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Comparison of analgesic and hemodynamic effects of intravenous ketorolac and morphine sulfate with morphine sulfate alone in patients undergoing simple abdominal surgery

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ABSTRACT

Introduction: Postoperative pain can cause short-term and even long-term complications. Therefore, the present study is aimed to compare the hemodynamic and analgesic effects of intravenous ketorolac and morphine sulfate with morphine sulfate alone in patients who were candidates for simple abdominal surgery. *Materials and Methods*: This clinical trial was performed on patients who were volunteers for a simple elective abdominal surgical procedure. Patients were separated to 2 main groups receiving ketorolac plus morphine sulfate, and morphine sulfate group alone. Hemodynamic variables and pain scores and influencing factors in both groups were examined during follow-up periods. *Results*: Mann-Whitney test revealed that there was not any significant difference between the two studied groups in terms of age, gender, marital status, economic status, employment status, medical history, and weight, systolic and diastolic pressure ($P > 0.05$). The mean pain score in the intravenous ketorolac group plus morphine sulfate was 28.12, while the median for the morphine sulfate group was significantly lower compared to the other studied groups 41.78. Also, the comparison of the mean pain intensity straightly, 2, 6, 12, and 24 hours after surgery in the patients of the two groups showed significant differences where the amount of pain in both groups was significantly reduced over time. *Conclusion:* Our findings revealed that intravenous ketorolac/morphine sulfate had a more preventive effect in reducing pain compared to morphine sulfate. The results of this study can be a guide to reduce complications and pain in patients undergoing simple abdominal surgery.

Keywords: Pain, Intravenous ketorolac, Morphine sulfate, Simple abdominal surgery, Sedation

1. INTRODUCTION

According to the International Association for the Study of Pain (IASP), pain is an unpleasant sensory experience associated with an active or potential tissue injury or defined based on such similar damage (e.g., surgery tissue damage and the release of inflammatory mediators), (Miller et al., 2014). In the meantime, abdominal surgeries create different degrees of pain with different intensities by making incisions in the skin, separating muscles and manipulating the organs, depending on the type of operation, resulting in stimulation of the nerve fibers carrying pain sensation. Postoperative pain is divided into two levels of acute and chronic. Acute postoperative pain remains in rare cases and can become chronic and long-lasting pain. Postoperative pain management by anesthesiologists and its effectiveness is a necessary step towards better understanding of pain management strategy and developing appropriate guidelines for improving performance (Ahmed et al., 2013). The most widely used method today is the use of opioids by patient-controlled analgesia (PCA) pump (Miller et al., 2014).

One way to relieve pain is to use PCAs that are controlled by the patient. PCA is a method of allowing a patient in pain to administer their own bolus dose of analgesia for pain relief, depending on the severity of the pain they feel, with programmable injection pumps (Craft, 2010). One way to relieve pain is to use venous pain pumps (PCAs) that are controlled by the patient. PCA enables patients to use the bolus dose of analgesia they need to relieve pain, depending the pain severity they feel, with programmable injection pumps (Craft, 2010). Morphine is effective in reducing the discomfort of the patient by affecting the central nerve receptor, but it is not effective on the cause of pain and needs to be repeated (Seyyed Hossein Shaker, 2016). Side effects of morphine such as nausea, vomiting, constipation, drowsiness, hypotension, and respiratory distress at higher doses have led physicians to pursue the use of alternative or ancillary medications (Sirous, 2008).

Non-steroidal anti-inflammatory drugs (NSAIDs) are other commonly used drugs that, although less effective in the first 10 minutes, have the same effect as opioids (REZA et al., 2004). The analgesic effects of NSAIDs are due to inhibition of prostaglandins, which in turn reduce vasodilation, increase their permeability, and reduce inflammation (Travaglini et al., 2004). Ketorolac is one of the NSAIDs that has minimal gastrointestinal side effects and is suitable for consumption for a maximum of 5 days. In addition, this drug is recommended to be capable of reducing postoperative pain and the use of narcotic analgesics (Kalra, 2010). Therefore, the present study is aimed to conduct a comparative study on hemodynamic and analgesic effects of intravenous ketorolac and morphine sulfate in comparison with morphine sulfate alone in patients undergoing simple abdominal surgery.

2. MATERIALS AND METHODS

This clinical trial was performed on candidate's patients who were chosen for simple abdominal surgery in the method of controlling venous pain by the patient in hospitals affiliated to Zabol University - Iran in 2020-2021. Data were collected using a checklist and patients with inclusion and exclusion criteria were selected to be within this study.

Inclusion criteria included: age 18 to 65 years, patients who underwent simple elective abdominal surgery, patient satisfaction to participate in the study, and ASA class I and II. Exclusion criteria include: addiction, history of taking any sedatives and anti-nausea and vomiting drugs, contraindications and sensitivity to nitroglycerin and morphine in the patient and complications such as hypotension and headache, and nausea and vomiting or arrhythmias requiring treatment during use Pump and converting surgeries into complex surgeries.

Sample size

Size of the sample was determined based on the following formula and reference (Varrassi et al., 1994). In the present study, 22 people were estimated in each group, which was finally estimated to be 30 people in each group due to sample loss and increasing sample size accuracy.

Procedure

In this study, sampling was done by simple random method and allocation of two groups was done by systematic random method. It was determined that the first person was in the control group or the case group using Epi Info software (WHO-CDC 8.5), then they were placed one by one in the case or control group. One group of patients received morphine sulfate only and the other group received ketorolac and morphine sulfate. Simple elective abdominal surgeries included: herniorrhaphy, cholecystectomy, jejunoileostomy, all abdominal surgeries with a surgery time of less than two hours and a bleeding volume of less than 200 cc and a surgical incision length of less than 10 cm. The studied patients were non-addicted and without the history of continuous use of sedatives and antiemetic drugs during the last three weeks. Patients without a history of allergy to the drugs used in the study were included.

The patients did not receive premedication (anesthesia prodrug) which includes narcotics, sedatives and antiemetic drugs. In each group, patients were admitted to the operating room under the necessary monitoring as follows. Mean arterial blood pressure (MAP), Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured using an automatic monitoring device. SPO2 (arterial blood oxygen level) was measured using a continuous pulse oximeter. ECG was continuously monitored using the 5-lead method. Fluids were administered via 20G angiocatheter. Induction of anesthesia in all patients of the two groups was performed uniformly using propofol 2 mg/kg) Low Chain Molecular, fentanyl 3 µg/kg) AbuReihan, Iran), muscle relaxant 0.5 mg/kg (Rasht, Iran). After the operation and transfer of the patient to recovery, IVPCA (Lock Out) venous pain pump was installed with a volume of 100 ml with control of 2, 4, 6, 8 ml per hour (PouyanTeb Co., a product of China) through a separate angiocatheter No. 20. A specialized anesthesiologist filled the pumps which contained the following composition: Case group: Morphine (Iran Daru Co., Iran) 0.5 mg / kg and 1 mg per kg body weight of Ketorolac ampoule (Abu Reihan, Iran), 30 mg of ketorolac was administered intravenously. Control group: morphine 0.75 mg / kg was administered.

In each remaining group, 100 ccs with normal saline was used to fill the volume of pumps. The person filling the contents of the pump will not interfere in completing the medical file. On the pump, its contents were recorded only with A or B markers to prevent the completer of the questionnaire from knowing the contents of the questionnaire after completing the initial information of the form, including demographic information of age, sex, weight, anesthesia class, vital signs and hemodynamic indicators. Respiratory, pain, nausea, and vomiting immediately were evaluated according to VAS and sedation (0-5), just2, 6, 12 and 24 hours after surgery. Regarding the VAS score, the patient had to give his pain intensity from zero to 10, zero was a sign of no pain and 10 was a sign of maximum pain.

Data analysis

For comparing the mean of hemodynamic indices before and at different times studied, repeated measures analysis of variance and independent t-test were studied, if the data were normal. Mann-Whitney, Friedman and Wilcoxon tests were used for non-normally distributed variables, and relevant tests such as chi-square were used to compare pain and nausea. After data collection in SPSS-18 version software was used for analysis and a significance level of < 0.05 was considered.

Ethical considerations

The information of all patients remained confidential. Ethics statements of Helsinki and ethics research committees of the University of Medical Sciences were observed during the study. The project was carried out after approval by the Research Council of the Medical School (IR.ZBMU.REC.1399.158).

3. RESULTS

The present study was consisted of 62 patients; two of them were excluded due to lack of cooperation and one due to hypotension. The final sample was consisted of 59 patients who were candidates for simple abdominal surgery, 30 of whom were in the intravenous ketorolac group and morphine sulfate and 29 in the morphine sulfate group alone. The mean age of the individuals was 43.12 ± 8.17 years. The minimum and maximum age were 30 (16.6%) and 60 years and older (7%) respectively. The results of Mann-Whitney test didn't show any significant difference between the two studies groups in terms of age ($P = 0.29$). In terms of gender, 46.9% were male and 57.1% were female. In the intravenous ketorolac and morphine sulfate group, 22 (76.7%) were female and 8 (23.3%) were male, and in the morphine sulfate group, 21 (72.4%) were female and 8 people (27.6%) were men. The results achieved from Fisher's exact test, the two study groups did not differ significantly in terms of gender and were homogeneous in this regard ($P = 0.34$). In the group of intravenous ketorolac and morphine sulfate, 24 (80%) were married and 6 (20%) their spouses died. In the morphine sulfate group, 21 (72%) were married and 8 (28%) of their spouses had died. The results of Fisher's exact test showed that there was no significant difference between the two study groups in terms of marital status variable ($P = 0.26$).

The frequency of economic status in the two groups was examined. In the group of intravenous ketorolac and morphine sulfate, 25 patients (86%) had an acceptable economic status and 5 patients (14%) had less than reasonable. In the morphine sulfate group, the economic status of 21 (74.3%) was acceptable and 8 (25.7%) was less than reasonable. The results of Fisher's exact test showed that the two study groups did not differ significantly in terms of economic status ($P = 0.12$). In the group of intravenous ketorolac and morphine sulfate, 8 patients (26.6%) were employed and 22 patients (73.4%) were unemployed. In the morphine sulfate group, 9 people (31%) were employed and 20 people (69%) were unemployed. In the group of intravenous ketorolac and morphine sulfate, 14 patients (46.6%) had a history of drug therapy and 16 patients (53.4%) were detected without a history of drug therapy. In the morphine sulfate group, 11 patients (37.9%) had a history and 18 patients (62.1%) were detected without a history of drug therapy.

The results of Fisher's exact test showed that the research units in the two study groups were not significantly different in terms of the history of drug therapy and were homogeneous in this regard (P = 0.26). The comparison of the mean weight of the research units was determined to be 76.5 ± 2.46 in the intravenous ketorolac group and morphine sulfate and 78.2±7.48 kg in the morphine sulfate group. The results of Mann-Whitney test showed that the research units in the two study groups did not differ significantly in terms of weight and were homogeneous in this regard (P = 0.11). Mean and standard deviation of blood pressure were examined in the two groups. Patients of intravenous ketorolac and morphine sulfate group had a diastolic blood pressure was 13.53 ± 2.1 while the systolic blood pressure of 7.53 ± 1.6. In the morphine sulfate group, the systolic pressure was determined to be 7.79 ± 2.08 and the diastolic pressure was 13.99 ± 1.98. The results of Mann-Whitney test showed that the units in the study groups did not differ significantly in terms of systolic and diastolic pressure and were homogeneous in this regard (P = 0.29).

Pain scores were different in the studied groups. Intravenous ketorolac and morphine sulfate showed lower scores than morphine sulfate alone. The mean pain score in the group of intravenous ketorolac and morphine sulfate was 28.12 ± 3.53, while the score for morphine sulfate was 41.78 ± 5.08. The mean pain score at almost all different times after surgery in the intravenous ketorolac group and morphine sulfate was significantly lower than the morphine sulfate group alone. As could be seen between studied groups significant differences were observed statistically (P <0.001) (Table 1, Chart 1).

Table 1 Evaluation of pain score in the studied groups

Variable	GROUP		Total	P-value
	Morphine sulfate and intravenous ketorolac	Morphine sulfate		
Average pain score	28.12±3.53	41.78±5.08	34.85±4.74	<0.001
Low	25	18	43	
Medium	4	8	12	
Much	1	3	4	

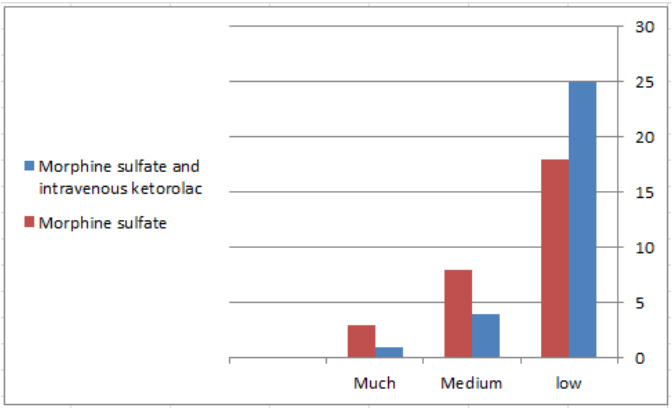

Chart 1 Evaluation of pain score in the studied groups

Table 2 Comparison of mean pain intensity at different times after surgery

Pain after operation	Group		Total	P-value
	Morphine sulfate and intravenous ketorolac	Morphine sulfate		
Instantly	33.72±3.06	48.18±4.43	39.93±4.75	0.04
Two hours	29.93±3.41	43.24±5.12	37.18±4.75	0.03
Six hours	27.62±3.12	40.06±4.62	33.69±4.75	0.01
24 hours	26.43±3.19	38.31±5.69	32.71±4.75	0.03

In table 2 and chart 2 Comparison of mean pain intensity immediately 2, 6, 12 and 24 hours after surgery in patients of the two groups showed significant differences (P<0.05). The amount of pain in both groups was significantly reduced over time and the lowest amount of pain was observed 24 hours after surgery (P<0.05). Ketorolac and morphine sulfate groups were effective in

improving pain, and pain score in this group showed a significant decrease. No significant differences were observed in postoperative nausea between the groups. In all patients of the two studied groups, the rate of nausea in almost all different times after surgery was not statistically significant (P<0.05) (Table 3).

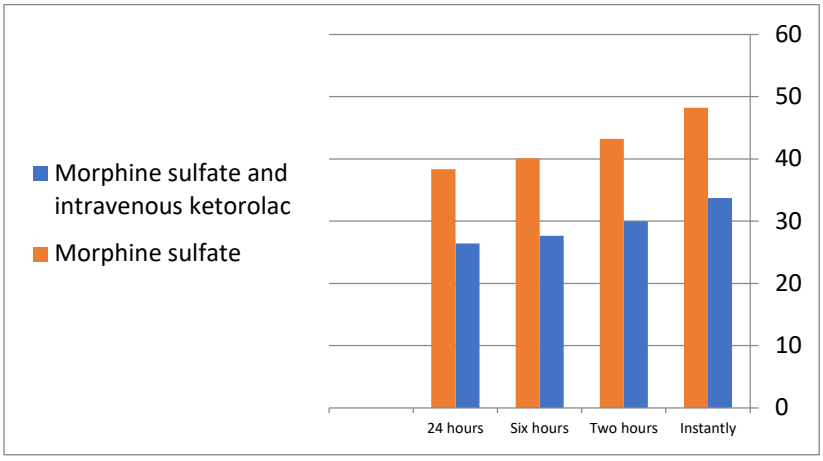

Chart 2 Comparison of mean pain intensity at different times after surgery

Table 3 Evaluation of nausea

Variable	Group				P-value
	Morphine sulfate and intravenous ketorolac		Morphine sulfate		
	yes	no	yes	no	
Instantly	16	14	13	16	0.04
Two Hours	11	19	12	17	0.03
Six Hours	5	25	7	22	0.01
24 hours	2	28	1	29	0.03

No significant difference was observed in postoperative sedation between the groups. The amount of sedation in almost all different times after surgery in patients of the two groups was not statistically significant (P<0.05) (Table 4). The mean duration of action in the ketorolac and morphine sulfate groups was 1.54 ± 0.38, while the mean duration for the morphine sulfate group alone was 2.07 ± 0.22. Statistical findings showed that the duration of surgery was not significantly different in the groups (P = 0.12). In Table 5 the mean hemodynamic parameters of SBP, diastolic pressure (DBP), heart rate (HR) and respiratory rate (RR) before, immediately, two hours, six hours, 12 hours and 24 hours after surgery in patients of the two study groups were assessed. There was not any significant differences between groups in terms of hemodynamic variables (P <0.05).

Table 4 Sedation in the studied groups

Variable	Group				P-value
	morphine sulfate and intravenous ketorolac		morphine sulfate		
	Ramsey Sedation Score		Ramsey Sedation Score		
	alert	Restless	alert	Restless	
Instantly	18	12	16	13	0.24
two hours	19	11	17	12	0.24
six hours	18	11	17	12	0.24
24 hours	21	9	19	10	0.24

Table 5 Comparison of mean postoperative hemodynamic indices in the two groups

	Time variable	Average indicators				P-value
		SBP	DBP	HR	RR	
Morphine sulfate and intravenous ketorolac	Instantly	108.92±4.11	63.56±6.12	124.5±7.94	21.99±2.17	
	two hours	118.32±4.05	68.56±6.19	117.21±7.12	2.46±2.33	
	six hours	109.74±4.01	63.56±6.1	114±6.14	20.19±2.16	
	24 hours	112.92±4.89	63.57±6.92	109.5±7.62	19.05±2.12	
Morphine sulfate	Instantly	111.32±5.75	64.03±6.02	124.5±7.9	21.74±2.45	
	two hours	110.58±5.82	68.17±5.77	118.43±7.12	21.03±2.17	0.19
	six hours	112.42±4.39	65.73±5.96	111.7±6.14	19.87±2.92	
	24 hours	113.92±4.81	64.16±6.07	113.92±7.98	18.8±247	

4. DISCUSSION

Postoperative pain can cause physiological complications, short-term and even long-term respiration, hypertension, heart rate, sympathetic stimulation, decreased respiratory power, decreased lung volume, atelectasis and lung infections (Mallinson, 2017). Therefore, the present study is aimed to compare the hemodynamic and analgesic effects of intravenous ketorolac and morphine sulfate with morphine sulfate alone in patients who are candidates for simple abdominal surgery. In this study, all the candidate patients (59 patients) for simple abdominal surgery were evaluated.Based on Mann-Whitney test there was no significant difference between the two study groups in terms of age, gender, marital status, economic status, employment status, drug history, weight, systolic and diastolic pressure (P>0.05). Pain scores were different in the studied groups. Intravenous ketorolac and morphine sulfate showed lower scores than morphine sulfate alone. Difference in the group of intravenous ketorolac and morphine sulfate was significantly less than the other group. Statistically, there were significant differences between the studied groups. Also, comparing the mean pain intensity 2, 6, 12 and 24 hours after surgery in patients of the two groups showed significant differences and the amount of pain in both groups significantly decreased over time. Ketorolac and morphine sulfate group showed to be effective in improving pain, where a significant decrease in pain score was found in this group.

Shakeri et al., (2016) showed that the highest amount of pain in both groups decreased significantly over time. So that the highest amount of pain was at zero hours and the lowest amount of pain was at 12 hours after surgery. There was a significant difference between pain in different hours after surgery. Therefore, the amount of pain after surgery, between 6 and zero hours, between 12 and 6 hours and also between 12 and zero hours has significantly decreased in both groups. They stated that it could be concluded that the use of non-narcotic analgesics not only had no advantage over the group of opioid analgesics, but the use of morphine-apotel had a greater analgesic effect (Shakeri et al., 2016). Based on the data from present study the number of nausea after surgery was not significantly different in the study groups. The rate of nausea was statistically similar at almost all different times after surgery, where no significant difference was observed. Furthermore, postoperative sedation was not significantly different in the studied groups. The rate of sedation was not found to be statistically significant at different times after surgery. In addition, there were not any differences between the studied groups in terms of the duration of surgery.

In a study by Singh et al., (2009) a comparison of intravenous injection of lidocaine and ketorolac in regional anesthesia showed no significant difference between the two groups in the sensory pain receptor block but the duration of analgesia was longer in the ketorolac group. Various studies have also shown that the need to add stronger analgesics is higher in the Lidocaine group compared to the ketorolac group (Jankovic et al., 2008). In the present study, the analgesic effect was well observed in ketorolac and morphine sulfate group. Mean hemodynamic indices of SBP, DBP, HR and RR before, immediately 2, 6, 12 and 24 hours after surgery in patients in the two groups were studied. The results revealed that there were not any significant differences between two studied groups in terms of hemodynamic variables. Mirkheshti et al., (2012) confirmed that intravenous ketorolac could delay theonset of postoperative pain.

Buccelletti et al., (2014) reported that ketorolac was very helpful in controlling acute pain in emergency department. Another study reported that ketorolac was not significantly different from morphine in controlling pain at two, four, eight and 24 hours after chest surgery (Rainer et al., 2000). Morphine sulfate was well identified in pain control at all times including two, six and 24 hours. However, some studies have not observed the effectiveness of ketorolac in controlling pain. Lee et al., (2010) compared paracetamol, ketorolac, and paracetamol plus morphine, where there were not any significant differences in controlling and reducing pain between the three groups.

In the present study, PCA method was used. Studies aimed to compare the effect of usual and PCA methods on postoperative pain intensity in abdominal surgery have shown the role of this method in pain intensity and amount of medication. Shariati et al., (2014) demonstrated a significant difference between the mean pain intensity and the amount of medication taken by patients after surgery. But there was not any significant difference in side effects and vital signs between the two groups. These findings showed that PCA is more useful in comparison with conventional methods in postoperative pain relief, so this method could be suggested for postoperative pain relief. Germán Ramos-Rangel et al., (2017) stated that the use of systemic opioids after cesarean section could be appropriate and reduced some of the side effects associated with intra-intestinal administration. Postpartum cesarean section has been proven to significantly reduce opioid use and its adverse effects. They stated the multiple model management using NSAIDs or paracetamol could be capable of improving the safety profile and analgesic quality and reducing the need for opiates.

A similar study by Karbasy et al., (2020) found that pain scores decreased similarly for both groups, where mean systolic blood pressure decreased in both groups. Anyway, evaluation of the mean diastolic blood pressure in two studied groups revealed that it is significantly higher in the case group compared to the control group. In addition, the rate of respiration in the case group decreased significantly and came close to normal. They stated that using the combination of nitroglycerin and morphine could significantly decrease the amount of postoperative pain. However, it resulted in more stable hemodynamic parameters and improved respiration, without any side effects (Karbasy et al., 2020). Other systematic findings have suggested the role of ketorolac in reducing severe pain. They have mentioned the prevalence of postoperative pain as a postoperative problem that can lead to irreversible complications, if it is not prevented from starting or insufficiently treated, especially in old age. Other studies have shown that postoperative pain is an unpleasant experience that is triggered by various stimuli, and patients respond to it during the recovery period. Increased pain causes physiological disorders in all systems of the body. The use of narcotics or local anesthetics in reducing and relieving pain can be effective in increasing patient satisfaction, and ketorolac could be effective in this regard (Zhili et al., 2020; Rezaei et al., 2021).

5. CONCLUSION

Based on the findings presented herein, intravenous ketorolac and morphine sulfate had a more preventive effect in reducing pain compared to morphine sulfate. At different times after surgery, the pain intensity of the patients was the same in the two groups receiving analgesia. Given that the patients' recovery after surgery is directly related to the complications of the disease, the results of this study can be a guide to reduce complications and pain in patients. Recognizing effective strategies for decreasing the side effects of surgery should be given more attention by health officials.

Consent for publication

All authors declare that they have Consent for publication

Authors' contributions

All authors contributed to the design of the study, as well as data collection and analysis, and the writing of the manuscript. All authors read and approved the final manuscript.

Ethical approval

The study was approved by the Medical Ethics Committee of University code: IR.ZBMU.REC.1399.158.

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Conflicts of interest

The authors declare that they have no conflict of interest.

Data and materials availability

All data associated with this study are present in the paper.

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