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A Comparison of the effects of intravenous Ketorolac Tromethamine or Paracetamol on pain scores on post operative orthopedic surgery Patients

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A B S T R A C T

Experiencing moderate to severe pains after surgery in patients brings about some consequences such as patient's longer stay in the hospital, an increase in drug consumption, and a lot of other side effects. The aim of this study was compare the effect of Experiencing moderate to severe pains after surgery in patients brings about some consequences such as patient's longer stay in the hospital, an increase in drug consumption, and a lot of other side effects. The aim of this study was compare the effect of Ketorolac and Paracetamol for pain relief after orthopedic surgery of the lower limbs (calf). In a clinical trial study that performed in Department of Anesthesia of Kerman University of Medical Sciences on patients underwent orthopedic surgery, effect of Ketorolac and Paracetamol for pain relief after orthopedic surgery of the lower limbs evaluated. The results showed that the use of cost-effective drugs such as Ketorolac and Paracetamol before and during the surgery can have a significant impact on reducing postoperative pains in patients. In fact, reducing the use of opioids and other NSAIDs which have much more side effects and replacing these drugs (Ketorolac and Paracetamol) can contribute in the recovery quality and in accelerating patients' discharge process.of the lower limbs (calf). In a clinical trial study that performed in Department of Anesthesia of Kerman University of Medical Sciences on patients underwent orthopedic surgery, effect of Ketorolac and Paracetamol for pain relief after orthopedic surgery of the lower limbs evaluated. The results showed that the use of cost-effective drugs such as Ketorolac and Paracetamol before and during the surgery can have a significant impact on reducing postoperative pains in patients. In fact, reducing the use of opioids and other NSAIDs which have much more side effects and replacing these drugs (Ketorolac and Paracetamol) can contribute in the recovery quality and in accelerating patients' discharge process.

Introduction

Musculo-skeletal injuries cause nearly half the cases of hospitalization. In the USA, over 33 million people are hospitalized per year in medical centers for this reason (1). It can be said that more than half of surgical procedures for the treatment of orthopedic injuries in America are performed in the lower limbs (2). Acute postoperative pain is one of the most common and serious problems that anesthesiologists and surgeons have to deal with. Experiencing moderate to severe pains after surgery in patients brings about some consequences such as patient's longer stay in the hospital, an increase in drug consumption, and a lot of other side effects (5-3). Research has also confirmed that effective postoperative pain control leads to positive psychological and physiological effects and prevents atelectasis, pneumonia and thrombosis of deep vasculature (6). Message transfer from the peripheral to the central nervous system is done by special nerve fibers. There are three types of nerve fibers which are named based on their size, message transmission speed and demyelination (9-7). Peripheral nerves and pain receptors are directly and indirectly adjusted by several chemicals. Prostaglandins and Leukotrienes, which are both products of arachidonic acid pathway increase pain through lowering the sensitivity threshold of pain receptors (7). Preemptive-analgesia is a new concept for pain relief. The term refers to the concept that prescribing analgesia (analgesic) before painful stimuli will prevent further pain or reduce it. For preventive effect on the nociceptive paths, Preemptive-analgesia is more effective than painkillers which are used after surgery (10). Preemptive-analgesia drugs prevent the excessive consumption of narcotics and their adverse effects. Moreover, they significantly reduce the cost of treatment (11).

Opioids, in addition to analgesic effects, cause Euphoria in patients too. This makes it easier for the patient to tolerate pain. On the other hand, opioids bring about several side effects such as drowsiness, itching, nausea, urinary retention and apnea. NSAID drugs are also used in the treatment of postoperative pain. Ketorolac is the COX2 inhibitor, which its analgesic effect is comparable to that of morphine. Acetaminophen is painkiller and refrigerant with no anti-inflammatory effects.

Few studies have compared these two drugs in terms of the postoperative pain control. In a study conducted by In Hwa Lee et al. (2009), these two drugs were compared in terms of controlling post-tonsillectomy pain in children who had similar results for 60 minutes after operation (12). In another study carried out by D Heinz et al. in Scandinavia, Paracetamol and Diclofenac were compared in terms of analgesic effects in reducing postoperative pain after orthopedic operation and both drugs revealed similar effects (13).

These two drugs are compared in few research studies and no other drug is added to these two in previous research. These two are not compared individually. These two drugs are available painkillers and their use is convenient and cost-effective. On the other hand, lower limbs fracture is prevalent in our country and most patients are young; therefore, the authors of this article are looking for a simple and low cost solution for a common serious problem. That is why this study is designed and is of paramount importance.

Materials and Methods

In a prospective double-blind study (clinical trial) which was conducted based on the sample size calculations in statistical

consultation, 90 patients with 1 and 2 ASA classes undergoing orthopedic surgery (lower limbs) with the same demographic conditions regardless of gender were included in this study. The exclusion criteria consisted of the chronic use of opioids and analgesics, steroids, younger than 18 years of age and older than 65 years of age, pregnancy, history of heart - liver - kidney failure, blood coagulation disorders, uncontrolled blood pressure, endocrine disease, BMI over 40, chronic alcoholism, heart beat rate below 50 per minute, the possibility of surgery duration for more than two hours. They were divided into three groups based on random numbers table. After entering the operating room and obtaining informed consent of the patients, they were instructed VAS in a suitable time position and place. Then, they were completely monitored. Before prescribing anesthetic drugs, the patients' VAS was measured and recorded. Ten minutes before induction, 30 mg of Ketorolac was injected for patients of the first group (Ketorolac) and the second group (Paracetamol) received one gram of Paracetamol and the third group (Control) took normal saline. Anesthesia methods were similar for all groups. Then, induction began with the premedication (midazolam 0.05 mg / kg and Fentanyl 2 mcg / kg) and anesthetic initiated with Sodium Thiopental (3-5 mg / kg) and Atracurium (0.5 mg / kg) and maintenance of anesthesia was done with a gas mixture of O₂ and N₂O (50%) and Isoflurane gas (1.2%) and Atracurium 0.2 mg / kg per half hour.

Blood pressure and heart beat rate of the subjects were recorded before induction and immediately after the initiation of the surgery, during the surgery, and after surgery every fifteen minutes until recovery complement. If an increase in heart beat rate was greater than 100 and the increase of

arterial blood pressure was more than 20%, 50 mcg of Fentanyl was repeated during the operation. In order to prevent the effects of opioids on patient's VAS, the injection of fentanyl was refused since 30 minutes to recovery from anesthesia. During the recovery of the patient's consciousness, VAS was checked (for VAS4-6 one Diclofenac suppository 50 mg and for VAS7-10 one Diclofenac suppository 100 mg). Twenty minutes after prescribing Diclofenac suppository and in the case of lacking response to Diclofenac suppository, Pethidine 20 mg just was prescribed as IV. At the end of recovery, obtained scores from VAS benchmark along with all demographic information of patients in P, K, N groups were recorded and their qualitative and quantitative data was analyzed using the statistical SPSS software Version 20, Chi-Square and Repeated-measurement.

Results and Discussion

One of the patients participating in the study after surgery and during the de-hospitalization process did not allow the researchers to use the data collected from him and because the study was conducted blindly, his treatment group was not known until the end of the study and there was no possibility to replace him. At the end of the study, it was found out that he was relevant to the placebo group.

Based on the results obtained, it was revealed that 45 patients had no need to postoperative analgesic (A), 24 patients required Diclofenac suppository 50 mg (B) and 20 subjects needed Diclofenac suppository 100 mg. The average pain intensity (VAS) was not significant ($p = 0.128$) for the three treatment groups over time (Figure 1). P-value for the maximum blood pressure variable during surgery was equal to .946, which indicates that the mean

of the maximum blood pressure changes was not significant over time in the three treatment groups. P-value for the minimum blood pressure variable during surgery was equal to .104, which indicates that the mean of the minimum blood pressure changes was not significant over time in the three treatment groups. P-value for the variable heart beat rate during surgery was equal to .426, which indicates that the mean of the heart beat rate changes was not significant over time in the three treatment groups. P-value for the variable maximum blood pressure at the time of recovery was equal to .295, which indicates that the mean of the maximum blood pressure changes was not significant over time in the three treatment groups. P-value for the variable minimum blood pressure at the time of recovery was equal to .003, which indicates that the mean of the minimum blood pressure changes was significant over time in the three treatment groups. P-value for the variable heart beat rate recover was equal to .002, which indicates that the mean of the heart beat rate changes was significant over time in the three treatment groups.

Although, during the one-hour operation period, the variables maximum blood pressure, the minimum blood pressure and heart rate for all three treatment groups

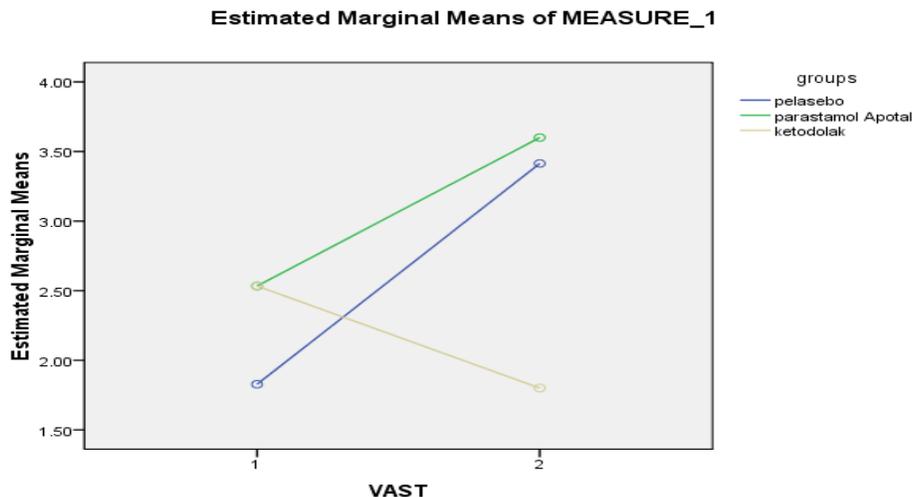
(placebo, acetaminophen and Ketorolac) had no statistically significant difference and, regarding the VAS variable, its mean for three treatment groups (placebo, acetaminophen, Ketorolac) was not significant over time and the change patterns of pain intensity in these groups are the same, more than half of the subjects in the placebo group (55%) needed 100 mg Diclofenac Suppository and 25% of subjects needed 50 mg Diclofenac Suppository and 26.7% of patients required no analgesia during the recovery period. Moreover, in the acetaminophen group, 40% of subjects need to 100 mg Diclofenac Suppository, and 29.2% and 33.3% of subjects required 50 mg Diclofenac Suppository or no analgesia, respectively. In the Ketorolac group, only 5% of people needed 100 mg Diclofenac Suppository, 45.8% required 50 mg Diclofenac Suppository and only 40% of them needed no analgesia (Table 1).

This study aimed to compare the effect of Ketorolac and Paracetamol on orthopedic postoperative pain to reduce the use of opioids and other NSAIDs of more complications and to improve the quality of recovery and to expedite the process of discharging patients through replacing these drugs (Ketorolac and Paracetamol).

Table.1 Results of Treatment

Groups	No need to analgesic	Need to 50 mg Diclophenac	Need to 100 mg Diclophenac	Total
Placebo	32.6%	55%	25%	26.7%
Paracetamol	33.7%	40%	29.2%	33.3%
Ketorolac	33.7%	5%	45.8%	40%
Total	% 100	% 100	% 100	% 100

Figure.1 Mean of Pain Score(VAS) in Three Groups



The results of the study showed that post-operative pain intensity of patients in recovery period and in studied drug groups was no of statistically significant difference. However, in patients who received placebo, pain was more acute after recovery transmission. Comparing Ketorolac and Paracetamol, it was revealed that non-steroidal anti-inflammatory drug Ketorolac significantly reduces pain intensity. However, during one-hour operation period, the variables maximum blood pressure, minimum blood pressure and heart beat rate in all three treatment groups (placebo, acetaminophen, Ketorolac) did not differ significantly. The mean of pain intensity (VAS) in the three treatment groups was not significant over time, and the change patterns of pain intensity were identical in the three groups.

In a study done by Zhu et al. in 2001, the effects of these two drugs on postoperative pain in knee arthroplasty operation were compared and it was stated that the pain was lower in the acetaminophen group; however, this difference was not statistically

significant. Elongation of relieving pain was estimated to be more by injecting Ketorolac 30 mg. This is similar to the findings of the current research. However, acetaminophen was more effective in reducing pain in our study.

Lee et al. studied these two drugs after thyroidectomy operation (15). In their study, 80 patients were placed in four treatment regimen relief groups since half an hour before the operation: normal saline (group Control), Ketorolac 30 mg (group Ketorolac), Paracetamol 1 g (group Paracetamol), and Paracetamol 700 mg plus morphine 3 mg (group Paracetamol). If the pain was not effectively controlled, Pethidine 25 mg would be injected. The Pain intensity (VAS) was monitored for six hours after surgery. Results showed that the pain intensity was less in all three treatment groups than the placebo group and fewer side effects were observed ($p < 0.05$). The results of this study, unlike our study, showed the equal efficacy of these drugs.

Although different studies produce different results, the comparison of their results directs us towards choosing a safe and effective method to treat pains after orthopedic surgery. Ketorolac is an emerging drug in the field of analgesia pharmacology. It has had effects similar to morphine in different studies. The difference is that it protects the patients from narcotic side effects. However, its effectiveness remains to be tested in further studies and clinical advantages and disadvantages of prescribing this drug should be tested.

Conclusion

The results showed that the use of cost-effective drugs such as Ketorolac and Paracetamol before and during the surgery can have a significant impact on reducing postoperative pains in patients. In fact, reducing the use of opioids and other NSAIDs which have much more side effects and replacing these drugs (Ketorolac and Paracetamol) can contribute in the recovery quality and in accelerating patients' discharge process.

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