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Original Research Article

A prospective randomized study to compare tramadol and morphine for postoperative analgesia in spine surgeries using intravenous patient controlled analgesia

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ABSTRACT

Background: Spine surgeries particulary spine fusion surgeries provide a unique challenge with respect to postoperative analgesia as the choices to provide analgesia are limited. Uses of NSAIDS and neuroaxial anaesthesia for post-operative analgesia in spine surgeries have been controversial. Patient controlled analgesia with opioids is commonly used and morphine remains the gold standard. The aim of this study was to compare tramadol with morphine for postoperative analgesia in spine surgeries using iv patient controlled analgesia.
Methods: A total of 80 adult patients of ASA grade I and 2 undergoing spine surgeries and divided into two groups i.e. morphine group M and tramadol group T with 40 patients in each group were included in the study. pain assessment was done by NRS (numeric rating scale) upto 48 hours postoperatively other parameters like nausea/vomiting and sedation were also noted. Both groups received boluses initially to control pain. Group M patients received 1mg i.v demand dose of morphine with lock out time of 10-15 minutes and in Group T patients PCA device was set to deliver 20mg i.v demand dose of tramadol with lock out time of 10-15 minutes. A bolus of 25mcg fentanyl was given as rescue analgesia in both groups by the nurse if required. No background infusion or four-hour maximal limit was set on PCA pumps.
Results: Pain scores remained on lower side in both the groups, though slightly better with morphine and the difference was statistically significant at 4 hours, 12 hours and 24 hours. The total NRS mean value (0-48 hours) of morphine and tramadol is 3.270 and 3.629 with p value of 0.015 which is statistically significant. 7 patients in morphine group received rescue analgesia while it was received by 15 patients in tramadol group with p value of 0.78 which is statistically insignificant. Nausea and Vomiting was encountered more frequently in the tramadol group. Mean mobilization time in patients of tramadol group was 21.72 hours and that of morphine group was 17.10 hours with p value of 0.00 which is highly significant.
Conclusions: Morphine and tramadol when used in PCA mode provide adequate pain relief post operatively after spine surgeries with morphine showing slightly better analgesia profile and significantly less nausea and vomiting than tramadol.

Keywords: Morphine, Patient controlled analgesia, Spine surgeries, Tramadol

INTRODUCTION

Pain has been described as an unpleasant sensory or emotional experience associated with actual or potential tissue damage. Moderate to severe acute pain, regardless of site can affect nearly every organ and adversely influence postoperative morbidity and mortality. Pain has physical and psychological sequelae and patient feels traumatized despite otherwise successful operation.[1]

Uncontrolled acute pain leads to delayed wound healing, morbidity and risk of developing chronic persistent pain.[2] It is effective control of postoperative pain that results in reduction of surgical stress responses (endocrine, metabolic and inflammatory) which lead to reduced incidence of postoperative organ dysfunction and thereby to an improved outcome. Postoperative pain control has been attempted by various methods including oral medications, suppositories, i.v, i.m and regional techniques, but it is the patient controlled analgesia using opioids that has become the standard of care for management of postoperative pain.[3]

Spine surgeries are commonly performed for varying indications like herniated discs, fractures, spondylolisthesis, tumours, deformity correction like scoliosis. Many of these surgeries are decompression surgeries and spine fusion surgeries. Spine fusion surgeries include trans foraminal lumber interbody fusion (TLIF) surgeries that involve use of instrumentation for fusion and bone grafting as well. In fusion surgeries, the choice of postoperative analgesia remains limited because of certain studies showing delayed bone healing and fusion due to use of NSAIDS.[4] Neuroaxial blocks also have problems such as infections, sensory and motor blockade postoperatively interfering with neurological deterioration due to surgery or any other complication.

Patient controlled analgesia with opioids is the key in such cases of spine fusion surgeries and morphine remains the gold standard for i.v PCA, as the most studied and most commonly used i.v PCA drug. Tramadol has also been used as i.v PCA in postoperative pain management in numerous studies.[6,7] In this study we compared tramadol with morphine for postoperative analgesia in intravenous patient controlled analgesia in spine surgeries.

METHODS

After approval from Indian spinal injuries centres ethics committee informed consent was taken from all patients enrolled in the study conducted in department of anesthesiology and critical care Indian spinal injuries centre, New Delhi, India during the period extending from June 2015 to May 2016. A total of 80 adult patients of ASA grade I and 2 and numeric rating scale for pain (NRS) of 4 or more at the end of surgery were taken up for transforaminal lumber interbody fusion surgery under general anaesthesia. Patients of ASA grade 3 and 4, known allergy to opioids, h/o seizures, unable to follow verbal or written instructions, deranged KFT, psychiatric disorders, alcohol abuse, NRS pain score<4, and on chronic analgesia were excluded from the study. Preanaesthetic visit was done evening before surgery and use of PCA was explained to patients. On arrival of patient in operation theatre an 18 gauge i.v cannula was inserted and monitoring equipment consisting of ECG, NIBP, ETCo2 and pulse oximetry were attached to patient. Inj. Midazolam 1mg, Inj. Glycopyrrolate 0.2mg, Inj. Ondensetron 4mg and Inj. pantoprazole 40mg were given i.v for premedication. Preoxygenation was done with 100% oxygen for 3 minutes. Anaesthesia was induced with Inj. Propofol 2mg/kg and endotracheal intubation was facilitated with Rocuronium 1mg/kg. Fentanyl 2mcg/kg was given for analgesia. Anaesthesia was maintained with 66% nitrous oxide/isoflurane 1%. Further neuromuscular blockade was maintained with rocuronium. At the end of procedure patient was reversed with neostigmine 0.05mg/kg and glycopyrrolate 0.01 mg/kg i.v and shifted to the recovery room were patients were randomized by using computer generated numbers, into two groups i.e. morphine group M and tramadol group T with 40 patients in each group.

After surgery and as soon as the patient complained of pain in recovery room a baseline pain assessment was done by NRS (numeric rating scale). Other parameters like nausea/vomiting and sedation were also noted. Before starting PCA a loading dose of 2mg morphine was given in Group M patients, which was repeated (8-10mg total) after waiting for 5-10 minutes by slow iv injection till patient had pain relief. Similarly, in Group T patients a loading dose of 2.5mg/kg tramadol was given for pain relief before starting PCA. For Group M patients PCA device was set to deliver 1mg i.v demand dose of morphine with lock out time of 10-15 minutes and for Group T patients PCA device was set to deliver 20mg i.v demand dose of tramadol with lock out time of 10-15 minutes. A bolus of 25mcg fentanyl was given as rescue analgesia in both groups by the nurse if required. No background infusion or four-hour maximal limit was set on PCA pumps. Patients were monitored in recovery room for 30 minutes and at the end of 30 minutes were evaluated for all parameters as earlier and shifted to ward. They were again evaluated at 4 hours, 12 hours, 24 hours and 48 hours, postoperatively. Ondansetron 4mg i.v was given as prophylaxis for nausea and vomiting in each group. Paracetamol 1gm slow i.v infusion was given in both groups as multi modal analgesia. Again, a bolus of 25mcg fentanyl was given as rescue analgesia by the nurse in ward if required.

In summary following parameters were recorded in all patients after surgery at O hours, 30 minutes, 4 hours, 12 hours and 48 hours.

- Postoperative pain using numeric rating scale (NRS)0-10
- Sedation assessed by Ramsay sedation score (0-6)

- Nausea and vomiting on scale of 1-3
- Time of initiation of mobilization
- Presence of bowel complaints/ other associated problems
- Comparison of rescue analgesia between two groups.

The results were statistically evaluated using student 't' test, Mann whitney test, chi-square tests and Fisher's exact test using SSPS computer software comparing between groups and within group. The p value of <0.05 was considered significant and value <0.01 was considered highly significant.

RESULTS

There were no differences between the two groups and the two groups were comparable in terms of age, sex and type of surgery (Table 1).

Table 1: Demographic data.

Age (years)	Group M (n=40)	Group T (n=40)
<35	6	6
36-45	9	5
46-55	10	9
56-65	15	20
Sex male/female	21/19	19/21

The pain scores by NRS at 0 hours, 30 minutes, 4 hours, 12 hours, 24 hours, and 48 hours are depicted in Figure 1. The total loading doses in recovery room were 12.1±3.4 for morphine and 282.6±146.6mg for tramadol. After the patients were brought to the ward, the subsequent doses were 26.0±12.2mg in 24 hours and 42±16.4 in 48 hours for morphine versus 560.8±250.8 mg in 24 hours and 850.5±408.2 mg in 48 hours for tramadol. The mean frequency of PCA delivery was less in tramadol group than in morphine group at 24 hours and 48 hours period.

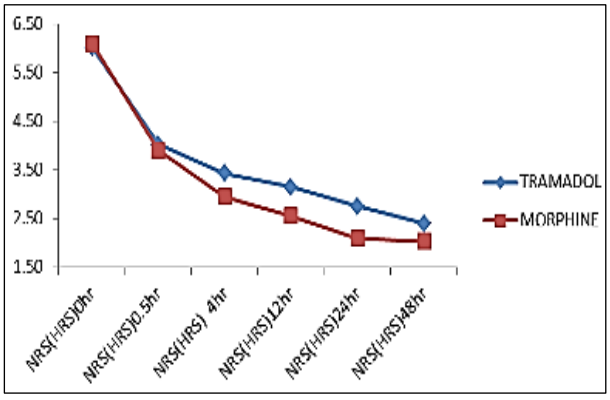

Figure 1: NRS scores of the two groups.

The pain scores in both the groups reduced significantly in the immediate postoperative period after patients received bolus doses of morphine and tramadol. Subsequently in next 24 hours the pain scores continued to remain on lower side in both the groups, though slightly better with morphine and the difference was statistically significant at 4 hours, 12 hours and 24 hours (Figure 1). The total mean value (0-48 hours) of morphine and tramadol is 3.270 and 3.629 with p value of 0.015 which is statistically significant.

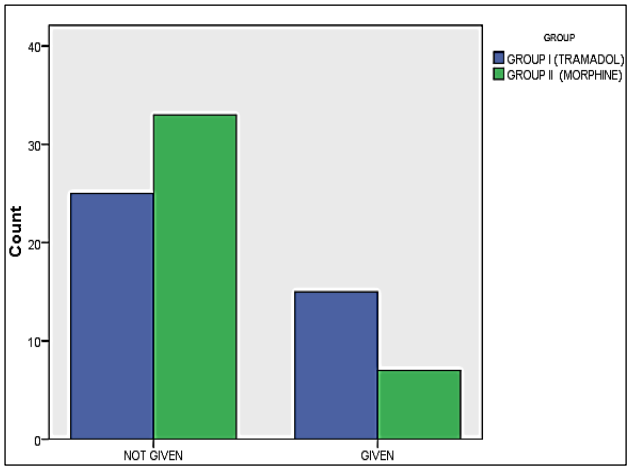

Figure 2: Rescue analgesia consumption of the two groups.

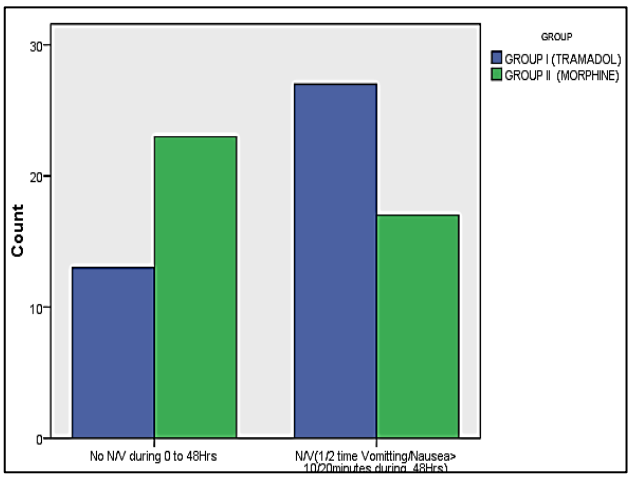

Figure 3: Pattern of nausea and vomiting events between the two groups upto 48 hours.

In terms of rescue analgesia total, no of patients who received it in morphine group was 7 and that in tramadol group was 15 with p value of 0.78 which is statistically insignificant (Figure 2).

Overall patients in morphine group were more sedated than tramadol group but none of the patients had sedation score of 3 or more (unarousable sleep). Bowel complaints included gastritis; abdominal distension and constipation were seen more in tramadol group than morphine group although statistically insignificant.

Nausea and vomiting was encountered more frequently in the tramadol group (67%) than in the morphine group (42%) and it was statistically significant (Figure 3). Mean mobilization time in patients of tramadol group was 21.72 hours and that of morphine group was 17.10 hours with p value of 0.00 which is highly significant.

DISCUSSION

This study revealed that using PCA tramadol at high dose (20mg demand dose) provide effective analgesia like that of morphine (1mg demand dose) but with higher incidence of nausea and vomiting. Tramadol being a non-opiod with weak mew agonist activity does not possess the euphoric and addictive liability that is associated with morphine.[7] Houmes et al, found less respiratory depression associated with tramadol than with morphine, similarly pethidine also induced sedation and respiratory depression while tramadol did not as in a single dose study by Tarradell et al, comparing 100mg pethidine with 100mg tramadol for post-operative on analgesia.[8,9] This safety feature of tramadol makes tramadol a suitable analgesic in wards and in older age group patients.

The rescue analgesia requirements were slightly higher in tramadol group than the morphine group and these findings although insignificant were similar to findings of Zimmermann A et al, who used tramadol and morphine in patients undergoing cardiac surgery and found no statistical difference in rescue analgesia used in two groups.[10] So, tramadol provides clinically effective analgesia when compared with morphine though with slightly better analgesia scores of morphine in first 24 hours and early mobilization time. Nausea and vomiting was encountered more frequently in the tramadol group than in the morphine group and it was statistically significant. Similar findings were observed by Hopkins D et al and Silvasti M et al in orthopedic and microvascular breast surgery.[11,12]

Majority of patients in both the groups were cooperative, oriented, and tranquil. However almost 10% of patients in tramadol group were restless, anxious and agitated in the first 24 hours. None of the patient in either of the study groups was overtly sedated with either the loading dose or after demand doses. Sedation was also not observed by Hadi et al in his study comparing morphine and tramadol for major surgeries.[13]

Tramadol has no dependence potential as per current concepts on mechanism of action of tramadol and considering its equipotency with opioids in terms of pain relief it is encouraging to use it for PCA for management of post-operative pain. The only problem that has led to poor use of tramadol in postoperative pain is its principal side effect i.e. nausea.[14]

CONCLUSION

Both morphine and tramadol used in PCA mode are safe and efficacious for postoperative pain relief after TLIF surgeries with marginally better pain scores with morphine in at least first 24 hours with nausea and vomiting being the commonest side effect observed more frequently with tramadol.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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