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Efficacy of Nalbuphine versus Butorphanol as an Adjuvant in Spinal and As a Post Operative Analgesic in Patients Undergoing Lower Limb Surgeries-A Comparative Study

Dr.Pankaj Soni[1], Dr.Sakshi[2], Dr.Rajeev kumar[2]
[1]*Head of Department, Department of Anesthesia and Critical Care, EMC Hospital, Amritsar.*
[2]*Post-Graduate, Department of Anesthesia and Critical Care,EMC Hospital,Amritsar.*
[2]*Consultant Cardiovascular Anesthesia, Department of Anesthesia and Critical Care, EMC Hospital, Amritsar.*

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ABSTRACT:
INTRODUCTION- The present study compared the effect of two opioid drugs-Nalbuphine and Butorphanol as as an adjuvant for pain relief, vas score and effect of drugs in lower limb surgery.
METHODS-A total of 60 patients belonging to age group 18-55 years who were scheduled for lower limb surgeries randomly divided into two groups of 30 each. Group B for injection Butorphanol 25 mcg and Group N for injection Nalbuphine 3mg as adjuvant with hyperbaric bupivacaine in spinal anaesthesia withpost operative iv infusion of Butorphanol(2mcg/kg/hr) and Nalbuphine(50mcg/kg/hr) respectively.
RESULT-Overall, on comparison of the equianalgesic doses for butorphanol and Nalbuphine it showsgood analgesic activity of Nalbuphine over Butorphanol.

I. INTRODUCTION :

Post-operative pain give rise to various physiological and psychological problems and may prevent early mobilization and prolonged hospital stay may cause psychological and financial stress to patients..Multiplicity of mechanism involved in post-operative pain,to reduce various multimodal analgesia regimen and patient controlled analgesia are used in combination of opioids and non-opioid analgesics has become the treatment of choice for facilitating the recovery process.

Although,tradionally, mainstay of the postoperative analgesia is opioid based and regional blocks anesthesia.To enhance outcome of patient and experienceof pain free stay postoperatively. Increasingly more evidence exists to support a multimodal approach with the intent to reduce post operative complications {such as nausea,vomiting, arrhythmia) and improve pain scores and surgical outcome.

The failure to provide good post-operative analgesia is multifactorial such as insufficient knowledge, fear of complications associated with analgesic drugs, poor pain assessment and inadequate approach are among the causes. This study will focus on management of acute post-operative pain and good haemodynamic stability and surgical outcome. Recent trends in minimally invasive surgery and enhanced recovery protocols have addressed pain management in terms of these goals.

This study is conducted to evaluate postop analgesic benefits in patients administered with intrathecal and intravenousNalbuphineand Butorphanol for lower limb surgeries to compare their postoperative efficacy with respect to onset of sensory and motor blockade and duration of analgesia,VAS score and its side effects.

Nalbuphine is agonist-antagonist opioid analgesic which is also synthetically derived. It is equal in potency as an analgesic to morphine and is about one-fourth as potent as nalorphineas an antagonist. It also has minimal ceiling effect on respiratory depression. Sedation is commonly seen when used in post-operative period as an analgesic.

Butorphanol is synthetically derived agonist-antagonist opioid analgesic. It is agonist on kappa receptor and either antagonist or partially agonist on meu receptor and may reduce the efficacy of morphine or other full agonist at m receptor. It isconsidered to be more effective for visceral pain than musculoskeletal pain. Prolong use may cause mental or physical dependency.It produces respiratory depression by direct action on brain stem respiratory centres to both increase in carbon diaxoide tension and electrical stimulation.It causes reduction in motility associated with increase in smooth muscle tone at the antrum of stomach and duodenum.

II. MATERIAL AND METHODS

Study was conducted on patients as per inclusion and exclusion criteria after explaining in detail about the study protocols and procedure to all the patients and their attendents .A written informed consent was obtained. A total of 60 patients were

selected for the study and duration of study from may 2022 to may 2023. .

INCLUSION CRITERIA

a. ASA I and II patients.
b. Surgeries of the lower limb
c. Age 18-55 years old
d. Weight 40-70kg

EXCLUSION CRITERIA

1. History of drug abuse
2. Coagulopathies
3. ASA III and IV patients
4. Local infection
5. Known allergy to study drugs
6. Recent MI
7. Diabetic patients
8. Neurological diseases(stoke,seizure or any neurogical deficit)
9. Pregnant patients
10. Patient with shock and dehydration
11. Patients on antiarrythmic drugs and centrally acting drugs like antidepressants
12. Patient not willing for procedure.

Patients were randomly divided into two groups of 30 each.

- Group B - Butorphanol group
- Group N - Nalbuphine group.

Pre-anesthetic evaluation

Pre anesthetic evaluation done a day prior of surgery. Detail clinical history, general and systemic examinations was done**.** Basic laboratory investigations such as complete blood count , PTI/INR, blood sugar, Renal function test and urine analysis, electrocardiography (ECG), and chest X-ray were carried out routinely in all patients.

The patients were explained about the procedure advantage and related complication. Informed consent was taken prior to procedure. They were taught about the usage of linear visual analog scale (VAS) for assessment of the intensity of post-operative pain and were instructed to mark on the scale at the point which he/she felt was representative of their level of discomfort.

Premedication

To allay the anxiety and apprehension, all patients were pre medicated with Tablet Alprazolam 0.25 mg on the night before the surgery. The patients were also kept nil orally for 6 hrs before surgery.

Procedure Details

Venous access was secured with an 18 gauge intravenous cannula in the dorsum of the non-dominant hand. Ringer lactate solution was started at the rate of 4ml/kg/hr. Non- invasive blood pressure cuff, pulse oximeter and electrocardiography monitor (lead II and V5) were connected and basal parameters like heart rate, blood pressure and oxygen saturation were noted.

Nalbuphinegroup (Group N) received 3mg of nalbuphine (adjuvant)with 3 mL of 0.5% hyperbaric bupivacaine, Butorphanol group (Group B) received 25mcg of butorphanol(adjuvant) with 3 mL of 0.5% hyperbaric bupivacaine.

Parameters Observed and Analyzed

Pain scores were recorded. The VAS scale was used to assess pain.

Post-operative period

In the post-operative period, when the patients first complained of pain, intensity of pain was assessed using VAS scale. When the VAS score was >4, study drug was given through iv infusion.

Group N(Nalbuphine) iv infusion will be start at rate of 50 mcg/kg/hrand for Group B(Butorphanol) at rate of 2mcg/kg/hr.The intensity of pain was assessed using VAS from preoperative to 24hrs post-surgery., when the patient complained of Postoperative pain during the period of observation, intensity of pain was assessed using VAS to know the effect of the study drug given earlier. If it was >4, an intramuscular non-opioid analgesic(as a rescue analgesic) as per the institutionally approved protocol was given.

VAS consisted of a 10 cm line, marked at 1 cm each on which the patient makes a mark on the line that represents the intensity of pain he/she was experiencing. Mark “0” represents no pain and mark “10” represents worst possible pain. The numbers marked by the patient was taken as units of pain intensity.

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INTENSITY OF PAIN	LINEAR VAS SCORE
0-2	No pain to slight pain
2-5	Mild pain
5-7	Moderate pain
7-9	severe pain
10	Worst possible pain (intolerable)

Observations

1. Onset of analgesia
2. Duration of analgesia
3. Side effects such as drowsiness, nausea, vomiting.

Statistical Analysis

The mean comparisons between groups is done by ANOVA .Categorical variables are compared between groups using Chi-square test Software used was SPSS version 17. A probability level of $p < 0.05$ was considered significant.

III. OBSERVATIONS AND RESULTS

1:Comparison of study group as per age (years) and weight (kg)

The table shows comparison of study group as per age and weight.. No statistical difference was found by applying unpaired t test ($p>0.05$).

Table 1: Comparison of study group as per age and weight

Variable	Group N (Nalbuphine)			Group B (Butorphanol)			Unpaired T test	P value
	N	Mean	Std. Dev	N	Mean	Std. Dev.		
Age (years)	30	34.33	12.23	30	35.53	10.23	1.70	0.68
Weight (kg)	30	61.86	10.83	30	58.73	8.30	1.77	0.21

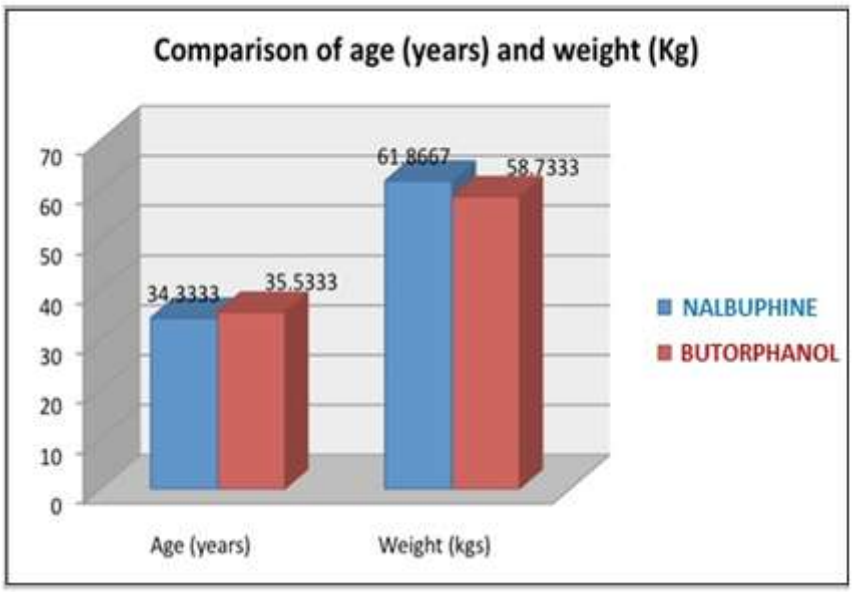

Fig 1: Comparison of study group as per age and weight

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2. Distribution of patients according to ASA Grading

Group N (Nalbuphine)had 20 patients (66.7%) with Class I grading and 10 (33.3%) patients with Class II grading, whereas Group B (Butorphanol) had 21 (70%) patients with Class I grading and 9 (30%) patients with Class II grading. The ASA Grading of the patients between two groups were comparable and statistically not significant as per Fisher's test (p>0.05).

Table 2: Distribution of patients according to ASA Grading

ASA Grading	Group N (Nalbuphine)		Group B (Butorphanol)		p Value
	N	%	N	%	
I	20	66.7%	21	70%	p>0.05
II	10	33.3%	9	30%	
Total	30	100%	30	100%	

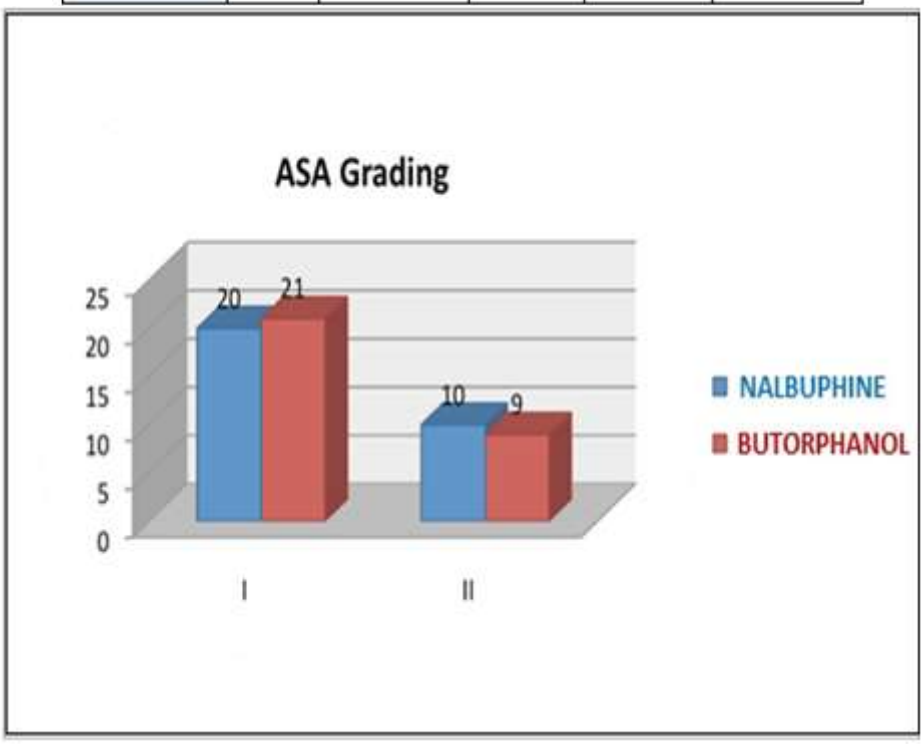

Fig 2 : Distribution of patients according to ASA Grading

3. Comparison of onset of sensory block (min) and motor block (min) among study groups

The table shows that onset of sensory blockade in group N (11.25+1.52 min) was earlier than in Group B (11.88+1.65 min). However this difference was statistically not significant after applying unpaired t test (p=0.129).Also the mean onset time for initiation of motor block was significantly lower in Group N (14.6+2.25 min) as compared to Group B (23.13+2.01 min) (p=0.01).

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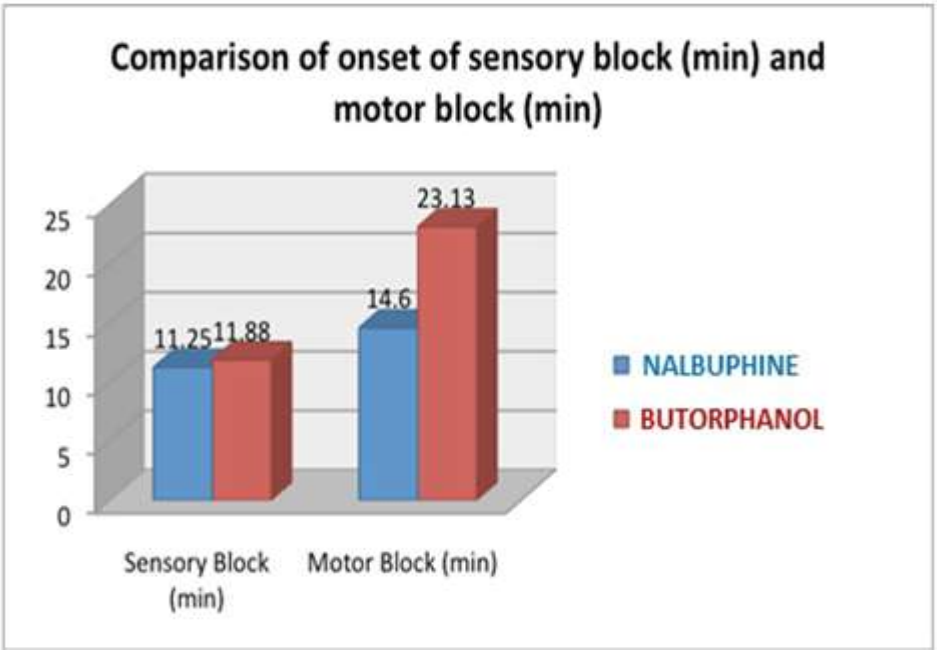
Table 3: Comparison of onset of sensory block (min) and motor block(min

Onset	Group N (Nalbuphine)			Group B (Butorphanol)			Unpaired t test	P value
	N	Mean	SD	N	Mean	SD		
Sensory Block (min)	30	11.25	1.52	30	11.88	1.65	3.12	0.129
Motor Block (min)	30	14.6	2.25	30	23.13	2.01	15.48	0.001



4. Comparison of duration (hrs) of sensory and motor block among study groups

The table shows that the duration of sensory blockade was longer in group N (12.11+0.71 hrs) as compared to group B (11.26+0.75 hrs) which was found to be statistically significant after applying unpaired t test (p=0.001).

Also the duration of motor blockade was longer in Group N (11.31+1.021 hrs) as compared to Group B (8.50+0.41 hrs) which was also found to be statistically significant after applying unpaired t test (p=0.001)

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Table 4: Comparison of duration (hrs) of sensory andmotor block among study groups

Duration (hrs.)	Group N (Nalbuphine)			Group B (Butorphanol)			Unpaired t test	p value
	N	Mean	SD	N	Mean	SD		
Sensory Block	30	12.11	0.71	30	11.26	0.75	1.68	0.001
Motor Block	30	11.31	1.02	30	8.50	0.41	12.71	0.001

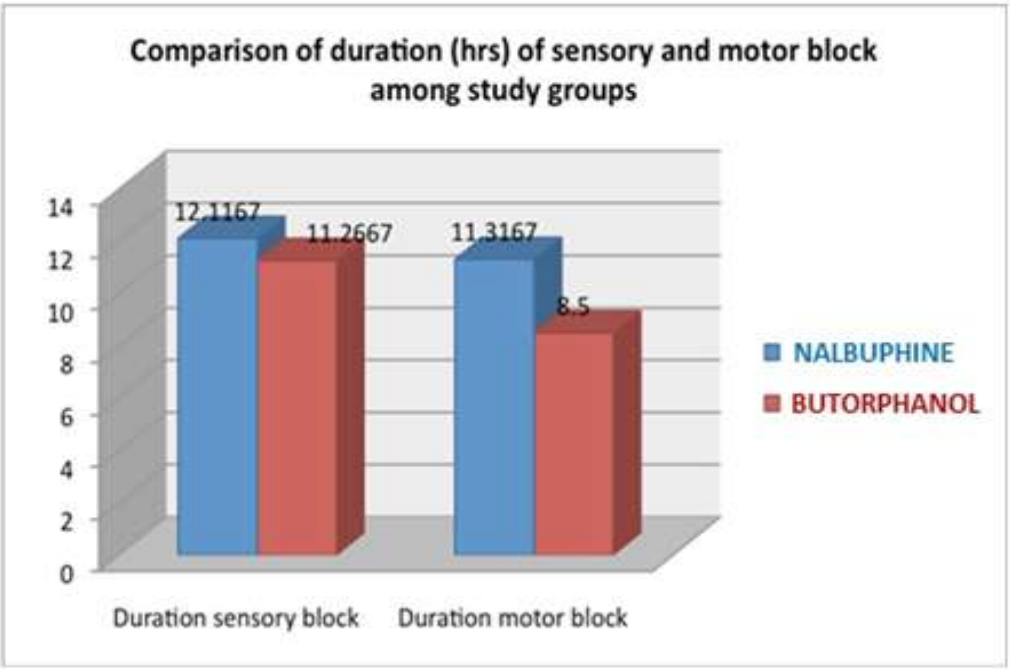

Fig 4: comparison of duration (hrs) of sensory and motor block among study groups

5. Comparison of Mean VAS Score between study groups

The post-operative pain score i.e. Visual Analogue Scores were lower in patients in Group N as compared to Group B. This difference in pain scores was found to be statistically significant especially from 8th hour onwards.

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Table 5: Comparison of Mean VAS Score between study groups

Time intervals	Group N (Nalbuphine)		Group B (Butorphanol)		p Value
	Mean	SD	Mean	SD	
Pre op	2.80	1.46	2.88	1.29	p>0.05
At incision	3.43	1.63	3.66	1.08	p>0.05
Post op	2.77	1.44	2.60	1.41	p>0.05
2 hrs Post op	2.42	1.29	2.58	0.77	p>0.05
4 hrs Post op	2.06	1.08	2.36	0.63	p>0.05
8 hrs Post op	1.24	0.58	2.10	0.84	p<0.05*
12 hrs Post op	1.46	0.73	1.85	0.76	p<0.05*
16 hrs Post op	0.85	0.44	1.12	0.66	p<0.05*
20 hrs Post op	0.61	0.71	1.28	0.78	p<0.05*
24 hrs Post op	0.34	0.72	0.96	0.86	p<0.05*

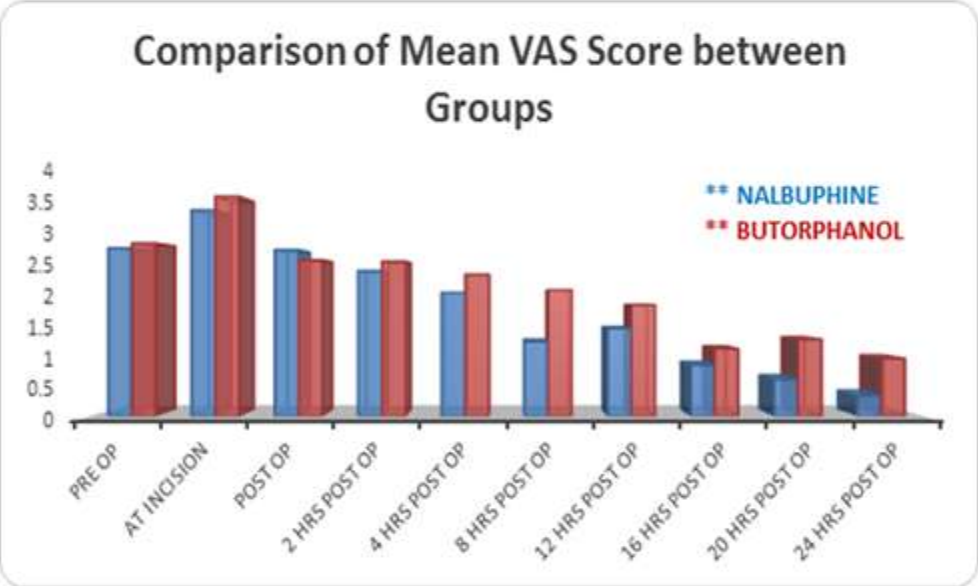

Fig 5 Comparison of Mean VAS Score between study groups

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6. Comparison of Side Effects among study groups

In Group N 3 (10%) patients had drowsiness in comparison with 4 (13.3%) patients in Group B. 6 (20%) patients in group N had nausea/vomiting as compared to 10 (33.3%) patients in Group B. There was no significant difference between the two groups as regards drowsiness and nausea/ vomiting.

Table 6: Comparison of Side Effects among study groups

Side Effects	Group N (Nalbuphine)		Group B (Butorphanol)		p Value
	N	%	N	%	
Drowsiness	3	10%	4	13.3%	p>0.05
Nausea/Vomiting	6	20%	10	33.3%	p>0.05

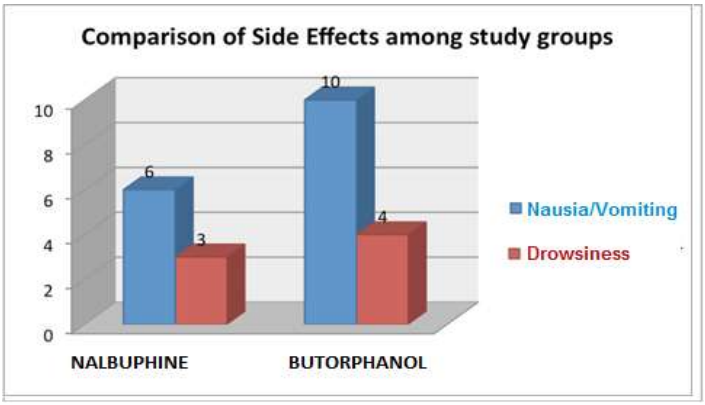

Fig 6: Comparison of Side Effects among study group

IV. DISCUSSION

Spinal anesthesia is the preferred technique for the lower limb surgeries. Opioids as adjuvants to regional anesthesia provide better perioperative sensory and motor blockade with prolongation of postoperative analgesia. Use of adjuvants such as nalbuphine and butorphanol has been very well established.[2-3]Pleasant postoperative period plays a vital role [4] in the surgical outcome reduces morbidity and prolong hospital stay.

In the present study, we compared injNalbuphine and injButorphanol as adjuvants to bupivacaine in spinal anaesthesia. , secondly we used aspost-operative intravenous analgesic in patients undergoing lower limb surgeries we did Comparison study of group as per age (years) andweight (kg)but no statistical difference was found.

Distribution of patients according to ASA grading between two groups were comparable and statistically not significant.

Comparison of Mean VAS Score between study groups post-operative pain score i.e. Visual Analogue Scores were lower in patients in Group N as compared to Group B. This difference in pain scores was found to be statistically significant especially from 8th hour onwards.

Comparison of Side Effects among study groups was done .In Group N 3 (10%) patients had drowsiness in comparison with 4 (13.3%) patients in Group B. 6 (20%) patients in group N had nausea/vomiting as compared to 10 (33.3%) patients in Group B. There was no significant difference between the two groups.

There are few studies done previously on intrathecalNalbuphine as an adjuvant. Various studies on usage of intrathecalNalbuphine (compared) by Arghya Mukherjee et al[5] ,ManishaSapate et al, compared the effect of adding 0.5 mg of Nalbuphine to spinal bupivacaine[6] , Lin et al, found that the addition of intrathecalNalbuphine 0.4 mg to hyperbaric Tetracaine, compared with intrathecal Morphine

0.4 mg for SAB, improved the quality of intraoperative and postoperative analgesia with minimal adverse effect.[7]

Recommendations

Nalbuphine and Butorphanolcould be advocated for regular postoperative analgesia due to its equianalgesic and minimal adverse effects.A pharmacogenomics evaluation could be undertaken[8].

V. CONCLUSION

The assessment of Nalbuphine and Butorphanol as a postoperative analgesic in lower limb surgeries under spinal anesthesia, was investigated. Outcomes of our study shows minor adverse effects and good analgesic activity of Nalbuphine over Butorphanol.Overall, on comparison of the equianalgesic doses for butorphanol and Nalbuphine it shows similar post-operative analgesic effect and mild sedation.

REFERENCES :

[1]. Intravenous postoperative pain management using nalbuphine and tramadol. A combination of continuous infusion and patient-controlled administration]

[2]. Singh H, Yang J, Thornton K, Giesecke AH. Intrathecal fentanyl prolongssensory bupivacaine spinal block. Can J Anaesth 1995;42:987‑91

[3]. Hindle A. Intrathecal opioids in the management of acute postoperativepain. ContinEducAnaesthCrit Care Pain 2008;8:81‑5.

[4]. Auburn F, Salvi N, Coriat P, Riou B. Sex and age related differences in morphine requirements for postoperative pain relief. Anaesthesiology. 2005; 103(1): 156-60.

[5]. Mukherjee, et al.: Optimal dose of intrathecalnalbuphine. Anesthesia: Essays and Researches; 5(2); Jul-Dec 2011.

[6]. ManishaSapate, MD, DA*, PreetySahu**, W. S. Thatte, A randomized, double blind, control study of the effect of adding nalbuphine to spinal bupivacaine for lower abdominal surgeries in elderly patients. Apicare ISSN 1607-8322, ISSN (Online) 22205799

[7]. Lin ML et al, The analgesic effect of subarachnoid administration of tetracaine combined with low dose of morphine or nalbuphine for spinal anaesthesia. Ma ZuiXueZaZhi. 1992 Jun;30(2):101-5

[8]. SapkalPravin S, KulkarniKalyani D, RajurkarSampda S, NandedkarPrerna D. Comparative study of intrathecal clonidine and intrathecalbuprenorpine for postoperative analgesia after lower limb orthopedic surgery. Int J Cur Res Rev. 2013;5:87–9