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COMPARATIVE STUDY OF INTRAVENOUS NALBUPHINE VERSUS INTRAVENOUS TRAMADOL FOR POSTOPERATIVE ANALGESIA EFFECT IN ADULT PATIENTS UNDERGOING ELECTIVE SURGERIES UNDER GENERAL ANAESTHESIA: A PROSPECTIVE, RANDOMIZED DOUBLE- BLINDED STUDY

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ABSTRACT

Aim: To compare the efficacy intravenous nalbuphine versus intravenous tramadol for the postoperative analgesia.

Materials and Methods: In this prospective randomized study 60 adult patients with the ASAI &II undergoing elective surgeries performed under general anesthesia duration <90 min received either intravenous nalbuphine (0.25mg/kg)or tramadol (2mg/kg).Visual analog scale(VAS) scores for pain and sedation, nausea and vomiting were also compared for 8hours between both groups.

Results: VAS score were not significantly different upto 2nd postoperative hour but after that VAS score were significantly low in nalbuphine group. Mean sedation scores were significantly more at 2nd&4th postoperative hour in nalbuphine group. Side effects like nausea, vomiting were significantly more in tramadol group.

Conclusion: Nalbuphine is better analgesic than tramadol as it provides better relief of postoperative pain with good sedation and lower incidence of PONV.

KEYWORDS : Nalbuphine, tramadol, postoperative analgesia, VAS.

INTRODUCTION

The surgical stress response maximum during the postoperative period. A pain and stress free postoperative period definitely helps in early mobilization and recovery ,hence decrease morbidity and mortality. Some examples of analgesics are opioids (such as morphine, buprenorphine, butorphenol,nalbuphine and fentanyl), NSAIDS (such as carprofen, meloxicam, ketoprofen) and NDMA receptor antagonists (ketamine)etc. Nalbuphine is a synthetic opioid analgesic. It is an agonist-antagonist opioid analgesic with cardiovascular stability [1,2]and lesser potential for respiratory depression.[3] Tramadol has dual mechanism of action, it acts on opioid receptors as well as inhibits neuronal uptake of norepinephrine and serotonin. Due to non-opioid action, tramadol has lesser risk of producing respiratory depression than other opioids.[4] However, has higher incidence of nausea and vomiting.[5]

MATERIALS AND METHODS

After clearance from Ethical Committee of the institute, the study was conducted at Department of Anaesthesiology, G.S. Medical College,UP.

After written and informed consent 60 ASA class I & II adults (20 -50 years) posted for elective surgery under general anaesthesia, duration<90min were included while patients with Mallampati grade III &IV, with any other comorbidities (COPD, IHD, HTN, DM), morbid obesity, pregnancy, could not be intubated within 15 sec of laryngoscopy and who did not give consent were excluded.

A night before surgery the patients were visited for pre-anaesthetic review and standard institutional preoperative advice was given. The patients were randomly divided into two groups (T & N) of 30 patients each. Randomization was performed by computer generated random numbers. This was done by an anesthesiologist who was unaware of the study protocol and was not involved in administering the drugs or observing results.

In the operating room, an 18G IV cannula was secured and infusion of Ringer lactate was started at 10 mL/kg/h. Standard monitoring including pulse oximetry, ECG,and noninvasive blood pressure was attached .All patients received premedication with Ivglycopyrolate0. 004mg/kg, IV midazolam(0 .05mg/kg) and fentanyl 1 mcg/kg. All patients were preoxygenated with 100% oxygen for 3 min and general anesthesia was induced with IVpropofol 2.0 mg/kg. After loss of response to verbal commands, IV succinylcholine 2mg/kg was given as per standard protocol and intubated . Patients were put on controlled ventilation. All patients received IVvecuronium 0.08 mg/kg for muscle relaxation and maintained on intermittent bolus doses of vecuronium 0.02 mg/kg as per requirement along with O2 ,NO2 and isoflurane 1%–1.5% .Before half an hour of completion of surgery study drug was given.

Group T-received inj tramadol 2mg /kg IV

Group N – received inj nalbuphine 0.25 mg/kg IV

The study solution was prepared by a person who was not a part of the ongoing study. Both the study drugs were diluted to 100 ml of normal saline before administration. After completion of surgery, residual neuromuscular blockade was reversed with IV neostigmine 0.05 mg/kg and IV glycopyrrolate 0.01 mg/kg. Patients were extubated after complete clinical recovery and were shifted to postanesthesia care unit. Immediately after extubation (0hr),VAS score and haemodynamic parameters were recorded. The patients were then transferred to the postoperative recovery room and all the parameters required for our study were recorded by the blinded investigator .In postoperative recovery room, patients were enquired about the pain and was recorded using VAS which was explained to them during their preanaesthetic visit.VAS score was recorded at regular intervals (1,2,3,4,6,8hrs)and the patients were given rescue analgesia with Inj. Diclofenac 75 mg IV when VAS score reached>3. The time for the first dose of rescue analgesia(duration of analgesia) was recorded in both the groups.

Sedation level was assessed using Pasero Opioid-induced Sedation scale in postoperative period which is as follows:1- awake and alert; 2- slightly drowsy, easily aroused;3-frequently drowsy, arousable, drifts off to sleep during conversation; & 4- somnolent, minimal or no response to verbal or physical stimulation. Most common side effects of opioids like nausea, vomiting, respiratory depression and pruritis were also noted.

Statistical analysis

Statistical analysis was done by chi-square test and unpaired t- test and results were expressed in mean ± S.D. P-Value <0.05 was considered significant. The data was analysed with the help of computer software MS Excel and SPSS 19.

RESULT

In our study demographic data (age, sex, ASA grade) and duration of surgery were comparable and statistically insignificant between both groups (P>0.05)(table 1). There were no significant variation in intraoperative and postoperative hemodynamic parameters between the groups.

Postoperatively pain scores on VAS were low in nalbuphine group in all study timings, but upto 2 hours difference was insignificant and become significant(p value<0.05) after that as comparison to tramadol group (Table-2).

Postoperative sedation score was comparable between group N and group T at 1st hour but mean sedation scores were significantly more in group N at 2nd and 4th hour, none of the patients of either group had sedation score more than 2(Table-3).

Postoperative Mean duration of analgesia (Ist dose of rescue

analgesia) was significantly more in group N (6.3±0.7 hour) compared to group T (5.7±1.2 hours).

Significant difference in incidence of nausea and vomiting was noted between the groups, only 2 patients in group N had nausea but no vomiting while in group T 7 patients had nausea and 5 patients had vomiting. No other side effects were noted in either group.

Table 1: **Demographic data (age, sex and weight distribution) and duration of surgeries**

	Group T	Group N
Age(years)	32.60±16.25	35.62±18.22
Sex	18:12	20:10
Weight(kg)	51.90 ± 11.05	53.80 ± 14.69
Duration of surgery(min)	81.33± 0.42	79.42± 0.57

Table-2: Postoperative visual analogue scale (VAS)score (Mean ± S.D)

VAS	Group N	Group T	P value
Just after extubation	0.36± 0.52	0.47± 0.36	0.18
1st hour	0.44±0.32	0.56±0.27	0.12
2nd hour	0.59±0.38	0.68±0.25	0.28
3rd hour	0.61±0.51	0.89±0.42	0.04
4th hour	0.84±0.31	1.05±0.43	0.03
6th hour	1.29±0.67	1.68±0.52	0.01
8th hour	2.31±0.73	2.82±0.99	0.02

Table –3 Postoperative sedation score

Sedation score	Group N	Group T	P value
After 1st hour	1.06± 0.58	0.86 ± 0.62	0.20
After 2nd hour	0.90 ± 0.54	0.6 ± 0.56	0.030
After 4th hour	0.6 ± 0.56	0.26 ± 0.44	0.010

DISCUSSION

Postoperative pain is a main concern among most of the patients undergoing surgical procedures, as inadequate pain relief can cause morbidity, unusual longer stay and may also adversely affect their quality of life and functions. Many analgesics have been used for this. Morphine is the standard opioid analgesic used for this purpose. However due to its intolerable side effects like nausea, vomiting, pruritis etc, many other drugs have been tried.

In an attempt to provide analgesia without the unwanted side effects of the pure agonists, Nalbuphine was evolved. Nalbuphine is a synthetic opioid which has both agonist and antagonist properties on opioid receptors. It acts on both mu (partial agonist) and k–receptors(antagonist) that results in its analgesic and anti-pruritic effects. It also exhibits ceiling effect for respiratory depression. [7] It is commonly used nowadays for treating postoperative pain.

Unlike other opioids the availability of nalbuphine is made easy since it does not require narcotic licence.

Tramadol, a synthetic opioid of the aminocyclohexanol group is a centrally acting analgesic with weak opioid agonist properties and effects on noradrenergic and serotonergic neurotransmission. These opioid & nonopioid modes of action appear to act synergistically. Tramadol also has been shown to provide effective analgesia for postoperative pain.

Many studies have been done to know the efficacy of nalbhupine in the field of anaesthesia especially in intraoperative and postoperative period. Khalid et al compared tramadol in dilatation and evacuation and found nalbuphine had better pain control than tramadol[4**].**

In our study pain scores on VAS were satisfactory law in both groups but it became significantly less in nalbuphine group after 2nd postoperative hours, means nalbuphine had better pain control than tramadol. Bone ME et al compared nalbuphine and fentanyl and found nalbuphine had significantly lower pain score than fentanyl.[6]

In our study postoperative sedation score was insignificant at 1st hour between the groups while significantly more in nalbuphine group at 2nd and 4th hours. RN Solanki et al has done a comparative study between intravenous nalbuphine and intravenous tramadolin patients undergoing surgeries under regional or general anaesthesia. IV Nalbuphine0.15 mg/kg and IV tramadol 0.2 mg/kg was used. VAS scores, sedation score and total number of rescue analgesics were noted at regular intervals. They concluded that Nalbuphine is betteranalgesic for the relief postoperative pain , provides good sedation, hemodynamic stability and lower incidence of nausea & vomiting .

In a similar study done by Jitesh kumar et al. inj nalbuphine 0.25mg/Kg and inj. tramadol 2 mg/kg have been compared in short surgical procedures. Both drugs were given 5 minutes before induction and postoperative VAS score, haemodynamic parameters, sedation scoring were noted. They have concluded that nalbuphine is better analgesic than tramadol for short surgical procedures, and provide good sedation, hemodynamic stability and lower incidence of PONV.

A comparative study among patients undergoing gynecological laparotomies reported that those in the tramadol group needed lesser rescue boluses and less amount of medicine during initial 12 h after surgery as compared to nalbuphine group.[7] However, in another study[5] among patients undergoing orthopedic procedures, use of rescue medicine was higher in the tramadol group as compared to nalbuphine group when given eight hourly.

Similar to other studies we also observed higher rate of nausea and vomiting in tramadol group. Pang ww et al. have reported more nausea & vomiting in Tramadol than Morphine (40 % vs. 11%) & (28% vs. 5%). [8] In a study done by FNMinai et al., less number of patients had nausea &vomiting in Nalbuphine group compared to Morphine.[9]

CONCLUSION

Post operative pain relief is a key to the earlier recovery. Good postoperative analgesia results in better surgical outcome, lessens the duration of hospitalization and hence early discharge of the patient. In our study both drugs can be effectively used to treat postoperative pain although Nalbuphine appears to be better analgesic for the relief of postoperative pain. It also provides good sedation and lower incidence of nausea & vomiting as compared to Tramadol.

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