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A COMPARATIVE STUDY OF NALBUPHINE WITH BUTORPHANOL FOR IMMEDIATE POSTOPERATIVE ANALGESIA IN LUMBAR SPINE SURGERIES.

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ABSTRACT Postoperative pain is acute pain and can affect nearly every organ function and may adversely influence postoperative morbidity and mortality. Pharmacological management with intravenous opioids is a common, effective and a well known method used to treat this pain. Our study aims at comparing the analgesic efficacy of nalbuphine and butorphanol as opioid analgesics for post operative pain relief for immediate postoperative period. Material and methods: double blind, randomized controlled clinical trial, 20 patients aged 18 to 60 years, ASA grade 1 or 2, posted for lumber spine surgery surgery under general anaesthesia. Patients were randomly allocated into 2 groups, Study design: Group N (Nalbuphine) and Group B (Butorphanol). Group N received 0.2 mg/kg of Nalbuphine hydrochloride whereas group B received 0.04 mg /kg of butorphanol , intravenously prior to induction of anaesthesia. Hemodynamic parameters, postoperative analgesia, time of rescue analgesia, respiratory depression, sedation scores and side effects were studied. Pain assessed as VAS. Results: scores were not significantly different to start with (60 mins) immediate postop in both the groups (p= 0.76). They were lower in both Group B and Group N at 15, 30, 45,60, 75,90 and 105 mins. At 120 mins, there was no significant difference between the mean VAS across both the groups. No significant differences were seen in recovery from anaesthesia. No significant side effects of nausea, vomiting, and respiratory depression were noted. Excessive sedation were noted in group B which was significant(p = 0.036). Conclusion: both butorphanol and nalbuphine provide excellent analgesia in immediate post operative period except that butorphanol causes excessive sedation specially in elderly age group.

KEYWORDS : Nalbuphine, Butorphanol, Immediate Postoperative Period, Lumbar Spine.

INTRODUCTION:

Perception of pain is a major concern for most of the surgical patients. Postoperative pain is an acute pain which initiate a systemic stress response that encompasses a wide range of neuroendocrine, immunological, and haematological responses. The overall metabolic effect is one of catabolism of stored body fuels . Despite the efforts and innovations in pain management, many patients continue to experience intense pain after surgery. Modern day anaesthesia is not just concerned with relieving pain but also to improve quality of life of the patient and fast recovery and thus to reduce medical cost. Opioids have long been the mainstay of therapy for the treatment of acute postoperative pain, especially for moderate to severe pain. However, the use of mu agonists like morphine may result in serious side effects e.g. pruritus, urinary retention, nausea and vomiting and delayed respiratory depression.(1). These side effects may lead to patient discomfort and prolonged hospital stay thus limiting their usefulness for postoperative pain. Nalbuphine and Butorphanol are partial agonist–antagonists, having agonist action on kappa receptor and antagonistic or partial agonist property at mu receptor. Benefits of a partial agonist include analgesia with a decrease in unwanted side effects, such as respiratory depression. They can be given through intramuscular, intravenous, epidural, and transnasal routes. They are widely available without restriction as compared to some of the potent opioids like morphine or fentanyl, specially fentanyl which is highly lipid soluble (2). Various modalities have been tried for the management of postoperative pain out of which intra vascular injectable opioids is an established and accepted technique. However, the use of opioids is associated with an increased risk of hypoxemia and apnea which is undesirable for geriatric patients (3).

AIMS AND OBJECTIVES:

To compare the analgesic efficacy and other effects of Nalbuphine and Butorphanol, administered intravascular, in postoperative patients who have lumber spine surgeries under general anaesthesia.

MATERIAL AND METHODS:

After obtaining institutional ethical committee approval and written informed consent, forty adult patients of ASA class 1 and 2, weighing 45 to 70 kgs of either sex, belonging to 21-60 years of age, posted for elective lumber spine surgery. Patients with ventricular dysfunction, coronary insufficiency, valvular heart diseases, hypertension, physical dependency on opioids, and history of drug allergy, bronchial asthma, COPD, renal and hepatic diseases were excluded from study. Patients were premedicated with 0.25 mg of oral alprazolam given on the night before and on the morning of surgery. Patients, after being shifted to the operation theatre, were subjected to monitoring of ECG, pulse oximetry, and noninvasive blood pressure and continued into postoperative period. Visual Analogue Scale (VAS) was used to assess the intensity of pain and pain relief. Before the surgery patients were shown a VAS scale consisting of a 10cms`line with 0 being no pain and 10 being worst pain ever felt and they were asked to express the intensity of pain on the scale. The patients, when they first complained of pain, were asked to express the intensity on the pain scale. When it reached 5 mark on the scale, patients in Group N received IV Nalbuphine 10mg and patients in Group B received IV Butorphanol 2mg. Intensity of pain was assessed at every 30 minutes for 2 hours in post operative period. Duration of analgesia is time interval between the start of analgesia (i.e when the VAS score is at 5), till the patient complaints of pain (i.e when VAS score is >5) when rescue analgesia was given.

The following parameters were recorded 1. Onset of analgesia 2. Duration of analgesia 3. Quality of analgesia: assessed by pain score 4. Cardiorespiratory effects: mean blood pressure. Statistical analysis

Continuous data was analysed by student t-test and categorical data by Chi-square test. Any possible significance has been determined considering it statistically significant if the p<5% level of significance.

Observations and Results Demographic data: minimum age of the patients in this study was 21 and maximum being 60 years. The mean age of the patients in group N was 40.66± 8.90 and in Group B was 40.70 ±10.69. In both groups both male and female patients were equally distributed. Both groups were comparable with regard to age, sex, weight and height distribution.

TABLE 1: Demography

sno	Group N	Group B
1	52	40
2	41	49
3	33	29
4	36	64
5	40	41
6	55	50
7	28	45
8	45	42
9	48	28
10	50	64
11	51	38
12	56	57
13	66	23
14	62	33
15	47	32
16	48	60
17	35	58
18	34	53
19	41	48
20	45	45
mean	45.65	44.94
SD	9.9	9.91
p	0.86	

TABLE 2: Analgesia.

	onset (min)	duration (hr)
Group N	6.23±2.12	7.34±1.02
Group B	4.21±1.32	5.11±1.45
p value	0.022	0.93

TABLE 3: VAS Mean.

VAS	Group N	Group B
0-2	4	2
2 to 4	15	16
4 to 6	1	2
6 to 8	0	0
8 to 10	0	0

TABLE 4: Hemodynamic Parameters.

Time (sec)	mean BP Group B	mean BP Group N	p value
0	94.23±5.02	98.4±2.11	0.001
15	82.12±3.67	90.11±3.08	0.00001
30	80.87±1.32	84.31±3.17	0.0002
45	76.72±4.65	81.11±5.37	0.09
60	78.17±2.32	80.65±4.77	0.04
75	76.22±3.68	78.61±4.23	0.06
90	75.44±3.76	76.35±5.22	0.53
105	75.03±2.31	77.81±3.47	0.005
120	74.66±4.19	75.24±4.62	0.67

The onset of analgesia was 6.23 sec in group N where as in group B was 4.21 which was statistically significant with p value .022. The total duration was 7.34 in group N as compared to 5.11 sec in group B. The mean pain score was comparable in both the groups.

There were more fall in mean blood pressures in group B As compared to group N in early minutes.

DISCUSSION :

Management of postoperative pain in lumber spine surgeries remain a challenge. It is inevitable to nullify any pain or discomfort after surgery. There is always some pain or discomfort after any type of surgery. In ancient times, opioids has been considered as back bone of analgesia. The newer opioids like butorphanol, nalbuphine, buprinorphine, fentanyl etc has become more user friendly in terms of use and availability.

In this clinical study the efficacy and safety of equianalgesic doses of IV Nalbuphine and compared with IV Butorphanol in the management of postoperative pain after lumber spine surgeries. There was no significant difference in the demographic profile of the patients in the study. The onset was faster in group B with significant results.

Analgesic effects of both the groups were comparable. A study, in patients undergoing surgery, reported duration of analgesia in Butorphanol Group and Nalbuphine Group was 253.33±34.97 and 327.33±42.99 min. respectively which is statistically significant (p<0.05) (4). Del Pizzo found the duration of analgesia provided by intravenous Butorphanol to be about 2 hour (0.5 mg dose) or 2-4 hours (1-2 mg dose) (5). Both these studies were consistent with our study.

In our study sedation was more in Butorphanol group (62%) when compared to Nalbuphine group (20.2%) and this was statistically significant. At no occasion did the severity of sedation evoke concern on the possibility of the patient going into respiratory depression. Sedation is unavoidable side effect of both Butorphanol and Nalbuphine when given in adequate doses with possible peak plasma concentrations of the drug at 60 to 180 minutes. Such sedation relieves surgery related anxiety, provides the much needed comfort for a post-operative patient and should therefore be considered a beneficial effect of the study drug.

Safety of Nalbuphine was been widely accecpted in many studies, producing beneficial sedation which was maximum at 60 min after injection. Increasing the dose of Nalbuphine from 10 mg to 20 mg produced no significant additional sedation or intraoperative benefit (6) (7). At equipotent doses,we can conclude that butorphanol provides longer duration of analgesia but at the cost of excessive sedation as compared to nalbuphine.

Conflict of interest: none.

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