics. One of the main disadvantages is the limited duration of block achieved with local anaesthetics.In the last decades benzodiazepines, alpha 2 agonist, acetylcholine esterase inhibitors like neostigmine and NMDA receptor antagonist like ketamine are all used as adjuvants to local anaesthetics.

Among the neuraxial adjuvants, Midazolam and Clonidine are becoming increasingly popular, because of their prolonged duration of analgesia, good intraoperative comfort like anxiolysis, sedation and sparing effect on postoperative analgesic consumption. Comparative studies with Midazolam and Clonidine as adjuvants to intrathecal bupivacaine are very few.In order to address these existing problems we need better pain management which is helpful for early recovery of motor function and reduction in requirement of postoperative analgesics.This research is designed to study the post operative analgesic requirement and adverse effects of such combination in our setup and compare the results with the previous studies done at other institutions.

AIM OF THE STUDY

To evaluate the efficacy of intrathecally administered adjuvants Midazolam and Clonidine with Bupivacaine for post-operative analgesic requirement and adverse effects of the combination

MATERIALS AND METHODS

Study Design: Double blinded randomized case control study.

After obtaining approval from the institutional ethics committee, Thanjavur Medical College, Thanjavur, the study was conducted in 60 ASA grade I or II patients undergoing elective lower abdominal surgeries like Hernia repair and appendicectomy under spinal anesthesia. Before including the patients for the study, all patients were explained about the procedures and a written informed consent was obtained.

INCLUSION CRITERIA

- Adult Patients aged 20-60 years of either sex
- ASA I & II Patients
- Weight: 35- 70 kg
- Height : 150-170 cm

EXCLUSION CRITERIA

- Infection at the site of injection
- Spinal deformity
- H/o Bleeding diathesis
- H/o Chronic pain and on analgesics
- H/o Drug Allergy.
- H/o Psychiatric illness

PREOPERATIVE PREPARATION: After routine preoperative assessment all patients were familiarized with Visual Analog Scale (VAS). The patients were shown a 10 cm long scale marked 0-10 on a blank paper and told that 0 represented “no pain” and 10 represented worst possible pain.At the patient's waiting room in the OT, basal line readings of the vital parameters were recorded. Intravenous line started. Each patient received inj. ranitidine 50 mg and inj. metoclopromide 10 mg before shifted to theatre. The patients were randomly allocated into two groups of 30 each by using closed cover technique. In the operating room, appropriate equipment for airway management and emergency drugs were kept ready. The horizontal position of the operating table was checked. Patients were shifted to the operating room and positioned.Noninvasive blood pressure monitor, pulse oximeter and ECG leads were connected to the patient. Preoperative baseline systolic and diastolic blood pressure, mean arterial pressure, pulse rate, respiratory rate and oxygen saturation were recorded. Patients were preloaded with 10ml/ kg of ringer lactate 15min prior to the subarachnoid block. The Patient was placed in right lateral position. The skin over the back was prepared with antiseptic solution and draped with sterile towel.

BM GROUP

Patients received 3ml 0.5% bupivacaine (15mg)

0.4 ml Midazolam (2 mg) preservative free
0.1 ml normal saline

BC GROUP
Patients received 3 ml 0.5% bupivacaine (15mg)
0.2 ml clonidine (30 g)
0.3 ml normal saline Lumbar puncture performed with a 25G Quincke's spinal needle at L3 – L4 inter space via midline approach. After confirming free flow of CSF, the prepared solution was injected. The patients were made to lie supine immediately after injection and the time at which the spinal anaesthesia performed was noted.

The following parameters were recorded.
- Time to first dose of Postoperative analgesic
- Total dose of Postoperative analgesic
- Systolic and diastolic blood pressure, mean arterial Blood pressure pulse rate and oxygen saturation were recorded every 2 minutes for the first 10 minutes and thereafter every 5 minutes up to one hour.
- Hypotension is said to have occurred if the MAP falls less than 70mmHg and was treated with 100% 02, increasing the infusion rate of IV fluids and inj. Ephedrine in incremental doses of 6 mg at an interval of 2 minutes.
- Bradycardia was defined as heart rate less than 60/min and was planned to be managed with intravenous atropine in incremental doses.
- Respiratory depression was said to be present if respiratory rate was less than 8 per minute and / or SpO2 <90%. It was planned to be managed with mask ventilation or intubation and IPPV.4.

RESULTS :
We conducted a double blinded randomized control study in Thanjavur medical college, Thanjavur to evaluate the effects of two adjuvants added to intrathecal bupivacaine.The collected data were analyzed by chi square test and results obtained in the form of range, mean and standard deviation. The probability value 'P' of less than 0.05 considered statistically significant.

Patient's demographic data that includes age, sex and duration of surgery between two groups were comparable.

Figure : 1 Comparison Of Time To First Postoperative Analgsia And Total Dose Of Postoperative Analgesia

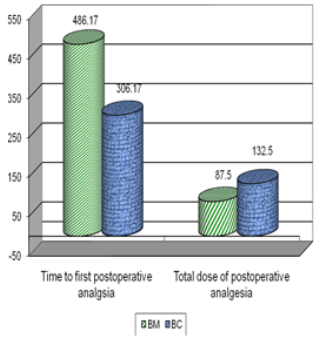

Figure : 2 Comparison Of Adverse Effects

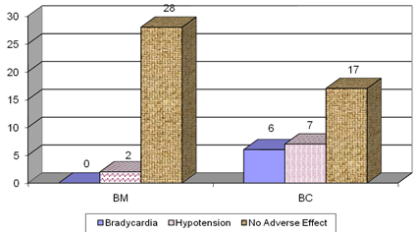

Table :1 Adverse Effects

Sl.no	Adverse effects	Group sample		Statistical inference
		BM Group (n=30)	BC Group (n=30)	
1	Bradycardia	0	6 (20%)	X2=11.467 Df=2 0.003 < 0.05 **Significant**
2	Hypotension	2 (6.7%)	7 (23.3%)	
3	No Adverse effects	28 (93.3%)	17 (56.7%)	

The incidents of bradycardia and hypotension in group BM was Significantly lower than that of group BC. Analysis was done using chi Square test. The 'P' value obtained was significant (0.003 < 0.05).

DISCUSSION
The study was conducted to evaluate the effects of intrathecal midazolam and clonidine as adjuvant to bupivacaine to assess hemodynamic stability in spinal anaesthesia. Sixty patients were randomly selected and equally divided into two groups. BM group received 3ml of 0.5% heavy bupivacaine, 0.4ml (2mg) of midazolam (preservative free) and 0.1ml of normal saline. BC group received 3ml of 0.5% heavy bupivacaine, 0.2 ml (30 mcg) of Clonidine and 0.3ml of normal saline. Prakash et al, [1]conducted a placebo controlled study to evaluate the two different doses of intrathecal midazolam (1 mg and 2 mg) with 0.5% bupivacaine (10 mg) and concluded that intrathecal midazolam 2 mg with bupivacaine provided a moderate prolongation of postoperative analgesia and reduced requirement of Postoperative analgesic supplements. M.H Kim and Y.M Lee [2] evaluated 2 mg of intrathecal midazolam with 5 mg of bupivacaine and proved prolonged Postoperative analgesia than 1 mg of intrathecal midazolam. Adam. P Tucker et al,[3] has proved that the 2 mg of intrathecal midazolam will not increase the incidents of neurological side effects. Hence in our study we have chosen 2 mg intrathecal midazolam as adjuvant with bupivacaine.Hema Suxena et al,[4] evaluated 3 different doses of clonidine (15, 30, 37.5 mcg) as adjuvant with bupivacaine (13.5 mg) in spinal anaesthesia. Even with small doses of clonidine, there was significant improvement in onset and duration of sensory and motor block with relative hemodynamic stability. They have concluded 30 mcg dose provides maximum benefit and minimum side effects. Hence we have selected 30 mcg of clonidine as adjuvant with bupivacaine for comparative study In our study the level of sensory block varied from T4 to T8 level. Among all patients, 46 patients attained maximum level of sensory blockade at T6 level. Nine patients attained up to T8 level and five patients attained T4 level. Any patient in either group does not complain of discomfort related to the sensory levels. The results of Nanji Gowda et al[5] study, has shown that 2 mg midazolam to intrathecal bupivacaine did not have any effect on peak level. In BM group the time to achieve maximum sensory level was 7.37 minutes and in BC group was 10.17 minutes.

In our study the duration of sensory block was 211.67 minutes in BM group and 156.33 minutes in BC group. This is very similar to the findings of BM groups (211.67±15.44 Vs 210.84±68.44) and BC groups (156.33±12.03 Vs 169.28±63.69.In our study, in BM group the duration of complete motor recovery was 292 minutes whereas in BC group it was 319 minutes. This shows that the duration of motor block was longer in clonidine group In our study in BC group, six (20%) patients developed bradycardia while none of the patients in BM group developed the same. Seven patients in BC group (23.3%) developed hypotension whereas in BM group only two (6.7%) patients. This shows that intrathecal clonidine had statistically significant adverse effects comparing to BM group. After administration of intrathecal midazolam, sympathetic nervous system function remains intact Hence incidence of bradycardia and hypotension were low in intrathecal midazolam. In our study also, intrathecal midazolam has better hemodynamic stability when compared to intrathecal clonidine. Adam P Tuker et al, evaluated 574 patients and observed for one month and concluded administration of 2 mg of intrathecal midazolam did not increase the neurological side effects. Shadangi et al[6], and Nanje Gowda et al [6]found no significant adverse effects in patients who received intrathecal midazolam.

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