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A COMPARATIVE STUDY OF INTRAVENOUS NALBUPHINE VERSUS TRAMADOL FOR POSTOPERATIVE ANALGESIA IN PATIENTS UNDERGOING LOWER ABDOMINAL SURGERIES UNDER SUBARACHNOID BLOCK

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ABSTRACT Tramadol is a weak opioid agonist and is used in mild to moderate pain relief. Nalbuphine is a newer opioid drug with antagonism at μ receptor and agonism at κ receptor. The aim of this study was to compare the analgesic efficacy and side effects of these two drugs.

KEYWORDS : Nalbuphine; Tramadol; Postoperative analgesia.

INTRODUCTION:

Although pain is a predictable component of the postoperative experience, inadequate management of the pain is very common. This is confirmed by many recent studies.[1,2,3] The untreated post-operative pain may result in altered physiological and psychological changes that increase morbidity and mortality in patients. In our randomized study, we were able to demonstrate the comparative analgesic efficacy and safety profile of the nalbuphine vis-à-vis the commonly used drug tramadol, both administered intravenously.

Most of the opioid agonists are suitable to treat acute pain. However their use is not always without side effects. Nausea, vomiting, pruritis, excessive sedation and respiratory depression limit their generous use in treating the patients with acute post-operative pain[4,5,6]. Also, opioid agonists are limited by their availability in recent days[7].

Tramadol is a weak agonist at μ opioid receptor and is commonly used to treat post- operative pain in the dose of 1-2mg/kg. However, analgesic effect in patients of post-surgical period is not always proved to be adequate at its regular dosage. Wei-Wu Pang and colleagues showed that tramadol PCA can provide effective analgesia following major orthopedic surgery provided if sufficiently high doses are given as loading dose and by patient demand. They observed the higher incidence of nausea and vomiting and also thus a decreased patient satisfaction in these patients where such high doses were used.[2]

W.T Beaver an G.A Feise demonstrated that nalbuphine is almost equipotent with the morphine.[3] We used nalbuphine at the dose of 0.1mg/kg and tramadol at the dose of 1mg/kg which is similar to the doses used by other authors.

AIMS AND OBJECTIVES:

To compare the analgesic efficacy of tramadol with nalbuphine in the postoperative period.

MATERIALS AND METHODS:

This study was approved by Institutional ethical committee of AJ institute of medical sciences. Fifty patients undergoing lower abdominal surgeries were randomized into two equal groups of 25 each – group N and group T.

Inclusion criteria was patients of ASA grade 1-2 between the age group of 35-60 yr posted for lower abdominal surgeries.

The study was done was done from Nov 2016 to April 2018.

EXCLUSION CRITERIA:

1. Patients allergic to the study drugs.
2. Patients on
- oral anticoagulant therapy.
- neuroleptic agent.
- Mono amino oxidase inhibitor.

All patients were explained about the use of Visual analogue pain scale (VAS) and descriptor words of pain in a language familiar to the patient. The pain assessment was carried out using numeric visual analogue scale and verbal category scale which are described below.[4]

Visual Analogue Scale; VAS is a 10cms line anchored at the two end points "no pain" and "pain as bad as it can be". The patient is asked to place a mark on this line indicating the intensity of the pain. The VAS score is determined by measuring the distance in cms from the end signifying "no pain "to the point indicated by the patient on this scale.

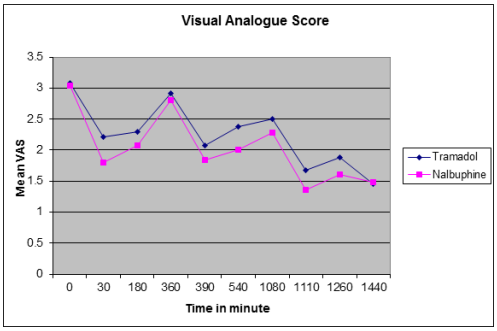
Verbal category scale; Verbal category scale consists of a series of words subjectively describing pain intensity and unpleasant experiences. The patient is asked to select one adjective that best describes his/her pain or feeling. As per the description the patient is classified into no pain, mild, moderate, severe pain category which is numbered 0,1,2,3 respectively.

Assessment of sedation was done using 4 point scale as follows

RESULTS:

Visual analogue score

Comparison of VAS score revealed that mean VAS score for nalbuphine group was lower than tramadol group throughout study period. But the difference was significant at only two intervals. At 30minute the mean VAS score for group T was 2.20±.41 versus 1.80 ±50 in group T (p=.003). Similarly at 540 min the VAS score was 2.38±.58 for tramadol versus 2.00±.29 for nalbuphine (p=.006).

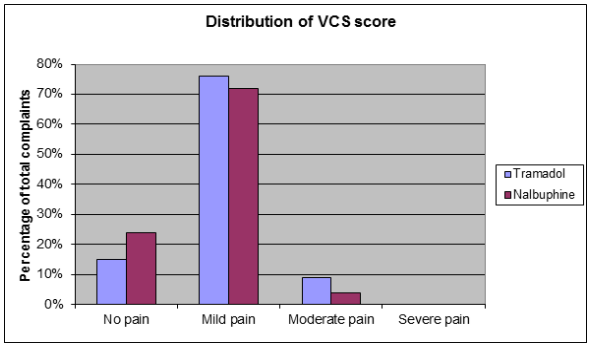


Verbal category score

The difference was significant at 30min and 540min and also at 1260 minute. Five patients complained no pain and 19 complained mild pain in group T versus 10 complained of no pain and 15 complained mild pain in group N at 30min.(p=0.046). Twenty two patients complained of mild pain and 2 complained of moderate pain in

group T where as in group N 5 patients complained of no pain and 20 complained of mild pain at 540min.(p=0.026). Similarly at 1260min 3 patients complained no pain and 21 complained mild pain in group T versus 10 complained no pain and 15 complained mild pain in group N (p=0.029).

Out of 240 complaints recorded in group T 37(15%) complaints were no pain, 182 (76%) complaints were mild pain, 21(9%) complaints were moderate pain. In group N recorded complaints were 250 out of which 60 (24%) were no pain, 179 (72%) were mild pain, 11 (4%) were moderate pain. The difference was statistically significant (p=.015).



DISCUSSION:

In our study, we selected the patients who received spinal anaesthesia and none other techniques of regional anaesthesia. This is important with respect to the analgesic effects observed during postoperative period. Had such situation arise, it might have influenced our study by a possible uniformly decreased pain scores expressed by the patient and thus a falsely high efficacy of study drugs. Left aside, we have administered analgesics only when spinal anesthesia effect is wore off, and patients complain of pain by VAS score of 2 to 3. All our patients had VAS scores of either 2 or 3 at the time of administering the analgesic injection. The time lag for developing this score varied between the two study groups. This may be related to the various factors affecting spinal anesthesia. and the duration of the surgical procedure. However this time-lag factor should not affect the outcome of study since the analgesia was administered and recording of parameters commenced only at a specific point (VAS pain scores 2 or 3), when the anaesthetic effect would have worn out. Because the plasma concentration achieved with intrathecal injection of bupivacaine is insignificant and no other drug is given intraoperatively, the possibilities of any drug interactions or influences with study drug are remote.

The assessment of pain in our study was by self reports of pain. These self reports are important components in evaluating treatment effectiveness. Clinical researchers have demonstrated that valid self reports of pain are useful in treating patients suffering from acute or chronic pain.[4]

Our study shows that pain relief with the nalbuphine is marginally better than tramadol throughout the study period. The observed VAS scores were lower in both groups at 30min after initial bolus dose. This is because the rapid onset of analgesia after their intravenous administration producing similar actions in lowering VAS scores. The observed statistical difference may be due to difference in the peak actions of two different drugs. However, the effects were similar at 180 and 360 minute of administration (p>0.05). The claimed duration of action of both the drugs were about 5-6 hours, thus may be responsible for lower but equal VAS scores in our patients.

All patients received analgesic drugs at regular intervals of 6hours. The assessment of pain revealed low VAS scores at 30 minute after each dose compared to other various time intervals owing to higher plasma levels of respective drugs after intravenous administration.
Assessment of pain at intervals during 180, 360, 390, 1080, 1110, 1260, 1440 minutes showed equal analgesic efficiency of drugs claiming the intravenous nalbuphine had similar analgesic actions to that of tramadol. Except for assessment at 30th minute and 540th minutes (only 2 assessment intervals among total 10) there were no statistically significant differences in analgesic actions were observed in our study, indicating equal analgesic efficacy of both drugs in our patients.

The assessment of pain were not possible in all patients from 540th minutes till 1080th minutes, as this was sleeping hour of the patients and thus could not be assessed. We believed patients were relieved of pain otherwise an additional analgesic was demanded. No patient required additional analgesics during sleep hours of the study.

Second method of pain assessment (VCS) too had similar observation except at 1260th minute. A single deviated observation will not affect the outcome of the study and may be bias induced. Out of 240 observations of VCS in tramadol 'no pain' was 37 (15%) in number in contrast to 60 (24%) out of 250 in nalbuphine (p<0.05) (table 9 and figure7). This proves the marginal superiority for nalbuphne over tramadol.

CONCLUSION:

Nalbuphine at the dose of 0.1mg/kg I.V. had marginally superior analgesic action than tramadol 1mg/kg I.V. Incidence of nausea and vomiting was seen more in tramadol. Nalbuphine had more sedative action with comparable effect on respiratory depression which is beneficial in stress full postoperative period and it can be used for postoperative pain relief in patients undergoing lower abdominal surgeries.

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