

A Hospital Based Randomized Clinical Assessment of Intrathecal Bupivacaine (3.5ml) with Nalbuphine (0.6mg) and Intrathecal Bupivacaine (3.5ml) with Nalbuphine (1.2mg) in Lower Abdominal Surgeries

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Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to compare 0.6mg VS 1.2mg of intrathecal inj. Nalbuphine with inj. bupivacaine heavy 0.5% 3.5cc to establish the most effective dose for maximum postoperative analgesia in lower abdominal and lower limb surgeries.

Methods: The present study was conducted in the Department of Anesthesiology, Government Medical College and Hospital, Bettiah, Bihar, India from January 2021 to December 2021. 50 patients with ASA physical status I or II, aged 20-60 years, weighing 40- 80 kgs, scheduled for elective lower abdominal and lower limb surgeries, of duration less than 2 hrs, under subarachnoid block, were included in the study.

Results: The difference in mean age, mean weight and mean duration in both groups was found to be not significant ($p>0.05$). Mean duration of onset of motor blockade in Group A was 80.1 ± 11.01 seconds and in Group B it was 79.02 ± 7.98 . The difference in mean duration in both groups was found to be not significant ($p>0.05$). Two segment regression time showed that mean duration in Group A was 62.2 ± 7.1 seconds and in Group B it was 76.9 ± 6.19 . The difference in mean duration in both groups was found to be statistically highly significant ($p<0.001$). It means there is more time required in Group B as compared to Group A.

Conclusion: Intrathecal Nalbuphine (1.2mg) added to Intrathecal Bupivacaine 0.5% heavy (17.5mg) provides prolonged postoperative analgesia without increasing risk of side effects. Further studies are required to determine optimal dosage of intrathecal Nalbuphine.

Keywords: Spinal Anaesthesia; Nalbuphine; Bupivacaine, lower abdominal surgery

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Introduction

The purpose of anesthesia is to induce unconsciousness through administration of drugs. Therefore, it is fundamental to provide patients with analgesia, anxiolysis, amnesia and suppression of hormonal, cardiocirculatory, and motor responses in the surgical stress setting [1]. Prys-Roberts 2 defined anesthesia as the state in which (as a result of drug induced unconsciousness) the patient neither perceives nor recalls noxious stimuli. He further stated that analgesia, muscle relaxation, and suppression of autonomic activity are not the components of anesthesia, but should be considered as desirable supplements to the state of anesthesia as a means to enable surgery to be performed [2] Intraoperative awareness during general anesthesia (GA) is the second most common concern of patients after post-operative vomiting [3] The causes for this event are frequently a consequence of

inadequate anesthesia technique, device failure, addicted patients, excessive use of neuromuscular blocking agents, and inadequate monitoring [4] Awareness during anesthesia with intraoperative memory occurs when the patient is able to process information and produces specific responses to several stimuli [5] . The different phases of intraoperative awareness or memory are independent. Explicit or declarative memory is when the patient remembers facts, events, or experiences that occurred during GA [6] Delivery by cesarean section (CS) is by far one of the most commonly performed obstetric operations all over the world. Nevertheless, it exposes women to the inherent risk of abdominal surgery; injury to the pelvic structures, infection and the need for blood transfusion [7]. Physiologically, towards the end of pregnancy, the uterus is perfused at a rate of 500-750

ml/min⁸ this massive hyper-perfusion results in an average blood loss of approximately 1000 ml during CS [8] Many factors would be implicated to affect intra-operative blood loss during CS e.g. maternal causes; weight, parity, previous CS, fetal causes; multiple gestation, polyhydramnious, malpresentation, technical causes; operative time, type of incision, placental separation technique, placental position and the type of anesthesia. Consequently, judicious estimation of operative blood loss during CS is crucially important in terms of decreased peri-operative morbidity and avoidance of the risks associated with unnecessary blood transfusion [9] Intra-operative estimation of blood loss for CS is both poorly reproducible and typically an under-estimate [10] Therefore, comparison of surgical blood loss from one institution to another, or from one obstetrician to another is a difficult task. Various studies had been undertaken to estimate intra-operative blood loss [11]

The aim of the present study was to compare 0.6mg VS 1.2mg of intrathecal inj. Nalbuphine with inj. bupivacaine heavy 0.5% 3.5cc to establish the most effective dose for maximum postoperative analgesia in lower abdominal and lower limb surgeries.

Materials and Methods

The present study was conducted in the Department of Anesthesiology, Government Medical College and Hospital, Bettiah, Bihar, India from January 2021 to December 2021. 50 patients with ASA physical status I or II, aged 20-60 years, weighing 40- 80 kgs, scheduled for elective lower abdominal and lower limb surgeries, of duration less than 2 hrs, under subarachnoid block, were included in the study. Patients were randomly allocated to one of two groups. They received either nalbuphine 0.6 mg (group A) or nalbuphine 1.2 mg (group B) diluted upto 0.5ml with normal saline, mixed with 17.5 mg of hyperbaric bupivacaine 0.5% (3.5 ml). After

overnight fasting, all the participants were premedicated with inj. Rantac 50mg i.v. 1 hour before surgery. Patients basal vital parameters were recorded preoperatively using multiparameter monitor in the O.T. Spinal block was performed with 25G Quincke's spinal needle at the level of L3-L4 or L4-L5 intervertebral space, in the left lateral position, maintaining aseptic precautions. Following free flow of CSF, drug was injected slowly over 10 seconds and patients were immediately placed in the supine position for surgery. I.V fluids were given intraoperatively as and when necessary. The onset of sensory blockade i.e. time taken from the end of injection to loss of pin prick sensation at L1 dermatome, onset of complete motor blockade i.e. time taken from the end of injection to development of grade II motor block (modified Bromage's criteria), two-segment regression time from highest level of sensory blockade, duration of complete analgesia i.e. time from the intrathecal injection to the first complain of pain, duration of motor blockade (time required for motor blockade to return to Bromage's grade 0 from the time of onset of motor blockade) were studied and recorded. The changes in pulse rate, systolic and diastolic blood pressure, oxygen saturation (SpO₂) and respiratory rate were monitored and recorded at 0, 5, 10, 20 and 30 min and thereafter at every 30-min intervals up to 120 min after subarachnoid Block. Any side effects in the form of intra or postoperative hypotension, bradycardia, sedation, respiratory depression, nausea and vomiting and pruritus were recorded and treated. Intensity of pain was assessed by visual analogue score at 0, 10, 15, 30 and 60 minutes and then at 30-min intervals till 300 min after injection or until the patient received a rescue analgesic. Patients reporting a visual analogue score 3 or more or demand analgesia, were given rescue analgesics in the form of injection Diclofenac 1.5mg/kg IM.

Results

Table 1: Comparative assessment of both groups

		Group A	Group B	P Value
Age in years	Mean	39.2	42.46	0.51
	SD	9.96	10.8	
Weight in Kg	Mean	56.2	57.2	0.36
	SD	7.1	5.2	
Duration of surgery in minutes	Mean	89.3	88.45	0.82
	SD	15.9	15.23	

The difference in mean age, mean weight and mean duration in both groups was found to be not significant ($p > 0.05$).

Table 2: Comparison of duration of onset of motor block between two groups

	Group A	Group B	P Value
Motor blockade onset in seconds	80.1±11.01	79.02±7.98	0.86

Mean duration of onset of motor blockade in Group A was 80.1 ± 11.01 seconds and in Group B it was 79.02 ± 7.98. The difference in mean duration in both groups was found to be not significant ($p > 0.05$).

Table 3: Comparison of duration of two segment regression time between two groups

Two segment regression time in seconds		Group A	Group B	p
	Mean	62.2	76.9	
	SD	7.1	6.19	

Two segment regression time showed that mean duration in Group A was 62.2 ± 7.1 seconds and in Group B it was 76.9 ± 6.19 . The difference in mean duration in both groups was found to be statistically highly significant ($p < 0.001$). It means there is more time required in Group B as compared to Group A.

Discussion

Spinal anaesthesia is a very commonly used anaesthesia technique for various lower abdominal and lower limb surgeries. This approach has various advantages like cost effectiveness, better performance, enhanced margin of safety, and also helps in providing good post-operative analgesia. The stress response associated with general anaesthesia and side effects of various drugs used for general anaesthesia were also blunted. Various adjuvants including opioids, have been used with local anaesthetics in spinal anaesthesia to reduce complications as well as to increase peri and postoperative analgesia. Nalbuphine is a semi synthetic opioid with mixed antagonist and k agonist properties. [12,13]

The difference in mean age, mean weight and mean duration in both groups was found to be not significant ($p > 0.05$). Mean duration of onset of motor blockade in Group A was 80.1 ± 11.01 seconds and in Group B it was 79.02 ± 7.98 . The difference in mean duration in both groups was found to be not significant ($p > 0.05$). Tiwari A.K. et al [14] in 2011, did a comparative study between two different doses of Intrathecal Nalbuphine admixed with 2.5ml of Bupivacaine. They randomly allocated 75 patients to 1 of 3 groups. Group A ($n = 25$) received 2.5 mL of 0.5% hyperbaric bupivacaine + 1ml sterile water Intrathecally; group B ($n = 25$) received 2.5ml of 0.5% hyperbaric bupivacaine + 1ml (200mcg) Nalbuphine Intrathecally and group C ($n = 25$) received 2.5ml of 0.5% hyperbaric bupivacaine + 1 mL (400 mcg) Nalbuphine Intrathecally. It was found from the study that, two segment regression time of sensory blockade as well as duration of analgesia were maximally prolonged in group C compared to group A and group B ($P < 0.05$).

Two segment regression time showed that mean duration in Group A was 62.2 ± 7.1 seconds and in Group B it was 76.9 ± 6.19 . The difference in mean duration in both groups was found to be statistically highly significant ($p < 0.001$). It means there is more time required in Group B as compared to Group A. Mostafa GM. et al [15] found that 2mg of Nalbuphine when used intrathecally as an adjuvant to Bupivacaine, has produced comparatively

prolonged analgesic and motor blocking effect lasting for 8.5 ± 3.67 hours and 5.9 ± 0.9 hours respectively. Mukherjee A et al [16] in 2011, studied the effect of varying dose of intrathecal Nalbuphine (0.2mg vs. 0.4mg vs. 0.8mg) on duration of analgesia and motor blockade when used as an adjuvant to Bupivacaine. The duration of analgesia was progressively prolonged in groups 0.2mg, 0.4mg and 0.8mg with $P < 0.05$. 0.8mg recorded the longest duration of analgesia with a mean of 278.5 min compared with 237.3 min in 0.4mg. They recommend 0.4 mg as the optimal dose of Nalbuphine if used Intrathecally along with bupivacaine. The motor blockade was not altered significantly with change in the dosage of Nalbuphine. Fournier et al [17] compared Intrathecal morphine with Nalbuphine for postoperative pain relief after total hip replacement. They concluded that administration of Intrathecal Nalbuphine resulted in a shorter duration of analgesia than Intrathecal morphine.

Conclusion

Intrathecal Nalbuphine (1.2mg) added to Intrathecal Bupivacaine 0.5% heavy (17.5mg) provides prolonged postoperative analgesia without increasing risk of side effects. Further studies are required to determine optimal dosage of intrathecal Nalbuphine.

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