ORIGINAL RESEARCH PAPER
Volume - 9 | Issue - 9 | September - 2020 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

OBSERVATIONAL STUDY OF INTRATHECAL NALBUPHINE AS AN ADJUVANT TO BUPIVACAINE FOR LOWER LIMB ORTHOPAEDIC SURGERIES.

Anesthesiology

Dr. Shalini Sardesai — Dean and Professor, Smt.Kashibai Navale Medical College, Pune.

Dr. Omkar Kale* — Department of Anesthesiology, Navale Hospital Campus, Narhe, Pune - 411041 *Corresponding Author

Dr. Ashwini V. Dhuru — Department of Anesthesiology, Navale Hospital Campus, Narhe, Pune - 411041

Dr. Jyoti Deshpande — Department of Anesthesiology, Navale Hospital Campus, Narhe, Pune - 411041

ABSTRACT

Introduction: Intrathecal Opioids as adjuvants reduce the required dose of local anaesthetic agent, motor block sparing and faster recovery allowing early ambulation of patients, giving hemodynamic stability and increase the duration of analgesia[1,2]. Nalbuphine is synthetic lipophilic opioid[3] with agonist action at the κ and antagonist activity at the μ opioid receptors[4]. The subsequent systemic absorption of intrathecal opiods result in centrally mediated analgesia .

Aim: To determine that Nalbuphine is a safe intrathecal adjuvant which provides good post-operative analgesia.

Methodology: An observational study was carried out between patients of either sex, aged between 18-60 years and falling under American Society of Anesthesiologists Grade(ASA)I& II.

Results: Mean duration of analgesia was 6-8hours(417±79.34 min) and incidence of Intra-operative shivering was reduced in these patients.

Conclusion: This study proves that Nalbuphine is a safe intrathecal adjuvant which provides prolonged post-operative analgesia.

KEYWORDS

Nalbuphine, Intrathecal, Opiods, Analgesia.

INTRODUCTION:

Spinal anaesthesia is more commonly used for lower abdominal and lower limb surgery. It is economical, easy to use and has advantages over general anaesthesia[3]; however with disadvantage of short duration of action.

Regional anaesthesia may reduce the incidence of major perioperative complications with certain surgical procedures, including deep vein thrombosis(DVT), pulmonary embolism(PE), respiratory complications and death. In addition, it provides superior pain relief after orthopaedic surgery. Regional anaesthesia may provide pre-emptive analgesia, evidence exists that regional analgesia may block the progression of severe acute postoperative pain into a chronic pain syndrome.[5]

So different additives have been co-administered into the CSF in conjunction with a local anaesthetic. Their co-administration allows for a reduction in the required dose of local anaesthetic, with the advantage of motor block sparing and faster recovery while still producing the same degree of analgesia.

Intrathecal opioids are synergistic with local anaesthetics and intensify the sensory blockade during Neuraxial anaesthesia. The first report on the use of intrathecal opioids for acute pain treatment was in 1979 by Wang and colleagues. The first reported use of intrathecal morphine described by Racoviceanu-Pitesti.[6]

They are transported supraspinally by bulk cerebrospinal fluid(CSF) flow where they modulate descending inhibitory pain pathways. Their subsequent systemic absorption results in centrally mediated analgesia.

Opioids with long duration of analgesia with less adverse effect are preferred.[7]

Nalbuphine is a synthetic lipophilic opioid, structurally related to oxymorphone.

It has agonist action at the κ and antagonist activity at the μ opioid receptors. Site of action in the spinal cord is substantia gelatinosa.

So we decided to observe the efficacy of Nalbuphine is an intrathecal adjuvant to providing good post-operative analgesia.

Methodology:

An observational study was carried out between patients of either sex, aged between 18-60 years and belonging to either American Society of Anesthesiologists Grade(ASA)I or II.

Patients not giving c onsent, having coagulopathies and other contra-indications for intrathecal/spinal anaesthesia, patients with pre-existing significant systemic diseases, pregnant females, with allergy to local anaesthetics and opioids and weighing more than 100kg or less than 40kg and height less than 150cm were excluded from the study.

Work Plan:

Informed, written, consent was taken from the patient. All the patients were fasted adequately pre-operatively. Pre-medication with Inj.Ondensetron(4mg) intravenously and preloading with Ringer's lactate solution 15ml/kg over 15 min was done. Standard monitors were attached.

Spinal anaesthesia was performed in all patients in the sitting position. Under strict aseptic precautions, using 25G Quincke needle mid-line spinal puncture was performed at the L3-L4/L4-L5 level. After observing the free flow of cerebrospinal fluid, Bupivacaine 15 mg + Nalbuphine 1.6mg was administered.

Patients were then positioned for surgery.

Haemodynamic variables such as Pulse, Blood Pressure, SpO2, Respiratory rate were noted at 0mins, 5min then every 10min till end of surgery.

Intra-operative hypotension, bradycardia and respiratory depression were managed accordingly. Adequate intra-operative intravenous fluids were given.

Sensory block level (loss of pain sensation to pinprick in the midclavicular line) was measured every 1min until T10 level, and the surgeons were asked to start. Post-operatively sensory, motor blockade and VAS was assessed at 0min, 30mins, 1hr then 1hourly till 6hrs.

The data was then tabulated, interpreted and conclusions drawn.

Assessment:

- *The onset of sensory block* (time taken from injecting spinal anaesthetics to achievement of highest level of sensory blockade)
- *Maximum level of sensory blockade achieved.*
- *Complete motor blockade*(Time taken for development of Grade IV motor block, by Modified Bromage's criteria),
- *Duration of sensory blockade*(two-segment regression time from highest level of sensory blockade),
- *Duration of motor blockade*(time required for motor blockade to return to Modified Bromage's Grade I)
- *Duration of effective analgesia*(time from the intrathecal injection to the first analgesic requirement, visual analogue scale [VAS] score ≥3).
- Any *side-effects*: hypotension, bradycardia, respiratory depression (respiratory rate <10 or SpO2 <90%) nausea, emesis and pruritus were recorded and treated accordingly.

Sample Size: 40 patients were included in this study.

Type of study: Observational Study.

Observations:

Demographic Characteristics:

Demographic characteristics:	
Age	37.85 ± 23.5 years
Sex (M:F)	1:1
ASA (I:II)	11:9
BMI	24.22 ± 3.12 kg/m2

Incidence of Intra-Operative and Post-Operative Complications:

Intra-operative Complications:	
Pruritis	0
Nausea and vomiting	0
Hypoxia	0
Tachycardia	0
Bradycardia	0
Hypotension	1
Post-operative Complications:	
Nausea, Vomiting	0
Shivering	0
Pruritis	1
Respiratory Depression	0
Bradycardia	0
Hypotension	0
Sedation	0

Result:

Summary of result	
Duration of analgesia	417 ± 79.34 min
Onset of sensory block	6.47 ± 0.81 min
Time required for max sensory level	8.16 ± 1.27 min
Regression of block by 2 segment	179.75 ± 24.02 min
Onset of motor block	8.94 ± 1.27 min
Complete recovery of motor block	263.50 ± 36.34 min

DISCUSSION:

In the present observational study, we found that intrathecal Nalbuphine when added to hyperbaric bupivacaine provides prolonged sensory and motor blockade in the patients and good post-operative analgesia without any significant complications.

Highest level of sensory blockade achieved was 8.16±1.27mins. Our results were comparable with the study done by Verma et.al;[8] where they used intrathecal Nalbuphine(2mg) with 2.5ml of 0.5% bupivacaine and found that time required to reach maximum sensory level was 9.20±1.34mins. In our study, two segment regression time was found to be 179.75±24.02min. Our result were comparable with Ahmed et al;[9] They, after evaluating the potentiating effects of 3 different doses (0.8, 1.6 and 2.4mg), observed two segment regression time was maximum with 1.6mg dose.

As per Mukherjee et al;[4] and Jyoti et al;[10] most effective dose of intrathecal Nalbuphine was 0.4mg and 0.8mg respectively. Also we did a pilot study and found that 0.8mg dose was not effective and Verma et al[8] study showed best results with 1.6mg dose so we have chosen 1.6mg dose in our study.

The mean duration of motor block was found to be 263.50±36.34minutes. Similar observations were found in study conducted by Pallavi Ahluwalia et al;[11]**.** They observed duration of motor blockade in patients receiving Nalbuphine intrathecally to be 256.41±33. 41mins.

The intra-operative mean arterial pressure at baseline was 92.82±7.78mmHg. Compared to baseline values, a gradual reduction in the mean arterial pressure was observed. The mean arterial pressure at 180minutes was 86.01±4.63mmHg.

This difference was not clinically significant (Increase is not more than 20% from base line) and didn't require clinical intervention.

Comparable hemodynamic stability was observed in similar study done by Jyothi B, Shruti Gowda;[10] In a comparative study for analgesic effect of different doses of intrathecal Nalbuphine hydrochloride with bupivacaine and bupivacaine alone, Pallavi Ahulwalia et al;[11] also observed similar hemodynamic changes after giving intrathecal Nalbuphine with Bupivacaine.

Hydrophilic opioids such as morphine, demonstrate greater spread as a result of slower uptake and elimination from the CSF, hence having a greater risk of late respiratory depression than lipophilic opioids.[3] Since respiratory depression is predominantly μ receptor-mediated and Nalbuphine is a μ receptor antagonist, respiratory depression effect is expected to be attenuated by nalbuphine.[12,13] as found by Recart A et al in their study.

Romagnoli and Keats,[14] Tiwari *et al.*[15]: Nalbuphine exhibits ceiling effect for respiratory depression.

Nalbuphine has a slower onset of action as compared to Fentanyl due to its lesser lipophilic nature.[16]

Intrathecal nalbuphine has antishivering effect due to its κ receptor action.[17]as demonstrated by Ashraf M. Eskandr et aI their study.

Sapate et al.[18] in 2013 concluded that intrathecal nalbuphine added to bupivacaine provides better quality of block and longer post-operative analgesia (8–9 hours) than bupivacaine alone without any significant adverse effects.

Limitations:

1. This study is done in a limited population. Hence we recommend a multi-centric trial using a larger population.
2. The study was an observational study with no comparable group. Hence we suggest a randomized control trial with another group to justify the efficacy of Nalbuphine over other additives.

CONCLUSION:

This study proves the efficacy of Nalbuphine (1.6mg) as a safe intrathecal adjuvant.

It provides prolonged sensory and motor blockade in the patients and good post-operative analgesia without any significant complications.

Nalbuphine had an added advantage of reduced incidence of respiratory depression, nausea, vomiting and shivering over other opioids.

REFERENCES:

1. Tawfik MO. Mode of action of intraspinal opioids. Pain Rev. 1994;1:275–94.
2. Terajima K, Onodera H, Kobayashi M, Yamanaka H, Ohno T, Konuma S, et al. Efficacy of intrathecal morphine for analgesia following elective cesarean section: Comparison with previous delivery. J Nippon Med Sch. 2003;70:327–33.[PubMed: 12928713]
3. Richard Brull, Alan J.R. Macfarlane, Vincent W.S. Chan. Spinal, Epidural, and Caudal Anesthesia. In Ronald D. Miller, Neal H. Cohen, Lars I. Eriksson, Lee A. Fleisher Jeanine P. Wiener-Kronish, William L. Young (Eds) Miller's Anesthesia 8thed. Philadelphia: Saunders Elsevier; 2015.p1684-1720
4. Mukherjee A, Pal A, Agrawal J, Mehrotra A, Dawar N. Intrathecal nalbuphine as an adjuvant to subarachnoid block: what is the most effective dose? Anesth Essays Res 2011;5:171–5.
5. Michael K. Urban. Anesthesia for Orthopedic Surgery. In Ronald D. Miller, Neal H. Cohen, Lars I. Eriksson, Lee A. Fleisher Jeanine P. Wiener-Kronish, William L. Young (Eds) Miller's Anesthesia 8thed. Philadelphia: Saunders Elsevier; 2015.p2386-2406.
6. Breen TW, Shapiro T, Glass B, Foster-Payne D, Oriol NE. Epidural anesthesia for labor in an ambulatory patient. AnesthAnalg 1993;77:919-24.
7. Xavier Culebras, Giovanni Gaggero, Jiri Zatloukal, Christian Kern, and Rene´Andre´as Marti, 2000. Advantages of Intrathecal Nalbuphine, Compared with Intrathecal Morphine, After Cesarean Delivery: An Evaluation of Postoperative Analgesia and Adverse Effects (Anesth Analg;91:601-605).
8. Verma D, Nathani U, Jain DC, Singh A. Postoperative analgesic efficacy of intrathecal

tramadol versus nalbuphine added to bupivacaine in spinal anesthesia for lower limb orthopaedic surgery. J Evol Med Dent Sci 2013;2:6196-206.
9. Ahmed F, Narula H, Khandelwal M, Dutta D. A comparative study of three different doses of nalbuphine as an adjuvant to intrathecal bupivacaine for postoperative analgesia in abdominal hysterectomy. Indian J Pain 2016;30:23-8.
10. Jyothi B, Shruthi Gowda, Safiya, I Shaikh. A comparison of analgesic effect of different doses of intrathecal nalbuphine hydrochloride with bupivacaine and bupivacaine alone for lower abdominal and orthopedic surgeries. Indian Journal of Pain. 2014; 2014; 28(1): 18-23.
11. Pallavi Ahluwalia, Amit Ahluwalia, Rohit Varshney, Sunil Thakur, Shyam Bhandari. A Prospective Randomized Double-Blind Study to Evaluate the Effects of Intrathecal Nalbuphine in Patients of Lower Abdominal Surgeries under Spinal Anaesthesia. International Journal of Scientific Study. June 2015; Vol 3 Issue 3: 1923.
12. De Beer Jde V, Winemaker MJ, Donnelly GA, Miceli PC, Reiz JL, Harsanyi Z, et al. Efficacy and safety of controlled release oxycodone and standard therapies for postoperative pain after knee or hip replacement. Can J Surg 2005;48:277-83.
13. Recart A, Duchene D, White PF, Thomas T, Johnson DB, Cadeddu JA. Efficacy and safety of fast-track recovery strategy for patients undergoing laparoscopic nephrectomy. J Endourol 2005;19:1165-9.
14. Romagnoli A, Keats AS. Ceiling effect for respiratory depression by nalbuphine. Clin Pharmacol Ther 1980;27:478-85.
15. Tiwari AK, Tomar GS, Agrawal J. Intrathecal bupivacaine in comparison with a combination of nalbuphine and bupivacaine for subarachnoid block: A randomized prospective double-blind clinical study. Am J Ther 2013;20:592-5.
16. Kumkum Gupta, Bhawana Rastogi, Prashant K. Gupta, Ivesh Singh, Manoranjan Bansal, Vasundhera Tyagi, Intrathecal nalbuphine versus intrathecal fentanyl as adjuvant to 0.5% hyperbaric bupivacaine for orthopedic surgery of lower limbs under subarachnoid block: A comparative evaluation. Indian Journal of Pain.2016;30:90-95.
17. Ashraf M. Eskandr, Ayman M. Ebeid, Role of intrathecal nalbuphine on prevention of postspinal shivering after knee arthroscopy, Egyptian Journal of Anaesthesia (2016)32,371–374.
18. Sapate M, Sahu P, Thatte WS, Dubey R. A randomized, double blind, control study of the effects of adding nalbuphine to spinal bupivacaine for lower abdominal surgeries in elderly patients. Anaesth Pain Inten Care 2013;17(2):145–8.