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Effect of intraperitoneal irrigation with ketamine in comparison with lidocaine on pain following laparoscopic cholecystectomy; a randomized triple-blinded clinical trial

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Abstract

Introduction: The most common complaint in patients undergoing laparoscopic cholecystectomy is pain, especially in the abdomen, back, and shoulder regions. Relieving of pain after laparoscopic cholecystectomy is one of the most important concerns in postoperative care.

Objectives: In this study, we aimed to determine the effect of intraperitoneal Ketamine, lidocaine, and normal saline irrigation in patients undergoing laparoscopic cholecystectomy.

Patients and Methods: In a randomized, triple-blinded clinical trial, 66 patients were equally assigned into three groups, and intraperitoneal irrigation was done in the first group with lidocaine+ normal saline, the second group with ketamine + normal saline, and the third group with normal saline alone. The intensity and duration of the patient's pain in the abdomen and shoulder area, as well as the need for analgesics at intervals of 6, 12, 18, and 24 hours during the post-surgery period, were evaluated using the standard visual analogue scale (VAS) pain measurement criterion.

Results: There were no significant differences between the three groups in terms of disease history, age and surgery duration, smoking, and gender. The overall intensity of shoulder pain was not different in the three groups (P=0.141, F=2.02). The overall amount of abdominal pain was not different in the three groups. (P=.078, F=2.663). Patients in whom intraperitoneal irritation was done by normal saline experienced less abdominal pain (regardless of time) than the other two groups.

Conclusion: Adding ketamine or lidocaine to normal saline for intraperitoneal irrigation has no any greater effect than normal saline alone in reducing pain, duration, and frequency of need for analgesics after surgery. With due attention to the relatively better effect of normal saline and lower cost and complications, it is recommended to irrigate the surgical bed, superior surface of the liver, and under the right hemi diaphragm with normal saline.

Trial registration: The trial protocol was approved in the Iranian registry of clinical trials (#IRCT 20151020024625N6; https://irct.behdasht.gov.ir/trial/29644, ethical code; IR.SEMUMS.REC.1395.94).

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Introduction

Laparoscopic cholecystectomy is a choice method for symptomatic gallstone surgery (1). More than 80% of patients experience post-operative pain and need to analgesics. The intensity of post-operative pain reaches its peak in the first hours and decreases within 48-72 hours. Various methods have been used to reduce pain after laparoscopic cholecystectomy, such as intraperitoneal lavage with local anesthetics (2-6), use of normal saline (7,8), sub-hepatic drain (9,10), intraperitoneal lavage with steroids (11-15) and ketamine (16,17).

In the study by Abdul-Raouf and Amer, which compared the analgesic effect of ketamine or magnesium sulfate against bupivacaine, in reducing pain after laparoscopic cholecystectomy and showed that the simultaneous administration of ketamine or magnesium sulfate with bupivacaine is very effective and reduces the need to receive analgesia following laparoscopic cholecystectomy (18).

In another study by Kshirsagar et al, the analgesic effect of hydrocortisone in addition to bupivacaine was investigated compared to bupivacaine alone. Based on the observed results, hydrocortisone + bupivacaine is better than bupivacaine alone in reducing pain after laparoscopic cholecystectomy (14).

By comparing the effect of intraperitoneal

Key point

The most common complaint in patients undergoing laparoscopic cholecystectomy is pain, and relieving pain after laparoscopic cholecystectomy is one of the most important concerns in postoperative care. We evaluate the analgesic effect of adding ketamine or lidocaine to normal saline for intraperitoneal irrigation, which has no any greater effect than normal saline alone in reducing pain, duration, and frequency of need for analgesics after surgery. Due to the relatively better effect of normal saline and lower cost and complications, it is recommended to irrigate the surgical bed, superior surface of the liver, and under the right hemidiaphragm with normal saline.

irrigation by lidocaine and/or nalbuphine in reducing pain after laparoscopic cholecystectomy, Morsy and Abdalla point to the finding that the intensity of pain after laparoscopic surgery and need to analgesics in the lidocaine group are lower than the nalbuphine and normal saline groups (19).

El-Gaby and Mohamed investigated the anti-inflammatory and analgesic effects of ketamine in intraperitoneal irrigation. The result of the study indicated that the group that received the ketamine did not complain of pain and the need for painkillers in the first 24 hours after surgery was lower than control group (20).

Agarwal et al investigated the analgesic effects of intraperitoneal irrigation by sodium bicarbonate and normal saline in reducing pain after LC surgery with control group and observed that in the sodium bicarbonate group, shoulder pain after surgery was less, compared to other groups (21).

Assessing the analgesic effect of ketamine and bupivacaine via intraperitoneal irrigation indicated that intraperitoneal instillation of low dose ketamine to bupivacaine significantly reduced post-operative shoulder pain and analgesic requirement when compared to bupivacaine alone (22).

Objectives

Pain is a common complaint after laparoscopic cholecystectomyو and sometimes as one of the main problems, it causes increased morbidity and long-lasting hospitalization, while there is still no definite way to prevent its occurrence. In this clinical trial, intraperitoneal irrigation with ketamine as an antagonist of N-methyl-d-aspartate receptor (NMDAR; this receptor responsible for postoperative pain) was compared with lidocaine (a common local anesthetic) in order to achieve a reliable method to reduce pain after laparoscopic cholecystectomy and its outcomes.

Patients and Methods

Study design

In a triple-blinded clinical trial (the patient, outcome assessor and biostatistician do not know the content of the intervention), 66 patients with chronic cholecystitis who were candidates for laparoscopic cholecystectomy and classified in classes I and II based on American Society of Anesthesiologists score, enrolled in study.

Patients were randomly assigned to one of the three study groups using the randomization method with blocks of six. The groups receiving lidocaine, ketamine and normal saline were marked with the letters A, B and C respectively in the checklist. Flow diagram of the study presented in Figure 1.

Patients with a history of drugs or alcohol abuse, psychological disorders and the use of psychiatric medications, which are effective on post-operative pain, the presence of empyema of the gallbladder and acute cholecystitis, the presence of severe inflammation and adhesions that requires open surgery, bile leakage during laparoscopic surgery due to the rupture of the gallbladder, massive bleeding during surgery so that there is a possibility of peritoneal irritation due to the blood in the peritoneum, excluded from study. Before the surgery, informed consent was obtained from the eligible patients after providing full explanations about the study.

All patients were anesthetized by general anesthesia and using the same method combined with intravenous midazolam and fentanyl and O_2 to prepare them before induction of anesthesia. Propofol and intravenous atracurium and O_2 used to induction of anesthesia and then isoflurane gases (23) and O_2, propofol, atracurium and fentanyl to maintain anesthesia, and the pneumoperitonial pressure was maintained at 15-14 mm Hg during surgery.

After laparoscopic cholecystectomy, the surgical bed, superior surface of the liver and under the right hemidiaphragm were irrigated. In the first group, irrigation performed by 100 cc of 0.9% normal saline solution containing 3 mg/kg lidocaine 1%, in the second group by 100cc of normal saline 0.9% containing 0.5 mg/kg ketamine, and in the third group by 100 cc of normal saline 0.9% for 5 to 10 minutes. Then, all the liquid in the surgical bed was suctioned as much as possible. Then, in all 3 groups, the pneumoperitoneum was evacuated from the entrance of the ports and the air behind the liver was actively suctioned (18).

For all patients in the three groups, in the post-operative period, diclofenac sodium suppository, 100 mg rectal every 8 hours prescribed and 1 g of Apotel in 100 cc normal saline 0.9%, was infused within 15 minutes every 8 hours. At 6, 12, 18 and 24 hours after surgery, the intensity of pain in the shoulders and in the right upper quadrant of abdomen was evaluated and recorded using the standard pain measurement chart (VAS: visual analog scale). The frequency and dose of additional analgesics requested by the patient in the first, second, third and fourth six hours up to 24 hours were recorded in the checklist (18,24).

The VAS is a standard measurement chart that measures the intensity and quality of pain in patients. It is scored from zero to ten. There are six images in this scale, from “smiling”, which means absence of pain, to

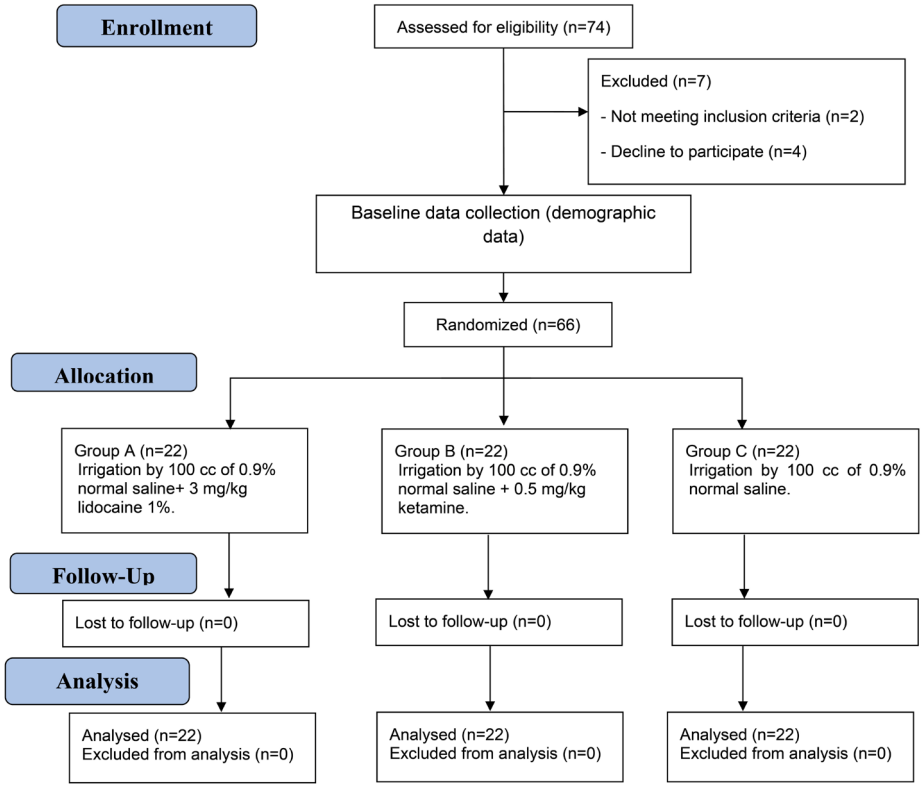

Figure 1. Flow diagram of the study.

"crying", which means the most intense pain, and each of the images between these two describes a degree of pain. After laparoscopic cholecystectomy, the outcome assessor talks to the patient, explains the images, and asks him to state which image expresses the intensity of his/her, pain.

Statistical analysis

The data were analyzed by chi-square, Fisher's exact tests, one-way ANOVA and repeated measure ANOVA in SPSS software version 23. Additionally, *P* value less than 0.05 is considered statistically significant.

Results

In this study, 66 patients who candidates for laparoscopic cholecystectomy and fulfilled the inclusion criteria were equally assigned in three groups including lidocaine, ketamine and normal saline groups. There were no statistically significant differences across the three groups in terms of gender ($P=0.109$) and age ($P=0.279$ and F=1.301).

There was no statistically significant difference in the frequency of smoking between the three groups ($P=0.348$). Surgery duration ($P=0.31$ and F=1.193) and history of disease ($P=0.83$) had no statistically significant difference between the three groups.

Intensity of abdominal pain in all three groups decreased significantly over time ($P<0.001$, F=346.949), on the other hand, the interaction effect between group and time was not significant, and therefore the change process of abdominal pain in the three groups was not different ($P=0.188$ and F=1.515). It was observed that the total severity of abdominal pain was different but not significant between three groups ($P=0.078$ and F=2.663). Therefore, the total severity of abdominal pain (regardless of time) was lower in the normal saline group than in the lidocaine group. Abdominal pain intensity 24 hours after the operation was not reported in any of the patients greater than 5 and only in 6 patients (9%) pain intensity of grade 4 was reported (Table 1, Figure 2).

Shoulder pain was not different in three groups

Table 1. Comparison of abdominal pain intensity (mean ± SD) in three intervention groups

Time of assessment (after surgery)	Intervention groups					
	Normal saline alone		Ketamine + Normal saline		Lidocaine + Normal saline	
	Mean	SD	Mean	SD	Mean	SD
6th	7.1	2.1	7.3	1.7	8.1	1.7
12th	4.5	1.4	5.4	1.3	5.5	1.4
18th	2.8	1.2	3.5	1.4	5.3	1.5
24th	2.1	0.7	2.1	1.1	6.2	0.8

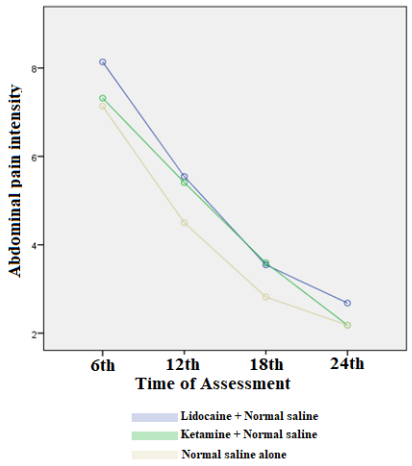

Figure 2. Abdominal pain intensity trend in three intervention groups.

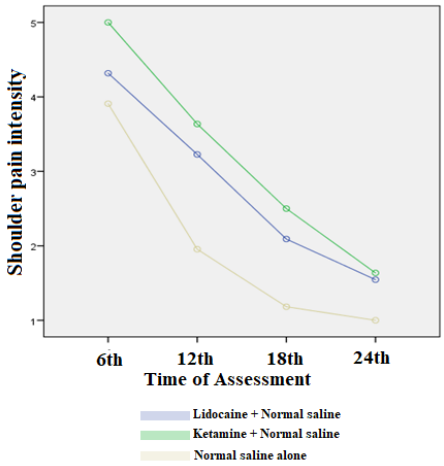

Figure 3. Shoulder pain intensity trend in three intervention groups.

($P=0.141$ and F=2.02). Shoulder pain in all three groups significantly decreased over time ($P<0.001$, F=91.07). However, the interaction effect between group and time was not significant, and therefore the trend of shoulder pain change in three groups was not different ($P=0.336$ and F=1.15). The intensity of shoulder pain 24 hours after the operation was not reported more than 5 in none of the patients, and in only 5 patients (5.7%) pain intensity of grade 4 was reported (Table 2, Figure 3).

There was no significant difference in receiving analgesics between the three groups ($P=0.385$, F=0.969). The number of analgesics received in the three groups significantly decreased over time ($P=0.005$ and F=8.563), however, the interaction effect between time and group was not significant, and therefore the process of receiving analgesics over time was not different in the three groups. None of the patients in three groups requested additional analgesics during the second 12 hours after the operation (Table 3, Figure 4).

Discussion

In our study, we compared the intensity of post laparoscopic cholecystectomy pain between three groups, including: irrigation the surgical bed, superior surface of the liver and under the right hemidiaphragm by lidocaine + normal saline, ketamine + normal saline and normal saline. The abdominal and shoulder pain intensity was evaluated at 6, 12, and 18 and also 24 hours after the operation, in addition, the number of received analgesics were recorded.

The findings showed that in all three groups, intensity of pain reduced after laparoscopic cholecystectomy, but the process of pain reduction was not different, and adding analgesics to normal saline did not have a greater effect on pain reduction or the time and frequency of receiving analgesics. The severity of abdominal pain in the normal saline group compared to the lidocaine group was not statistically significant, but the normal saline group was significantly better than the lidocaine group (P=0.07).

During the first 24 hours after the surgery, none of the

Table 2. Comparison of shoulder pain intensity (mean ± SD) in three intervention groups

Time of assessment (after surgery)	Intervention groups					
	Normal saline alone		Ketamine + Normal saline		Lidocaine + Normal saline	
	Mean	SD	Mean	SD	Mean	SD
6th	3.9	2.8	5	2.6	4.3	2.3
12th	1.9	1.8	3.6	2.5	3.2	2.5
18th	1.1	1.5	2.5	1.7	2	2.1
24th	1	1.3	1.6	1.4	1.5	1.6

Table 3. Comparison of analgesics doses in three intervention groups

Time of assessment (after surgery)	Intervention groups					
	Normal saline alone		Ketamine + Normal saline		Lidocaine + Normal saline	
	Mean	SD	Mean	SD	Mean	SD
6th	7.2	4.1	1.9	5	4.2	5.1
12th	0	0	2.0	1.0	2.0	1.0
18th	0	0	0	0	0	0
24th	0	0	0	0	0	0

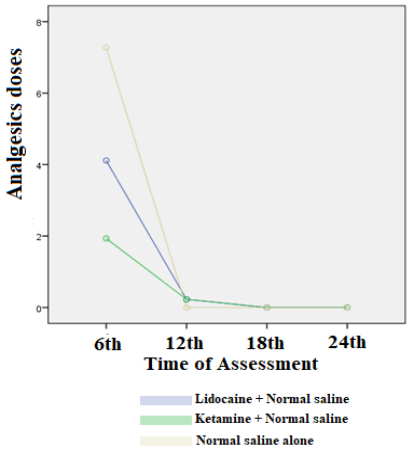

Figure 4. Analgesics doses trend in three intervention groups.

patients had pain intensity scores higher 5, and during the second 12 hours after the surgery, there was no request for analgesics.

Agarwal et al, had findings similar to our study (21). We showed that the severity of shoulder and trocar site pain, and frequency of receiving additional analgesics were not significantly different between groups. However, the findings of the study by Goma et al (24), El-Gaby and Mohamed (20), contradicted the findings of our study and ketamine and lidocaine were more effective than normal saline.

The findings of a study by Morsy and Abdalla are contrary to our study and the combination of lidocaine + nalbuphine compared to normal saline has a greater effect on pain reduction after laparoscopic cholecystectomy and a reduction in need to analgesics in the first 24 hours after surgery (19). On the other hand, in our study, the reduction of abdominal pain was greater in the saline group compared to lidocaine + saline, which may be due to the combined use of nalbuphine with lidocaine in the study by Morsy and Abdalla (19). Of course, other studies have reported better and longer effects in pain control by adding ropivacaine to normal saline (18,25,26), which is in contrast to our study and this may be due to the type of analgesic agent.

Although some studies point to the effectiveness of adding ketamine or lidocaine to normal saline for intraperitoneal irrigation in pain relief, the present study showed that despite the results of others, adding ketamine or lidocaine to normal saline for intraperitoneal irrigation had not accompanied with a greater effect in reducing pain intensity, duration and need to analgesic after laparoscopic cholecystectomy, and on the other hand, the overall amount of abdominal pain was relatively better in the normal saline group than in the lidocaine + normal saline group.

According to the results of present study, we recommend a study with a larger sample size, so that in case of the effectiveness of irrigation by normal saline on reducing pain and the need for analgesics in laparoscopic cholecystectomy, intraperitoneal irrigation by normal saline should be done, which is low-cost and without complication.

Conclusion

Adding the ketamine or lidocaine to normal saline for intraperitoneal irrigation has no any greater effect than normal saline alone in reducing pain, duration and frequency of need to analgesics after surgery. With due attention the relative better effect of normal saline and lower cost and complications, it is recommended to irrigate the surgical bed, superior surface of the liver and under the right hemidiaphragm by normal saline.

Limitations of the study

One of the limitations of our study was the small sample size and the lack of a control group, which may lead to different or more acceptable results with a larger sample size or comparison with control group. According to the results of present study, we suggest that a study be conducted with a larger sample size and with control group, so that the findings can be generalized with more confidence.

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Authors' contribution

Conceptualization: Hamid Reza Hemmati, Raheb Ghorbani.
Data curation: Amir Molaei, Hamid Reza Hemmati.
Formal analysis: Raheb Ghorbani.
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Methodology: Raheb Ghorbani.
Project administration: Hamid Reza Hemmati
Supervision: Hamid Reza Hemmati
Validation: Hamid Reza Hemmati.
Visualization: Hamid Reza Hemmati, Raheb Ghorbani, Amir Molaei.
Writing–original draft: Shahrzad Izadi and Amir Molaei.
Writing–review and editing: Hamid Reza Hemmati.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical issues

This randomized controlled trial was conducted in the Surgical ward of Kowsar Hospital in Semnan, Iran. It was approved by approved by the ethics committee of Semnan University of Medical Sciences (Ethical code #IR.SEMUMS.REC.1395.94). This clinical trial was registered on the IRCT website under the main ID: IRCT 20151020024625N6. This study adheres to the principles outlined in the Declaration of Helsinki. Informed consent was obtained for studying the patient's medical records. Besides, ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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