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The Effect of Gall Bladder Bed Infiltration on Analgesia in Laparoscopic Cholecystectomy

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Laparoskopik Kolesistektomide Safra Kesesi Yatağı İnfiltrasyonunun Analjezi Üzerine Etkisi

ABSTRACT

Objective: *Gallbladder is highly innervated by parasympathetic and sympathetic nervous system through anterior and posterior hepatic plexus and the phrenic nerves. The aim of the current study is to evaluate the efficacy of infiltration of lidocaine into gallbladder bed in controlling postoperative abdominal pain and reducing analgesic consumption following laparoscopic cholecystectomy.*
Methods: *This randomized prospective double-blind study was conducted on 70 patients applied for laparoscopic cholecystectomy. Six patients were excluded or dropped out and the patients were allocated into 2 groups as control group (n=32) in which gallbladder bed was infiltrated with normal saline and infiltration group (n=32) in which lidocaine was infiltrated into gallbladder bed. Pain within the first postoperative 24 hours, time to the need for first rescue analgesia and analgesic consumption were recorded.*
Results: *The postoperative visual analogue score within the first 24 hour for visceral pain at rest, during coughing, and movement was significantly lower in the infiltration group than the control group, but it was similar for somatic pain. Time to first rescue analgesia was significantly longer in the infiltration than the control group. Significantly smaller number of patients required morphine and the total dose of postoperative analgesic consumption was lower in the infiltration than the control group.*
Conclusion: *Gallbladder bed infiltration with lidocaine was associated with decreased visceral pain intensity at rest, coughing, and movement with reduced analgesic consumption in the first postoperative 24 hours.*

Keywords: *Analgesia, lidocaine, cholecystectomy, gall bladder bed, laparoscopy*

ÖZ

Amaç: *Safra kesesi, anterior hepatik pleksus, posterior hepatik pleksus ve frenik sinirler yoluyla parasempatik ve sempatik sinir sistemi tarafından yüksek oranda innerve edilir. Bu çalışmanın amacı, laparoskopik kolesistektomi sonrası postoperatif abdominal ağrıyı kontrol altına almak ve analjezik tüketimini azaltmak için safra kesesi yatağına lidokain infiltrasyonunun etkinliğini değerlendirmektir.*
Yöntem: *Bu randomize prospektif çift kör çalışma, laparoskopik kolesistektomi için başvuran 70 hasta üzerinde yapıldı, 6 hasta çalışma dışı bırakıldı veya çalışmadan ayrıldı. Hastalar safra kesesi yatağına normal salin infiltre edilen kontrol grubu (n=32) ve lidokain infiltre edilen infiltrasyon grubu olarak 2 gruba ayrıldı (n=32). Postoperatif ilk 24 saatte, postoperatif ağrı, ilk kurtarıcı analjezi süresi ve analjezik tüketimi kaydedildi.*
Bulgular: *Postoperatif ilk 24 saatte, postoperatif visual analog skor, visseral ağrı için, istirahatte, öksürme ve hareket esnasında infiltrasyon grubunda kontrol grubuna göre anlamlı olarak düşüktü ve somatik ağrı için benzerdi. İlk kurtarıcı analjezi süresi infiltrasyonda kontrol grubuna göre anlamlı olarak daha uzundu. Kontrol grubuna göre infiltrasyon grubunda, morfin ihtiyacı olan hasta sayısı anlamlı derecede daha azdı ve postoperatif analjezik tüketiminin toplam dozu daha düşüktü.*
Sonuç: *Lidokain ile safra kesesi yatağı infiltrasyonu, postoperatif ilk 24 saatte istirahatte, öksürme ve hareket esnasında viseral ağrı yoğunluğunun ve analjezik tüketiminin azalması ile ilişkiliydi.*

Anahtar kelimeler: *Analjezi, lidokain, kolesistektomi, safra kesesi yatağı, laparoskopi*

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INTRODUCTION

Cholecystectomy is one of the most frequently performed abdominal surgeries [1]. Laparoscopic cholecystectomy is associated with minimal surgical trauma, good cosmetic surgical results, insignificant blood loss, reduced severity of postoperative pain and early discharge from hospital [2]. Inappropriate management of pain after laparoscopic cholecystectomy results in prolonged hospital stay and increased incidence of patient readmission after hospital discharge [3].

Postoperative pain following laparoscopic cholecystectomy manifests itself as somatic, visceral and shoulder tip pain. Somatic pain is localized to incision sites for the insertion of surgical ports through abdominal wall. Visceral pain is a dull aching diffuse deep pain that is caused by surgical dissection, stretching and manipulation of tissues in the region of gallbladder bed and is perceived by the nociceptors of the visceral peritoneum that covers neighboring abdominal viscera [4]. Shoulder tip pain is a referred type of pain that is caused by residual carbon dioxide and it usually occurs on the second postoperative day [5].

There is a strong evidence that intraperitoneal instillation of local anesthetics is associated with significant reduction of postoperative abdominal and shoulder pain and opioid consumption after laparoscopic gynecological [6] and gastric [7] procedures but this evidence is weak after laparoscopic cholecystectomy [8].

Visceral pain is more severe and predominant than somatic pain [9]. Surgical dissection of gallbladder from its bed in the inferior surface of the liver may cause injury and cauterization of Glisson's capsule (visceral peritoneum of the liver) resulting in increased intensity of postoperative abdominal pain and increased need for opioid analgesia after laparoscopic cholecystectomy [4].

The gallbladder is innervated by parasympathetic and sympathetic nervous system through three routes which are anterior hepatic plexus, posterior hepatic plexus and the phrenic nerves [10].

The current study was designed to evaluate the efficacy of infiltration of a mixture of lidocaine and epinephrine into gallbladder bed in reduction of postoperative abdominal pain and analgesic consumption following laparoscopic cholecystectomy.

MATERIAL and METHODS

This randomized prospective double-blind study was conducted after approval of the ethics committee and a written informed consent from each patient enrolled in the study were obtained. The current study included 70 patients of either sex aged 20-65 years with an American Society of Anesthesiologists physical status (ASA) I or II undergoing elective laparoscopic cholecystectomy.

Patients were excluded from the study if they had one or more of following: common bile duct exploration, T tube drain insertion, presence acute cholecystitis, severe systemic disease, body mass index > 40 kg m^{-2}, allergy to lidocaine or administration of analgesics within 24 hours prior to surgery. Four patients were excluded from the current study, 2 patients refused to participate in the study and another 2 patients were not meeting the inclusion criteria. The intervention was discontinued in 2 patients as they were explored by open laparotomy.

Anesthetic management

All patients were evaluated preoperatively by reviewing data concerning medical history, clinical examination and investigations. The patients received 0.05 mg kg^{-1} IV midazolam as a premedication in the preoperative holding area. All patients were transferred to the operating room and monitored with measurements of noninvasive arterial blood pressure (NIBP), heart rate (HR), electrocardiography (ECG), pulse oximetry (SpO_2) and capnography. Anesthesia was induced with IV propofol (2 mg kg^{-1}) and fentanyl (1 µg kg^{-1}). Orotracheal intubation was facilitated by using atracurium (0.5 mg kg^{-1}). All patients were mechanically ventilated with adjustment of the ventilator to keep the end-tidal CO_2 at 35-40 mmHg. Anesthesia was maintained with 1 MAC isoflurane in %50-50 O_2/air mixture. Lactated Ringer's solution (3-6 mL kg^{-1} h^{-1}) was infused throughout surgery. Incremental doses of intravenous fentanyl (25 µg)

were given if heart rate or blood pressure exceeded 20% of basal value in relaxed patients. Intra-abdominal pressure was not allowed to exceed 14 mmHg during the procedure. All patients received metoclopramide 10 mg, dexamethasone 4 mg and ranitidine 150 mg as a prophylaxis against postoperative nausea and vomiting. All patients received IV 15 mg kg^{-1} paracetamol about half an hour before extubation. At the end of laparoscopy, neostigmine (0.04 mg kg^{-1}) and atropine (0.02 mg kg^{-1}) were administered to antagonize any residual neuromuscular blockade.

Randomization

An anesthetist who was not involved in the study and not aware of the assignment of patient groups prepared the mixture of drugs to be injected. The surgeon, and nursing staff who collected the postoperative data and patient were unaware of given drugs and group allocation. The patients were randomly allocated by a computer-generated randomization table, and group assignments were concealed in sealed opaque envelopes and each group included 32 patients.

Infiltration group (n=32): The gallbladder bed was infiltrated with 50 mL of the mixture of lidocaine, normal saline and epinephrine.
Control group (n=32): The gallbladder bed was infiltrated with 50 mL normal saline plus 5 µg mL^{-1} lidocaine-free epinephrine.

Distribution of the infiltration mixture or cocktail

Patients received 3 mL kg^{-1} volume of 5 mg kg^{-1} lidocaine, normal saline and epinephrine 5 microgram (µg) mL^{-1} mixture or cocktail that were distributed as follows:

1. Periportal: In all patients of both groups 5 mL of lidocaine epinephrine mixture was infiltrated at each site of laparoscopy port entry (15-20 mL, total volume) before skin incision. At the end of surgery another 5 mL of this mixture was infiltrated at the site of drain entry site.

2. Intraperitoneal: In all patients of both groups after extracting 50 mL of saline or the lidocaine cocktail for gallbladder bed infiltration, the remaining solution (about 140 mL for a 70 kg-individual) was immediately sprayed after carbon dioxide insufflations into the peritoneum, as follows: the surgeon sprayed 70 mL of the total solution in the right subphrenic space, and another 70 mL over the parietal peritoneum with the patient maintaining the Trendelenburg position for at least 2 minutes to allow the sprayed local anesthetic mixture to spread all over the subphrenic space.

3. Gall bladder bed infiltration:

a-The infiltration group: Fifty milliliters of lidocaine epinephrine mixture was infiltrated into the gallbladder bed and pedicle after clamping the cystic duct and artery. Infiltration was done through a laparoscopic suction needle with a size of 0.9/330 mm.
b-The control group: Fifty milliliters of normal saline plus 5 µg mL^{-1} epinephrine were infiltrated into gallbladder bed using the same method as in the infiltration group.

Postoperative care

A 10-point visual analogue scale (VAS) was used to assess pain intensity of both somatic (localized to abdominal wall) and visceral abdominal pain (dull, aching, non-localized deep pain) following laparoscopic cholecystectomy during the first 24 postoperative hours. Zero (0) denotes absence of pain and 10 points intolerable pain. If the VAS score for visceral pain was >3 pts, incremental doses of 2 mg morphine and ketorolac 15 mg were administered intravenously.

Data collection

The primary outcome measures were total dose of morphine and ketorolac consumption and VAS scores within the first postoperative 24 hours. The postoperative VAS scores for both somatic and visceral pain at rest were calculated immediately after recovery from anesthesia, and at 2, 4, 8, 12, 16 and 24 hours, postoperatively. The VAS scores for both somatic and visceral pain were calculated during cough and movement within 12 hours after surgery. The secondary outcome measures were occurrence

of shoulder tip pain, time to the administration of the first rescue analgesia, the frequency of using rescue analgesia and the number of patients who required morphine for supplementary postoperative analgesia within the first postoperative 24 hours. Postoperative nausea and vomiting, time to the recovery of normal bowel movements after surgery and patient satisfaction as regards analgesic regimen were recorded.

Statistical analysis

The sample size was calculated based on the reduction of total dose of opioid consumption within the first postoperative 24 hours compared to baseline values by about 50% as in a previous similar study [11] (0.0301±0.04 versus 0.0639±0.04) mg kg^{-1} and the difference required a total sample size of 31 patients for each group to obtain 95 % power at a 5% significant level. The number of patients in each group was increased to 35 patients as drop out of 10% of patients was expected. Statistical analysis of the collected data were done using IBM's SPSS statistics (Statistical Package for the Social Sciences) for windows (version 25, 2017). Shapiro-Wilk test was used to check the normality of the data distribution. The distribution of data was estimated using mean ± SD for quantitative data, frequency, proportion for categorical data and median (range) for nonparametric data. The analysis of the data was performed to test statistically significant difference between groups. VAS scores were analyzed using Mann Whitney U-test. For intergroup comparison of quantitative data, Student's unpaired t-test was used. χ^2-test was used for categorical data. P was considered to be significant if it was less than or equal to 0.05 at confidence interval 95%.

RESULTS

A total 70 patients were included in this prospective randomized double-blind study, while 6 patients were excluded from the study or they discontinued. The patients were allocated into two groups as the control group (n=32) and infiltration group (n=32) (Figure 1). There were no statistically significant differences in patients' characteristics and duration of surgery in the studied groups (Table I).

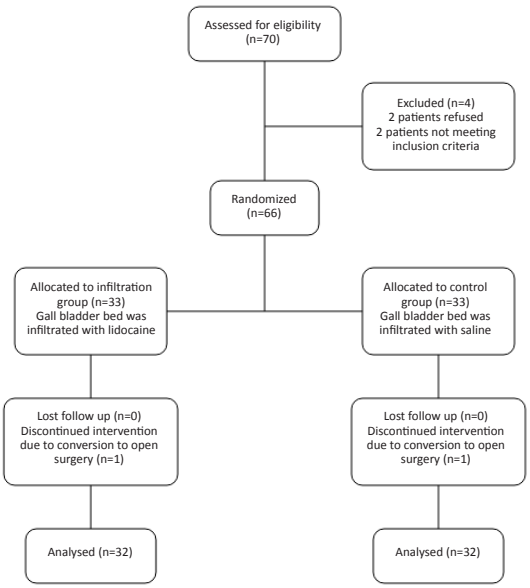

Figure 1. Flow chart outlining patient inclusion.

Table I. Patient's characteristics and duration of surgery

Variables	Control group (n=32)	Infiltration group (n=32)	P
Age (years)	41.07±13.9	46.09±13	0.124
Sex Male (n, %)	10 (31%)	6 (19%)	0.248
Female (n, %)	22 (69%)	26 (81%)	
BMI (kg m^{-2})	31.48±6.2	31.59±5.2	0.972
Duration of surgery (min)	33.75±3.26	34.43±4.47	0.356

Data are expressed as mean ± SD, number (n) and percentage (%) BMI: body mass index

The postoperative VAS scores for visceral pain at rest were significantly lower in the infiltration group than in the control group during the entire first postoperative 24 hours (Table II).

Table II. Visual analogue score for visceral pain at rest during the first postoperative 24 hours

VAS	Control group (n=32)	Infiltration group (n=32)	P
PACU	3 (1-4)	1 (0-2)	0.001*
2 hours	3 (2-5)	1 (0-3)	0.001*
4 hours	4 (3-5)	2 (1-3)	0.003*
8 hours	3 (2-5)	1 (1-3)	0.001*
12 hours	4 (2-6)	2 (1-4)	0.004*
16 hours	4 (2-5)	1 (0-2)	0.001*
24 hours	3 (1-4)	2 (1-4)	0.006*

Data are expressed as median (interquartile range). VAS: visual analogue score, PACU: post anesthesia care unit.

The postoperative VAS scores for somatic pain at rest were shown in Table III. It was comparable in both study groups during the first postoperative 24 hours.

Table III. Visual analogue score for somatic pain during the first postoperative 24 hours

VAS	Control group (n=32)	Infiltration group (n=32)	P
PACU	1 (0-3)	1 (0-2)	0.752
2 hours	2 (1-3)	1 (0-3)	0.682
4 hours	2 (1-4)	2 (1-3)	0.491
8 hours	4 (2-5)	4 (2-6)	0.324
12 hours	4 (2-6)	4 (2-5)	0.514
16 hours	4 (2-5)	4 (3-5)	0.768
24 hours	3 (2-4)	3 (1-4)	0.371

Data are expressed as median (interquartile range).
VAS: visual analogue score, PACU: post anesthesia care unit

The VAS scores during cough and movement for somatic pain at 12 hours after surgery were similar in both control and infiltration groups while for visceral pain they were significantly lower in the infiltration than in the control group. The incidence of shoulder pain was similar in both groups (Table IV).

Table IV. Visual analogue score for somatic and visceral pain on coughing and movement, and incidence of shoulder pain

Variables	Control group (n=32)	Infiltration group (n=32)	P
VAS on cough for:-			
Somatic pain	6 (3-7)	5 (2-7)	0.782
Visceral pain	5 (2-6)	2 (1-3)	0.003*
VAS on movement for:-			
Somatic pain	6 (4-8)	7 (5-8)	0. 697
Visceral pain	4 (2-5)	1 (0-2)	<0.0001
Shoulder pain incidence (n, %)	6 (19%)	4 (12.5%)	0.433

Data are expressed as median (interquartile range), number (n) and percentage (%).
VAS: visual analogue score.

The total dose of postoperative morphine consumption was significantly lower in the infiltration (2.14±0.86 mg) than in the control (5.24±1.62 mg) group (p<0.0001) (Table V and Figure 2). The total dose of postoperative ketorolac requirement was significantly lower in the infiltration (24.27±8.53 mg) than in the control (34.64±11.72 mg) group (p<0.0001) (Table V).

Table V. Time to first and frequency of rescue analgesia and total postoperative 24 hours analgesics consumption

Variables	Control group (n=32)	Infiltration group (n=32)	P
First rescue analgesia (hours)	2.64±1.15	6.45±2.46	<0.0001*
Frequency of rescue analgesia	3.48±1.12	1.63±0.65	<0.0001*
Morphine requirements n,(%)	32 (100%)	11 (35%)	<0.0001*
Total dose of (mg) morphine	5.24±1.62	2.14±0.86	<0.0001*
Ketorolac consumption(mg)	34.64±11.72	24.27±8.53	<0.0001*

Data are expressed as mean ± standard deviation (SD), number (n) and percentage (%).

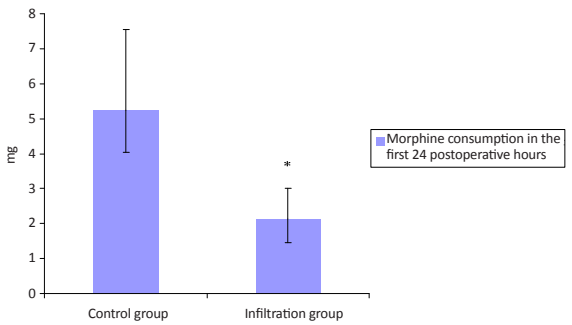

Figure 2. Total dose of morphine consumption during the first postoperative 24 hours.

Time to administration of the first rescue analgesia was significantly longer in the infiltration (6.45±2.46 hours) than the control (2.64±1.15 hours) group (p<0.0001) and the frequency of administering rescue analgesia was significantly lower in the infiltration (1.63±0.65) than in the control (3.48±1.12) group (p<0.0001) (Table V). During the first postoperative 24 hours, the number and percentage of patients who required morphine for rescue analgesia was significantly smaller in the infiltration (11, 35%) than in the control (32, 100%) group (Table V).

Time to recovery of normal intestinal sounds, incidence of nausea and vomiting and the state of patient satisfaction as regards analgesic regimen were similar in both infiltration and control groups (Table VI).

Table VI. Postoperative variables

Variables	Control group (n=32)	Infiltration group (n=32)	P
Time to intestinal sounds (hours)	12.91±0.71	12.7±0.63	0.187
Nausea and vomiting (n, %)	6 (19%)	4 (12.5%)	0.521
Patient satisfaction (n, %)	28 (87.5%)	31 (97%)	0.628

Data are expressed as mean±SD, number (n) and percentage (%).

DISCUSSION

The main findings of the current study have demonstrated that the infiltration of gallbladder bed with lidocaine during laparoscopic cholecystectomy is associated with effective control of visceral pain at

rest, during coughing and movement, increased time to the administration of the first rescue analgesia and decreased analgesic consumption within the first postoperative 24 hours.

Pain following laparoscopic cholecystectomy is either somatic, visceral or both. Minimally invasive laparoscopic surgeries are associated with minimal somatic pain. Visceral pain after laparoscopic cholecystectomy is more severe and predominant than somatic pain [9].

Yi SQ et al. [10] studied the surgical anatomy of gallbladder innervation in human and they demonstrated that the gallbladder and its bed in the liver are innervated by sympathetic and parasympathetic nervous system via anterior and posterior hepatic plexus, and phrenic nerve. Anterior and posterior hepatic plexuses pass through the hepatoduodenal ligament and contain branches arising from the hepatic branches of the vagus and celiac plexus. The nerves that innervate gallbladder pass along cystic duct and cystic arteries.

Another cause of the pain that originate from the gallbladder bed is injury and cauterization of Glisson's capsule (visceral peritoneum of the liver) during dissection of gallbladder from its bed in the inferior surface of the liver resulting in increased intensity of postoperative abdominal pain and increased need for opioid analgesia after laparoscopic cholecystectomy [4].

Rehan AG et al. [12] found that infiltration of 0.25% bupivacaine at port sites, under the right hemidiaphragm and gallbladder bed decreased the postoperative pain within the first 24 hours and significantly reduced the analgesic requirements.

Choi GJ et al. [13] performed a meta-analysis to evaluate the efficacy of intraperitoneal administration of local anesthetics for postoperative pain after laparoscopic cholecystectomy. They obtained their data from Cochrane Library, EMBASE and MEDLINE and included 39 controlled randomized English studies that compared the analgesic effects of intraperitoneally instilled local anesthetic agents with placebo (or nothing) used in the control group after laparoscopic cholecystectomy. They concluded that intraperitoneal instillation of local anesthetic had favorable effects on reduction of the intensity of postoperative abdominal visceral and shoulder pain at rest.

Kang Jk et al. [14] evaluated the analgesic effects of intraperitoneal administration of lidocaine after laparoscopic cholecystectomy. Their study was conducted on 40 patients scheduled for elective laparoscopic cholecystectomy who were randomly assigned into 2 groups. One group received 200 mL normal saline containing 200 mg lidocaine and the other group received 200 mL normal saline that was instilled into the gallbladder bed and the under surface of right diaphragm. They concluded that, the intraperitoneal instillation of lidocaine significantly reduces the severity of postoperative abdominal and shoulder pain for 24 hours.

Yang SY et al. [15] in their controlled randomized, double-blind placebo study evaluated the analgesic efficacy of intraperitoneal instillation or intravenous infusion of lidocaine when compared with placebo following laparoscopic cholecystectomy. They concluded that, intraperitoneal and intravenous lidocaine infusions were associated with significant reduction of postoperative pain severity and opioid requirements after laparoscopic cholecystectomy when compared with the control placebo group.

Kim TH et al. [16] administered ropivacaine into the peritoneal cavity immediately after pneumoperitoneum in laparoscopic cholecystectomy and they found a significant reduction of postoperative pain score in the ropivacaine group when compared to the placebo group.

The nociceptive pathway of visceral pain involves the nervous system that supplies the gut. Surgical manipulation of the viscera as gallbladder and irritation of peritoneum activates the silent nociceptors with signals transmitted through afferent neurons in the vagus nerve causing unpleasant sensations and autonomic reactions [17].

The antinociceptive effects of intraperitoneal administration of local anesthetics may be attributed to blocking of peritoneal nociceptors, its local anti-inflammatory action and/or its systemic absorption [18].

The peritoneum is the largest serous membrane in the body and its surface area is close to that of the skin. The concentration of local anesthetics are detectable in the systemic circulation within 2 minutes after their administration into the peritoneal cavity, reaching a peak systemic concentration after 10-30 minutes [19].

In the current study we used lidocaine (within the normal dose range) diluted in large volume of normal saline containing epinephrine to avoid the toxic effects and to prolong the analgesic action of lidocaine after its peritoneal administration as it was retained inside the peritoneal cavity for long period. Jain S et al. [20] reported that the intraperitoneal administration of large volume low concentration of bupivacaine (20 mL of 0.5% bupivacaine was added to 480 mL of normal saline) was associated with significant prolongation of the duration of analgesic action and reduced postoperative opioid requirements after laparoscopic cholecystectomy. The use of low volume (20 to 100 mL) and high concentration (0.5% to 0.125%) of bupivacaine for infiltration in gallbladder bed has been reported to produce ineffective [21] or short-acting analgesia [22].

The postoperative visual analogue scores for somatic pain were comparable in both groups during the first postoperative 24 hours. They were less than 3 points up to the 4th hours, but increased severely after then. The somatic pain was controlled in the first postoperative 4 hours by lidocaine infiltration around the sites of port entry into abdominal wall in both groups.

The incidence of shoulder pain was similar in both groups. Donatsky AM et al. [23] collected the data of their meta-analysis from pubMed and Excerpta Medica Database (EMBASE) to evaluate the effect of intraperitoneal instillation of normal saline with or without local anesthetic on the incidence and severity of shoulder pain after laparoscopic cholecystectomy. The study included only randomized clinical trials published in English. They reported that, the incidence and severity of shoulder pain could be minimized by intraperitoneal instillation of both saline and local anesthetics.

The incidence of nausea and vomiting was similar in both groups as all patients received 10 mg metoclopramide, 4 mg dexamethasone and 150 mg ranitidine as a prophylaxis against postoperative nausea and vomiting immediately after induction of anesthesia.

The limitations of the current study were the duration of action and the dose of lidocaine as we didn't use higher doses to avoid local anesthetic toxicity, so lidocaine was infiltrated into gallbladder bed as it is the main source of visceral pain after laparoscopic cholecystectomy.

CONCLUSION

From the findings of the current study we can conclude that, infiltration of gallbladder bed with lidocaine during laparoscopic cholecystectomy is associated with decreased intensity of visceral pain at rest, coughing and movement, prolonged time interval up to the administration of the first rescue analgesia and decreased analgesic consumption in the first postoperative 24 hours.

Ethics Committee Approval: Approval from the Institutional Research Board, Faculty of Medicine, Mansoura University given a code number (MS.18.09.277).
Conflict of Interest: None
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Informed Consent: The patients' consent were obtained.

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