Research Article

The Effect of Dexamethasone Administration on Postoperative Pain Following Laparoscopic Cholecystectomy: A Double-Blind Randomized Clinical Trial

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Abstract

Background: Laparoscopic cholecystectomy is the standard surgical procedure in symptomatic gallstones. Laparoscopy is a minimally invasive surgical method. The aim of the present study was to investigate the effect of dexamethasone (DX) administration on postoperative pain management following laparoscopic cholecystectomy.

Materials and Methods: 165 patients with laparoscopic cholecystectomy surgery were studied in this double-blind clinical trial. They were randomly divided into three groups: A) DX1 (Intravenous DX): Injection of 0.1 mg/kg DX intravenously, B) DX2 (Local DX): Injection of 0.1 mg/kg of DX, diluted with normal saline, injection volume of 10 mL, injection into the bed of the removed gallbladder through a laparoscopic 10 mm subxiphoid trocar, and C) Control: Injection of placebo, the volume and injection site are similar to group B. The amount of postoperative pain in patients was recorded using the Visual Analogue Scale score in 5 times (15 minutes, 30 minutes, 1 hour, 6 hours, and 12 hours after entering the recovery room).

Results: In terms of postoperative pain, there was a statistically significant difference between the studied groups so that the amount of postoperative pain 6 hours and 12 hours after surgery in the intravenous DX group was lower than that in the local DX and placebo groups ($P = 0.001$).

Conclusions: The results of this study showed that the administration of intravenous DX has a better effect than the administration of local DX in pain management after laparoscopic cholecystectomy.

Keywords: Cholecystectomy, dexamethasone, laparoscopy, pain, postoperative

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Introduction

Gallstones are one of the common diseases of the digestive system. Currently, the gold standard for the treatment of gallstones is laparoscopic cholecystectomy (LC).[1] LC is among the most frequently performed elective surgical procedures globally.[2] Because of the significant progress in anesthesia and surgery management, more patients undergoing elective LC patients can be discharged on the day of surgery.[3] During minimally invasive procedures, the activation of various metabolic, hormonal, inflammatory, and immune responses may interfere with the clinical healing process. Optimum management and reduction of these adverse physiological responses can lead to more favorable surgical results and faster recovery in the post-anesthesia care unit (PACU) and ambulatory surgery unit (ASU-Phase II) and

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reducing hospital stay length.[4,5] Postoperative pain (POP) is one of the specific complications of elective LC, which often occurs immediately after surgery.[6,7] Since pain has a significant impact on the duration of hospitalization, patient satisfaction, recovery time, and return to daily activities, discovering effective strategies to optimally manage and decrease POP has consistently posed a significant challenge for surgeons. The usual method for POP management is the use of opioids, the administration of which leads to serious side effects such as respiratory failure and drug abuse.[8,9] Given the side effects of opioids, prescribing safer drugs with fewer side effects has always been a challenge.[10,11] Since prostaglandins are important mediators in causing pain, it seems that the use of glucocorticoids (due to the inhibition of cyclooxygenase and lipoxygenase pathways) in pain management is a logical choice.[12] Due to the extensive side effects and, in some cases, the ban on the use of narcotic drugs and NSAIDs, their administration is not convenient, so glucocorticoids can be used as an alternative pain reliever.[13,14] Many studies have reported the positive effect of dexamethasone to manage pain, nausea, and vomiting after tonsil, ear, gall bladder, genital surgery, correction of eye deviation surgery in children, and hemorrhoidectomy.[15-18] Dexamethasone is one of the utmost effective corticosteroids, exhibiting a biological half-life ranging from 36 to 72 hours.[19] This drug alone or together with other antiemetic drugs is effective in reducing nausea and vomiting after laparoscopic surgery.[20] In addition, low doses of steroids are efficient in decreasing POP, improving mood, diminishing fatigue, and enhancing appetite.[21] Therefore, long-acting steroid administration such as dexamethasone to patients with LC may decrease clinical outcomes and enhance the quality of recovery during the first 24 hours following surgery. According to these explanations, this study was designed and conducted with the aim of the effect of dexamethasone administration on POP following LC in Golestan Hospital of Ahvaz.

Materials and Methods

Study design and patients

This randomized, double-blind clinical trial was carried out in 165 patients undergoing LC. Subjects having an age of 18 to 75 years, American Society of Anesthesiologists' (ASA) class I or II, and LC were included. Those with contraindication or sensitivity to the used drugs and participants who used narcotics, methadone, and systemic glucocorticoid daily in the past 3 months were excluded from the present investigation. The blinding of this study was double-blind (researcher and participants did not know the type of injectable pain medication).

Grouping

The study population was randomly assigned to one of three intervention groups:

A) DX1 (Intravenous dexamethasone): Injection of 0.1 mg/kg dexamethasone intravenously when gallbladder removed.

B) DX2 (Local dexamethasone): Injection of 0.1 mg/kg of dexamethasone, diluted with normal saline, injection volume of 10 mL, injection into the bed of the removed gallbladder through a laparoscopic 10 mm subxiphoid trocar.

C) Control: Injection of placebo, the volume and injection site are similar to group B.

Data gathering

Demographic information, clinical data including history of hypertension, cerebrovascular disease, and post-medical history were collected for all three groups. Indeed, surgery time, hospitalization, need for narcotics, and the amount of postoperative pain were also reported for all patients in all three groups.

Anesthesia, surgery, and follow-up

After routine monitoring, the patients were anesthetized with midazolam (0.03 mg/kg), fentanyl (2 μg/kg), sodium thiopental (5 mg/kg), and atracurium (0.5 mg/kg). Patients were intubated. Routine analgesic treatment (remifentanil 0.1 μg/kg/min; exactly from the moment of blowing CO2 and creating pneumoperitoneum until the completion of sutures at the trocar site) was given to all patients during surgery. Immediately after anesthesia induction, morphine sulfate (0.1 mg/kg) was administered to the patients. The patient's hemodynamics were recorded before induction of anesthesia, 15 minutes after surgical incision, 15 minutes after cholecystectomy, immediately after extubating, immediately after recovery room entering, 15 minutes after recovery, and during transfer to the ward. During the surgery, the patient's hemodynamics were checked every 5 minutes. The amount of postoperative pain in patients was recorded using the Visual Analogue Scale (VAS) score in 5 times (15 minutes, 30 minutes, 1 hour, 6 hours, and 12 hours after entering the recovery room). The minimum VAS score is zero, and the maximum score is 10. A score of 10 indicates the most pain, and a score of zero indicates no pain. Before the surgery, during informed consent, the patients were trained through verbal explanation on how to evaluate pain intensity with the VAS score. In case of VAS above 8, pethidine was injected to the patient and the amount of narcotic consumption (in milligrams) was recorded in the recovery room and in the ward.

Statistical analysis

Data were presented as Mean ± SD for qualitative variables and frequency and percent for quantitative variables. To examine the relationship between variables, independent sample *t*-test and Chi-square test as well as logistic regression were used. To examine the hypothesis of normality of the data, Kolmogorov–Smirnov test was used. Data analysis were performed using SPSS version 27 software. P value < 0.05 was considered significant.

Results

The results of this study showed that 55 patients (33.3%) were in the intravenous dexamethasone group, 55 patients (33.3%) were in the local dexamethasone group, and 55 patients (33.3%) were in the control group. According to ANOVA test, there was no notable difference in the average age of the patients (in terms of years) in the groups of intravenous dexamethasone (44,20 ± 12,84), local dexamethasone (47,27 ± 12,77), and control (55,94 ± 13,19). In the intravenous dexamethasone group, 38.2% of the patients were male (61.8% female); in the local dexamethasone group, 43.6% of the patients were male (56.4% female); and in the control group, 30.9% of the patients were male (69.1% female). In the intravenous dexamethasone group, 56.4% of patients did not have post-medical history (PMH) (43.6% with PMH); in the local dexamethasone group, 45.5% of patients did not have PMH (54.5% with PMH); and in the control group, 60% of patients did not have PMH (40% with PMH). 30.9% of the patients in the intravenous dexamethasone group, 34.5% of the candidates in the local dexamethasone group, and 16.4% of the subjects in the control group had diabetes. 29.1% of the patients in the intravenous dexamethasone group, 38.2% of the candidates in the local dexamethasone group, and 36.4% of the subjects in the control group had hypertension. 12.7% of patients in intravenous dexamethasone group, 16.4% of patients in local dexamethasone group, and 20% of the patients in the control group had cardiovascular disease.

In terms of surgery time, no statistically notable difference was reported (P = 0.051) between the three groups of intravenous dexamethasone (9.92 ± 96.8 minutes), local dexamethasone (97.90 ± 11.49 minutes), and control (99.27 ± 11.36 minutes).

Statistically, in terms of hospitalization time, there was no notable difference (P = 0.370) between the three groups of intravenous dexamethasone (2.25 ± 0.47 days), local dexamethasone (2.14 ± 0.35 days), and control (2.18 ± 0.38 days).

In terms of the need for narcotics, there was a statistically significant difference between the three groups of intravenous dexamethasone (4.17 ± 7.36 mg), local dexamethasone group (10.18 ± 5.35 mg), and the control group (10.72 ± 5.80 mg). So the need for narcotics in the intravenous dexamethasone group was less than that in the other groups (P = 0.002).

The amount of postoperative pain intensity in patients was recorded using the VAS score in 5 times (15 minutes, 30 minutes, 1 hour, 6 hours, and 12 hours after entering the recovery room). The results related to postoperative pain intensity are presented in Table 1.

In terms of pain intensity 15 minutes after entering the recovery room, there was no statistically remarkable difference (P = 0.188) between the three groups of intravenous dexamethasone (4.70 ± 0.87), local dexamethasone group (4.20 ± 0.73), and the control group (3.92 ± 0.71). In terms of pain intensity 30 minutes after entering the recovery room, there was no statistically considerable difference (P = 0.091) between the three groups of intravenous dexamethasone (4.61 ± 0.70), local dexamethasone group (4.85 ± 0.62), and the control group (4.87 ± 0.69). In terms of pain intensity 1 hour after entering the recovery room, there was no statistically substantial difference (P = 0.247) between the three groups of intravenous dexamethasone (5.12 ± 0.69), local dexamethasone group (5.43 ± 0.60), and the control group (5.61 ± 0.49). In terms of pain intensity 6 hours after entering the recovery room, there was statistically dramatic difference (P < 0.0001) between the three groups of intravenous dexamethasone (5.50 ± 0.63), local dexamethasone group (6.30 ± 0.60), and the control group (6.25 ± 0.64). So, the amount of pain in the intravenous dexamethasone group was significantly lower than that of the other two groups. In terms of pain intensity 12 hours after entering the recovery room, there was a statistically notable difference (P < 0.0001) between the three groups of intravenous dexamethasone (5.69 ± 0.46), local dexamethasone group (6.43 ± 0.60), and the control group (6.52 ± 0.50). So, the amount of pain in the intravenous dexamethasone group was significantly lower than that of the other two groups.

Table 1: The level of VAS in the studied groups

Variable	Groups	*N*	Mean	SD	*P*
Vas 1 h	Intravenous dexamethasone	55	5.12	0.69	0.247
	Local dexamethasone	55	5.43	0.60	
	Control	55	5.61	0.49	
Vas 6 h	Intravenous dexamethasone	55	5.50	0.63	*(P<0.0001)
	Local dexamethasone	55	6.30	0.60	
	Control	55	6.25	0.64	
Vas 12 h	Intravenous dexamethasone	55	5.69	0.46	**(P<0.0001)
	Local dexamethasone	55	6.43	0.60	
	Control	55	6.52	0.50	
Vas 15 min	Intravenous dexamethasone	55	4.07	0.87	0.188
	Local dexamethasone	55	4.20	0.73	
	Control	55	3.92	0.71	
Vas 30 min	Intravenous dexamethasone	55	4.61	0.70	0.091
	Local dexamethasone	55	4.85	0.62	
	Control	55	4.87	0.69	

*Intravenous dexamethasone versus control group and intravenous dexamethasone versus local dexamethasone. **Intravenous dexamethasone versus control group and intravenous dexamethasone versus local dexamethasone. Abbreviations: Vas: Visual Analogue Scale. P less than 0.05 was considered significant

Discussion

Dexamethasone has been found to diminish postoperative vomiting and nausea post laparoscopic cholecystectomy. Nonetheless, its impact on other surgical outcomes has been unknown. The current study was performed to compare the effects of intravenous and local dexamethasone on the

postoperative pain in patients who underwent laparoscopic cholecystectomy. In terms of pain intensity 15, 30, and 60 minutes after entering the recovery room, no statistically notable difference was observed between the three groups of intravenous dexamethasone, local dexamethasone group, and the control group. It seems that patients were under the effects of anesthesia drugs and dexamethasone did not induce its effect during these periods. In terms of pain intensity 6 and 12 hours after entering the recovery room, there was a statistically significant difference between three groups. So, the amount of pain in the intravenous dexamethasone group was significantly lower than that of the other two groups.

In 2021, Gasbjerg *et al*.[22] conducted a randomized clinical trial entitled the effect of dexamethasone as an analgesic aid in the treatment of multimodal pain after total knee arthroplasty. In this study, 485 patients were studied in three groups: DX1) (n = 161) 24 mg dexamethasone + placebo, DX2) (n = 162) 24 mg dexamethasone + 0 mg dexamethasone, and Placebo) (n = 162) placebo + placebo. The intervention was performed before and 24 hours after surgery. All patients received paracetamol, ibuprofen, and local infiltration analgesia. The primary outcome analysis included data from 472 patients, accounting for 97.3% of the total. The mean consumption of morphine in 0–48 hours was: 37.9 mg for DX1 (20.7 to 35.0), 56.7 mg for DX2 (20.6 to 52.0), and 43.0 mg for placebo (28.7 to 64.0). POP was decreased within 24 hours with a single dose and within 48 hours with two doses of dexamethasone. In the present study, the amount of pain after intravenous dexamethasone administration compared to the local administration and placebo has decreased.

In 2020, Ali *et al*.[23] studied 75 patients undergoing elective LC in a prospective clinical trial entitled comparative study of dexamethasone versus ondansetron as intraperitoneal bupivacaine adjuvant to reduce POP in patients undergoing elective LC. Patients were divided into three groups: A) Control group (n = 20): 25 mL bupivacaine 0.5% with 2 mL normal saline injected in the gallbladder bed, B) Dexamethasone group (n = 25): 20 mL bupivacaine 0.5% and 2 mL dexamethasone (8 mg) injected in the same place, and C) Ondansetron group (n = 25): 20 mL of 0.5% bupivacaine and 2 mL of ondansetron (4 mg) injected in the same place. Pain intensity was assessed at 1, 9, 6, 3, and 12 hours postsurgery by VAS score. Pain in the ondansetron group at 1, 3, 6, and 12 hours after the operation was dramatically lower than that in the other two groups; also, the pain in the dexamethasone group was less than that in the control group. The results of the current research are consistent with the results of Ali *et al*.'s study in such a way that the amount of pain after intravenous dexamethasone injection has decreased compared to the local and control groups.

In 2020, Al-Radeef *et al*.[24] studied patients undergoing LC or open appendectomy in a randomized clinical trial entitled comparison of the impact of dexamethasone, normal saline, and metoclopramide on the suppression of postoperative nausea, vomiting, and pain. Patients were randomly divided into three groups: dexamethasone, normal saline, and metoclopramide. Compared to normal saline and metoclopramide, the dexamethasone group is more effective in reducing pain for patients who underwent LC or open appendectomy surgery under general anesthesia. Their findings were consistent with the findings of the current investigation, so in the present study, the amount of pain in the intravenous dexamethasone group was lower than that in the control and local dexamethasone groups.

In 2018, Emami *et al*.[25] studied 140 LC candidate patients in a randomized clinical trial entitled the effectiveness of a single dose of dexamethasone in reducing POP, nausea, and vomiting. In this study, POP was recorded in two periods of 4 to 8 hours and 8 to 12 hours after the surgery using the VAS score for the two groups of dexamethasone and normal saline. There was a significant difference between the two groups in both periods after surgery, 4 to 8 hours (dexamethazone group: 4.09 ± 1.01, normal saline group: 1.24 ± 4.49) and 8 to 12 hours (dexamethazone group: 2.06 ± 0.81, normal saline group: 2.47 ± 1.16). According to the findings of this study, one dexamethasone dose has a remarkable decreasing impact on POP and PONV in patients undergoing LC, which these findings are consistent with the results of the present study.

In 2014, Mohtadi *et al*.[26] studied 122 patients aged 18 to 60 who were selected for LC in a double-blind and prospective study entitled "The effect of single-dose dexamethasone administration on POP in patients undergoing LC". The intensity of POP in the dexamethasone group after 2, 6, and 12 hours after surgery was dramatically lower compared to the control group. There was no significant difference in pain intensity between the two groups at the beginning and 24 hours after surgery. The consumption of meperidine in the dexamethasone group was notably lower in comparison to the control group. These findings indicate that intravenous dexamethasone reduces POP, which is in line with the findings of the current research.

In 2013, Waldron *et al*.[27] conducted a systematic review on the effect of postoperative administration of dexamethasone on analgesia and postoperative complications and found that patients receiving dexamethasone had a lower pain score and used less opioids 2 and 24 hours after surgery. In cases of unbearable pain, these patients had a longer time interval until the first dose of painkillers, and the length of stay in the post-anesthesia care unit was shorter. In the present study also, the amount of pain and consumption of opioids after surgery was lower in the intravenous dexamethasone group than in the local dexamethasone and control groups, but the duration of hospitalization in the intravenous dexamethasone group was not significantly different from the other groups.

Murphy *et al*.[28] in 2010 in a study entitled "Preoperative dexamethasone improves the quality of recovery after LC" studied 120 patients undergoing outpatient LC (two groups: dexamethasone and placebo-saline). The QoR-40 global score on the first day after surgery was higher in the dexamethasone

group in comparison to the control group. The postoperative QoR-40 score in the dimensions of emotional state, physical comfort, and pain showed significant improvement in the dexamethasone group compared to the control group. Nausea, fatigue, and pain scores decreased in the dexamethasone group throughout the hospitalization period. Also, the need for painkillers after surgery and the total length of stay in the hospital decreased. In the present study also, the amount of postoperative pain and analgesia was lower in the intravenous dexamethasone group than in the control and local dexamethasone groups. However, the length of hospitalization in the intravenous dexamethasone group was not significantly different from the other two groups.

In 2014, Ahmadi *et al*.[29] investigated the effect of intravenous dexamethasone on pain after abdominoplasty surgery. The intervention group received intravenous dexamethasone (8 mg) and the control group did not receive medication. The average pain level immediately and 6, 12, 18, and 24 hours after abdominoplasty in the intervention group had a remarkable difference in comparison to the control group. The results of this study show that dexamethasone can reduce the severity of pain after abdominoplasty surgery. In the present study also, the amount of POP in the intravenous dexamethasone group was lower than that in the local dexamethasone and control groups.

In 2014, Gita *et al*. investigated the effectiveness of intravenous dexamethasone in the incidence and intensity of pain during intravenous injection of propofol. In all patients, one of the veins on the back of both hands was cannulated using a 20-gauge angiojet. Randomly and simultaneously, 2 mL of dexamethasone (8 mg) was injected into one of the veins and 2 mL of normal saline was injected into the other. After 30 seconds, 2 mm of propofol (20 mg) was injected simultaneously from each of the two venous catheters in 30 seconds. The average pain intensity during propofol injection in the dexamethasone group was dramatically lower compared to the normal saline group (1.61 vs 4.21 according to VAS score). Also, pain incidence was notably lower in the dexamethasone group than in the normal saline group. Injection of 8 mg of dexamethasone before propofol injection significantly reduces the intensity and incidence of pain during propofol injection.[30] Even in the study conducted by us, the amount of pain in the intravenous dexamethasone group was lower than that in the local dexamethasone and control groups.

In 2016, Dabirmoghaddam *et al*.[31] compared the effectiveness of intravenous injection of one dose of dexamethasone and local injection of bupivacaine in reducing pain and vomiting after tonsillectomy. Postoperative pain intensity was evaluated at 0.5, 4, 24, and 120 hours after extubation and transfer to the recovery room. The only significant decrease in POP parameter was related to the bupivacaine group and 4 hours after surgery. Considering the reduction of pain after tonsillectomy by intravenous dexamethasone and local bupivacaine, the simultaneous use of two drugs in tonsillectomy is recommended, and it is suggested to investigate the simultaneous use of two drugs. Even in the present study, intravenous dexamethasone was effective in reducing pain in patients after LC.

Limitations

There were no specific limitations in the present study, but increasing the sample size and increasing the follow-up time could have increased the accuracy of the study.

Conclusion

According to the results of the present study, it seems that the most pain caused after laparoscopic cholecystectomy was caused by peritoneal irritation, so the use of local dexamethasone was not effective, and dexamethasone shows its effect by suppressing pain systemically. Due to the reduction of pain by intravenous dexamethasone compared to local administration, it is recommended to use this drug intravenously. Considering the possible side effects, more studies in this area are suggested.

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Authors' contribution

Study concept and design: A.Gh. Analysis and interpretation of data: M.V. Manuscript preparation: M.V, A.Gh, A.A, and S.F.T. Data collection: A.Gh. Critical revision: M.V.

Availability of data

All data included in the article.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran (IR.AJUMS.HGOLESTAN.REC.1402.039), with IRCT registration number IRCT20230625058577N1.

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Conflicts of interest

There are no conflicts of interest.

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