Original Research Article

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A Prospective Randomized Double Blind Study on Postoperative Pain Relief in Lower Orthopedic Surgeries-Comparison between Intravenous Inj. Nalbuphine, Inj. Tramadol and Inj. Ketorolac

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Abstract

Introduction: Effective post surgical pain management is essential for the recovery and rehabilitation process. Intravenous injection brings more rapid pain relief than other methods.In this study, We had compared Inj. Nalbuphine, Inj. Tramadol and Inj. Ketorolac given intravenously for post operative pain relief in patients who underwent ower limb orthopaedic surgeries

Aim: To compare the analgesic efficacy and side effects of intravenous Nalbuphine, Tramadol and Ketorolac for postoperative pain relief in patients undergoing lower limb orthopaedic surgeries under spinal anesthesia.

Methodology: After obtaining informed consent and institutional ethical committee approval, 1 50 patients were randomly assigned to one of the three study groups (Group T, Group K, and Group N) based on computer generated random numbers

Each group consists of 50 patients

Group 'T' received Inj. Tramadol 2mg/kg IV

Group 'K' received Inj. Ketorolac 0.4mg/kg IV

Group 'N' received Inj. Nalbuphine 0.3mg/kg IV

Spinal anaesthesia was performed in sitting position using 25 G spinal needle under aseptic precaution using 0.5% Bupivacaine hyperbaric solution. Intra operatively hemodynamic variables like pulse rate, Blood pressure, ECG, SpO_2 monitored. 90 minutes after spinal Anaesthesia each group of patients were administered their respective drug intravenously irrespective of completion of surgery.

Post operatively following parameters were monitored every hour for a period of 24 hours.

1. hemodynamics
2. Pain score
3. Sedation Score.

Results: There is no significant difference in demography.The changes in hemodynamics and sedation are more in Group N than other groups.

Conclusion: Nalbupine has more analgesic effect than ketorolac and tramadol with more sedation.

Keywords: Ketorolac; Tramadol; Nalbupine.

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Introduction

The international association for the study of pain has described pain "as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage."Most patients who undergo major orthopaedic surgery experience moderate-to-severe pain and receive inadequate pain relief. Pain causes anxiety. Sleeplessness, metabolic, psychological, neuro-endocrinal and pulmonary problems that can adversely affect the patient and extend hospitalization. Effective post surgical pain management is essential for the recovery and rehabilitation process. Postoperative analgesic modalities include oral or parenteral analgesics, peripheral serve blocks, neuraxial blockade with local anesthetics, intraspinal opioids as well adjunctive techniques such as TENS (transcutaneous electrical nerve stimulation) and physical therapy.

Appropriate treatment begins with an understanding of the correct drug, route of administration and the mode of action. Early administration will achieve effective analgesic concentrations and make it easier to maintain the therapeutic level of the drug in the blood. Intravenous injection brings more rapid pain relief than other methods.

In this study, We had compared Inj. Nalbuphine, Inj. Tramadol and Inj. Ketorolac given intravenously for post operative pain relief in patients who underwent ower limb orthopaedic surgeries.

AIM

To compare the analgesic efficacy and side effects of intravenous Nalbuphine, Tramadol and Ketorolac for postoperative pain relief in patients undergoing lower limb orthopaedic surgeries under spinal anesthesia

Methodology

This is a prospective randomized double blinded study conducted at chengalpattu Medical College Hospital. A total of 150 patients undergoing lower limb orthopaedic surgeries under spinal anesthesia were included in this study.

Selection of Study Population

Inclusion Criteria

1. ASA I and ASA II Patients
2. Age between 20-50 years

Exclusion Criteria

1. Patient refusal
2. Coagulopathy
3. Contraindications to Spinal anaesthesia
4. Uncooperative patients
5. Patients with H/o Respiratory illness
6. Patients with H/o peptic Ulcer disease

Collaborating Dept

Orthopaedic surgery

Design of Study

Prospective randomized double blinded study

Period of Study

9 months (Feb 2011 to Nov 2011)

Materials and Methods

Preperative evaluation was done in preoperative assessment clinic in our hospital.

Investigations like Hemoglobin, Bleeding time, Clotting time, Platelet Count, Urine for Albumin & Sugar, Blood sugar, Blood urea, Sr. Creatinine, Electrocardiogram and X-ray chest were obtained.

After obtaining informed consent, patients were randomly assigned to one of the three study groups (Group T, Group K, and Group N)

Each group consists of 50 patients

Group 'T' Patients received Inj. Tramadol 2mg/kg IV

Group 'K' Patients received Inj. Ketorolac 0.4mg/kg IV

Group 'N' Patients received Inj. Nalbuphine 0.3mg/kg IV

After preparation and premedication as per the protocol, all the patients were preloaded with 20ml/kg of Ringer Lactate solution. Spinal anaesthesia was performed in sitting position using 25 G spinal needle under aseptic precaution. Local anaesthetic of choice for spinal anaesthesia was 0.5% Bupivacaine hyperbaric solution. Volume of the drug depended on the surgical procedure. Intra operatively hemodynamic variables like pulse rate, Blood pressure, ECG, Oxygen Saturation were monitored. 90 minutes after spinal Anaesthesia each group of

patients were administered their respective drug intravenously irrespective of completion of surgery.

Post operatively following parameters were monitored every hour for a period of 24 hours.

1. Pulse rate
2. Blood pressure
3. Respiratory Rate
4. SpO_2
5. Pain score
6. Sedation Score.

Pain score was assessed by **visual analogue scale** which is a tool used to help a person rate the intensity of pain. The visual analogue scale for pain is a straight line with one end meaning no pain and the other end meaning the worst pain imaginable. A patient marks a point on the line that matches the quality of pain he or she feels.

Once the VAS Score reached 3, the patients received the same drug as per their group as rescue analgesia. This was repeated on demand for a period of 24 hours.

Sedation in the post operative period was assessed by using Ramsay Sedation Score.

Ramsay Sedation Score

Score	Response
1	Anxious or restless or both
2	Cooperative, orientated and tranquil
3	Responding to commands
4	Brisk response to stimulus
5	Sluggish response to stimulus
6	No response to stimulus

Post operative nausea and vomiting was treated by giving Inj. Ondansetron 8 mg (5HT3 receptor antagonist) intravenously.

Observation and Results

Demographic Details

Demographic variable like age and weight of the three groups (group T, group K, group N) were analysed, using one way ANOVA (Analysis of Variation) test (Table 1).

Sex distribution between the three groups (group T, group K, group N) were analysed, using Chi square test (Table 2).

There is no significant difference in the demographic profile between the three study groups (group T, group K, group N), the p value being 0.77 for age, 0.66 for weight and 0.24 for sex distributions. Hence, the demographic profile of the groups included in the study was found to be similar.

Heart rate, mean arterial pressure, respiratory rate, pain score, sedation score of the patients in the three study groups (group T, group K, group N) were monitored every four hour till 16hrs then till 24 hrs. The results obtained were analysed, using one way ANOVA test.

The changes in pulse rate between the three groups (group T, group K, group N) was found to be statistically significant during 1 & 8 hours ($p<0.05$).

Table 1:

	Group T	Group K	Group N	P value (ANOVA)
Age in years	38.4± 11.9	40.16± 12	39.72±13.83	0.77
Weight in kgs	61.84± 5	62.94± 6.58	62.4±5.66	0.66

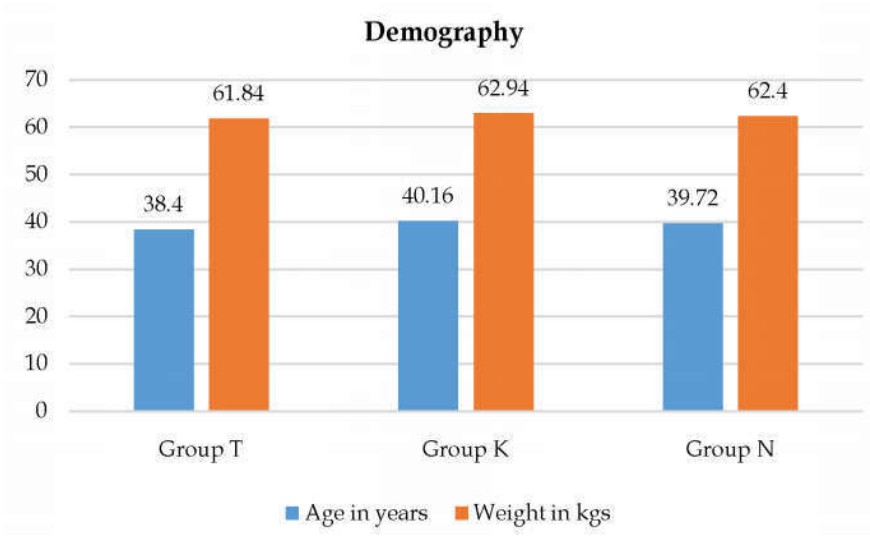
Table 2: Sex distribution between the three groups (group T, group K, group N) were analysed, using Chi square test

Sex	T	K	N	CHI SQ	P
Male	42(84%)	35(70%)	37(74%)	2.85	0.24
Female	8(16%)	15(30%)	13(26%)		

Table 3: Heart Rate

HR/hr	T	K	N	ANOVA	P
HR b	77.12±4.8	76.48±5.46	77.84±4.93	0.9	0.41
HR1	93.76±13.79	78.08±4.88	78.4±5.03	50.314	0.00
HR4	77.16±5.82	77.72±5.25	77.48±4.48	0.145	0.87
HR8	82.12±8.62	77.6±5.24	78.56±5.27	6.57	0.002
HR12	78.28±6.27	77.4±4.8	78.28±5.05	0.441	0.64
HR16	77.48±11.62	76.92±5.098	76.36±10.13	0.178	0.84
HR24	77.08±5.48	77.32±5.15	78.53±4.68	1.205	0.30

Graph 1:



Graph 2:

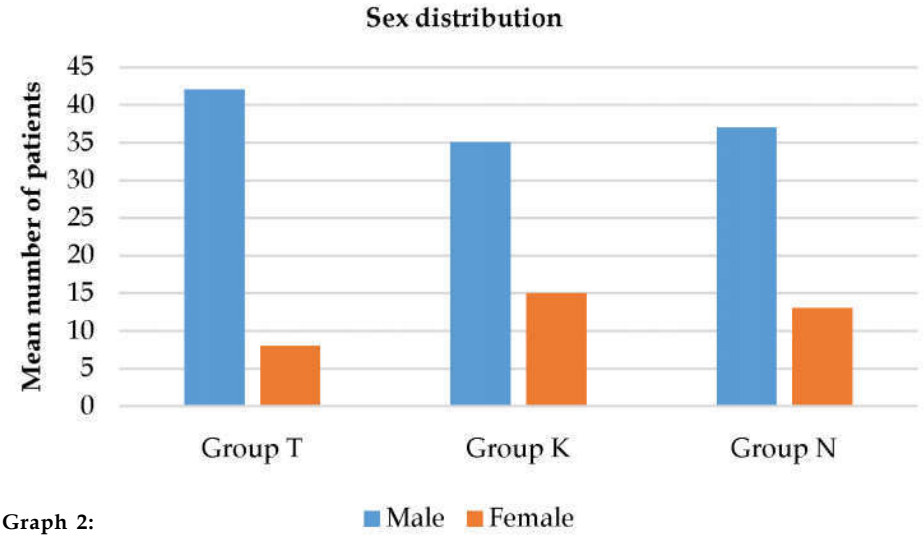
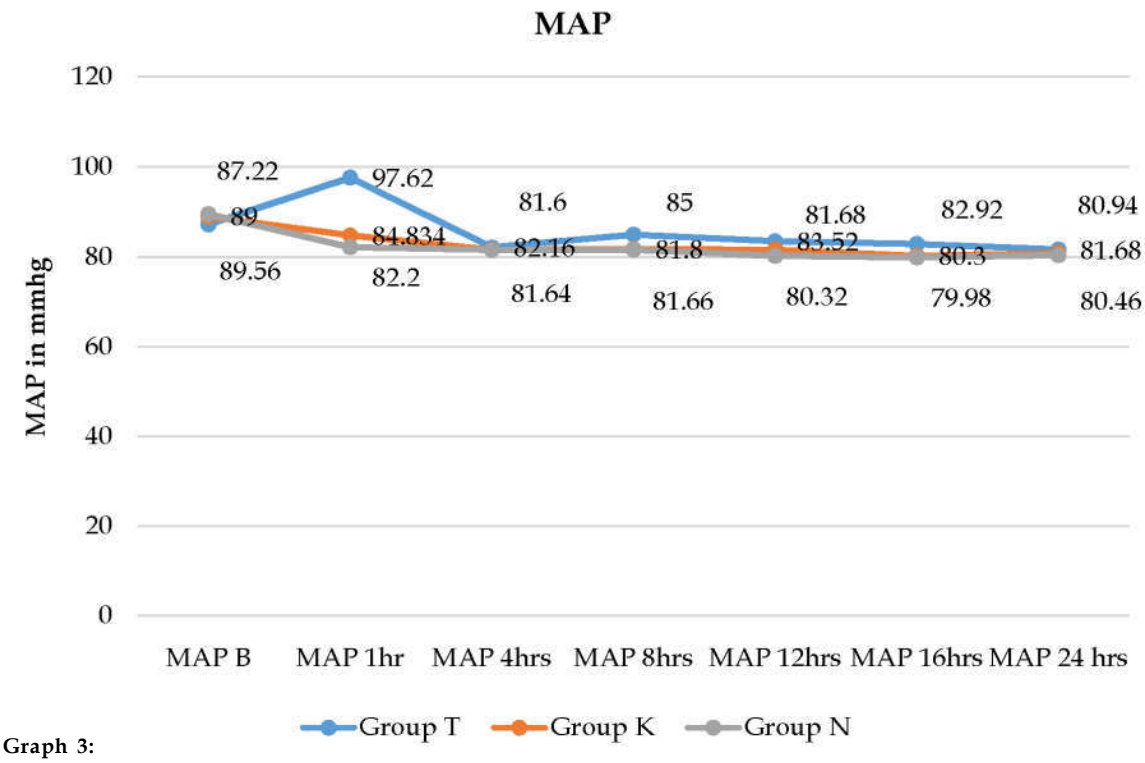


Table 4:

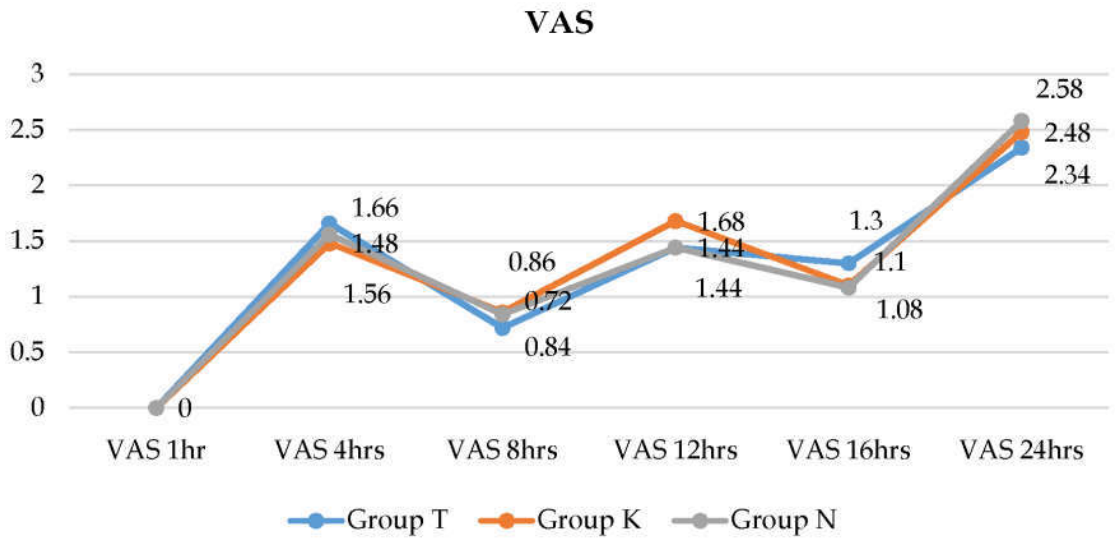
	Group T	Group K	Group N	P value (ANOVA)
MAP B	87.22± 6.22	89 ± 4.63	89.56 ± 4.82	0.07
MAP 1hr	97.62 ±12.78	84.84± 5.24	82.2± 6.42	0.00
MAP 4hrs	82.16± 6.74	81.64 ±6.39	81.6± 6.97	0.9
MAP 8hrs	85± 9.47	81.8± 6.17	81.66± 6.67	0.09
MAP 12hrs	83.52± 6	81.68± 7.57	80.32± 6.51	0.06
MAP 16hrs	82.92 ±7.23	80.3± 12.33	79.98 ±6.11	0.2
MAP 24 hrs	81.68± 6.24	80.94± 6.31	80.46± 12.84	0.79



Graph 3:

Table 5:

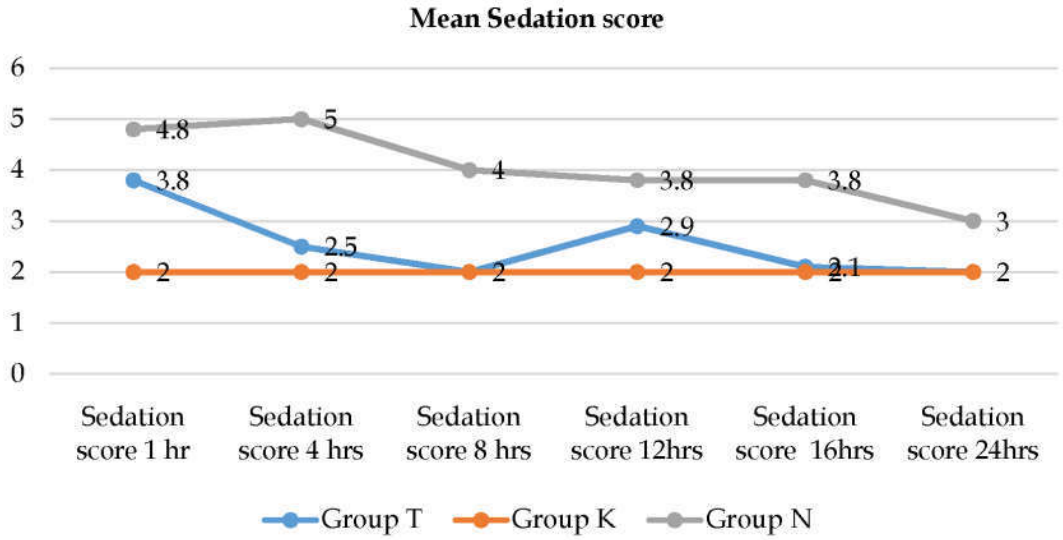
	Group T	Group K	Group N	P value (ANOVA)
VAS 1hr	0	0	0	
VAS 4hrs	1.66± 0.59	1.48± 0.58	1.56± 0.54	0.29
VAS 8hrs	0.72± 0.95	0.86± 1.13	0.84± 0.84	0.74
VAS 12hrs	1.44± 0.88	1.68± 0.68	1.44± 0.76	0.21
VAS 16hrs	1.3± 1.15	1.1± 1.1	1.08± 1.22	0.56
VAS 24hrs	2.34± 0.59	2.48± 0.51	2.58± 0.51	0.08



Graph 4:

Table 6:

	Group T	Group K	Group N
Sedation score 1 hr	3.8±0.4	2±0	4.8±0.2
Sedation score 4 hrs	2.5±0.5	2±0	5±0
Sedation score 8 hrs	2±0	2±0	4±0
Sedation score 12hrs	2.9±0.9	2±0	3.8±0.5
Sedation score 16hrs	2.1±0.4	2±0	3.8±0.3
Sedation score 24hrs	2±0	2±0	3±0



Graph 5:

Discussion

The study was conducted on a total of 150 patients belonging to ASA I and II who underwent lower limb orthopaedic surgeries under spinal anaesthesia. All the patients were adults ranging from 20 to 60 years. They were divided in to 3 groups of 50 each.

Group T: Received intravenous Tramadol 2 mg/kg

Group K: Received intravenous Ketorolac 0.4 mg/kg

Group N: Received intravenous Nalbuphine 0.3 mg/kg

All the 3 groups received their respective drug 90 minutes after spinal anaestheisa and the same drug was repeated when the pain score (VAS) reached 3 in the 24 hours period

Demographic Profile

The demographic profile shows the age, sex and weight distribution between the 3 groups. There was no significant difference between groups (group T, group K, group N) for age (p=0.77), weight (p=0.66) and sex (p=0.24)

Heart Rate and Mean Arterial Pressure

Alon E et al examined the analgesic of nalbuphine and tramadol in patients undergoing total abdominal hysterectomy. In his studies he found that blood pressure and heart rate were normal in both groups without significant differences between the groups. Putland et al, compared the analgesic efficacy of tramadol versus ketorolac in day care laparoscopic sterilization, in his study he found that blood pressure and heart were normal in both groups without significant differences between the groups. In our study patients in group T had a statistically significant increase in heart rate and mean arterial pressure in 1,7,8,15,19,20,21 hours ($p<0.05$). Whereas patients in other two groups had no significant change in the hemodynamic parameters.

Respiratory Rate

Ouaki et al compared the analgesic efficacy and side effects of tramadol and nalbuphine, he found that no significant changes in respiratory rate.

In our study group T showed statistically significant increase in respiratory rate in 1, 7, 8, 15, 19, 20, 21 hours over 24 hours ($p<0.05$). This significant variation in respiratory rate was not seen in Group K and Group N.

The significant increase in heart rate, mean arterial pressure, respiratory rate in group T could be due to nausea and vomiting following administration of tramadol.

The significant increase in heart rate, mean arterial pressure, respiratory rate in group T could be due to nausea and vomiting following administration of tramodol.

All the three groups (Group T, Group K and Group N) did not produce clinically significant respiratory depression over 24 hours.

Pain Score

Ali et al compared the analgesic efficacy of intravenous infusion of nalbuphine and tramodol in patients undergoing laparoscopic dye test,found that no significant differences between the two groups in post operative pain score(VAS)

Khalid Maudood siddiqui compared the analgesic efficacy of tramadol and nalbuphine in TIVA for dilatation and curettage, found that quality of analgesia was better in nalbuphine group

Diana Moyao – Garoia et al., compared the analgesic efficacy of nalbuphoine and tramadol through continous intravenous infusion for post operative pain relief found that tramadol appears to posses better post operative analgesic efficacy than nalbuphine.

Zackova M et al. compared the post operative analgesic efficacy of ketorolac and tramadol given intravenously during maxillofacial surgery found that there was no statistically significant difference between the ketorolac and tramadol groups in the pain scores measured.

Our study showed no statistically significant difference in pain scores in all the 3 groups ($p>0.05$).

Sedation Score

Khalid Maudood siddiqui et al. compared tramadol versus nalbuphine in total intranvenous anaesthesia for dilatation and evacuation found that tramodol had more sedating effect than nalbuphine. Patients receiving nalbuplhine woke up earlier and were well oriented compared to tramadol.

Ouaki, J et al. compared analgesic efficacy and side effects of tramadol versus nalbuphine in patients undergoing laparoscopic surgery for gastro-oesophageal reflux disease found that tramadol caused less early sedation than nalbuphine.

When Group T and Group N were compared, Group T showed statistically significant sedating effect in 2, 5, 8, 9, 10, 14, 15, 20, 21, 22 hours ($p<0.05$).

Post Operative Nausea and Vomiting

Zackova M et al. compared tramadol versus ketorolac in the treatment of post operative pain during maxillofacial surgery found vomiting was registered in more number of patients in tramadol group.

Diana Moyao Garcia et al. compared analgesic efficacy of nalbuphine versus tramadol administered through continous intravenous infusion for post operative pain control found that there was increased incidence of vomiting in tramadol group.

In our study Group T showed post-operative hausea, vomiting which is statistically significant in 1, 7, 8, 15 hous over 24 hours compared to Group K and Group N.

Total Number of Doses Requied Over 24 Hours

Total number of doses requied over 24 hours between Group T, group K and group N was found to be 3.28±0.453, 3.16±0.37, and 3.16±0.37 respectively with $p=0.23$.

Hence there was no statistically significant difference total number of doses required over 24 hours in all the 3 groups.

Cost Benefit

When cost benefit of three groups (group T, group K, group N) were compared, the cost benefit of group K is greater that group T which is greater than group N.

All the three drugs (group T, group K, group N) are equally efficacious in providing post operative analgesia. Tramadol caused significant post operative nausea and vomiting and sedation whereas Nalbuphine produced less sedatiion and did not cause vomiting when compared to tramadol. Ketorlac did not produce vomiting and significant sedation.

Conclusion

On comparing Tramadol, Ketorolac, and Nalbuphine it is found that Nalbuphine produced effective analgesia and clinically significant sedation and did not produce post-operative nausea and vomiting when compared to Tramadol and Ketorolac.

Hence it is concluded that Nalbuphine is an effective analgesic even though it is less cost effective.

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