Middle East Fertility Society Journal 23 (2018) 63-67

Contents lists available at ScienceDirect

Middle East Fertility Society Journal

journal homepage: www.sciencedirect.com

Original Article

Effect of intraperitoneal and incisional port site lidocaine on pain relief after gynecological laparoscopic surgery: A randomized controlled study



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ARTICLE INFO

Article history: Received 15 July 2017 Revised 21 August 2017 Accepted 22 August 2017 Available online 4 September 2017

Keywords: Laparoscopy Lidocaine Anesthesia

ABSTRACT

Objective: To evaluate the role of Intraperitoneal and port site use of local anesthetic (Lidocaine HCl) in gynecological laparoscopy for postoperative pain relief.

Study design: A prospective randomized controlled study.

Setting: Aswan University Hospital-Egypt.

Materials and methods: We included patients undergoing laparoscopic surgery in the laparoscopy unit either diagnostic or operative. They were classified into two groups: group A (patients underwent diagnostic laparoscopy) and group B (patients underwent operative laparoscopy). Each group was randomized to two sub groups. subgroup 1 or 2; subgroup 1 (control) which comprised 18 patients who were given routine care for surgery and 50 ml normal saline intraperitoneal washing and subgroup 2 (study). which included 18 patients who were given routine care plus pre- and post-incisional subcutaneous injection of 2% lidocaine HCl (xylocaine) 1 ml at each portal site and 10 ml 2% intraperitoneal lidocaine (200 mg) in 50 ml normal saline. The primary outcome of the study is the difference in mean pain score postoperatively between groups.

Results: There was significant reduction of the pain 1, 2, 4 and 8 h post-operatively shown by visual analogue scale pain scores in subgroup B2 compared to subgroup B1 and in subgroup A2 compared to subgroup A1 (P-value = 0.000). There was no significant difference in the incidence of nausea, vomiting, shoulder tip pain between both groups. Also there was no significant difference regards time of resumption of intestinal peristalsis and operation duration between subgroups.

Conclusions: This study clearly depicts that incisional and intraperitoneal infiltration of lidocaine is an easy, safe, inexpensive, and noninvasive method that provides good analgesia during the early postoperative period and also provides early recovery from laparoscopic surgery.

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1. Introduction

Gynecologic endoscopic surgery, in particular, has seen tremendous advances. Breakthroughs in video technology, instrumentation, adhesion prevention, and computer-enhanced technology have certainly allowed surgeons to routinely perform a number of procedures endoscopically rather than by laparotomies. These innovations have contributed to faster recovery time, smaller scars, less adhesion formation, fewer complications, lower cost, and, most importantly, better results [1].

However, patients undergoing laparoscopic procedures experience post-operative pain, especially in the upper and lower abdomen, back, and shoulder region. Pain intensity usually peaks during the first post-operative hours and usually declines over the following 2-3 days [2]. Pain after laparoscopy results from the stretching of the intra-abdominal cavity, peritoneal inflammation and phrenic nerve irritation caused by residual CO₂ in the peritoneal cavity [3].

Local pain is associated with incisions for the operative ports. Lower abdominal pain may depend on the extent of intraperitoneal manipulation during diagnostic laparoscopy [4].

The worst pain after gynecological laparoscopic surgery was felt in the shoulder in 1% of the patients, two hours after surgery but in 70% of the patients 24 h after surgery [5]. Pain attributed to



Peer review under responsibility of Middle East Fertility Society.

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http://dx.doi.org/10.1016/j.mefs.2017.08.005

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intraperitoneal gas was as frequent as abdominal wall pain at 24 h, but declined markedly by 48 h, along with a corresponding reduction in the retained gas shown on X-ray [6]. Incisional pain is usually mild to moderate in intensity and maximal immediately post-operatively, subsiding with time [7].

Although opioids provide powerful analgesia in the treatment of post-operative pain, they may lead to adverse effects such as sedation, nausea, vomiting and gastrointestinal ileus [8].

The aim of our study was to evaluate the role of intraperitoneal and port site use of local anesthetic agents in gynecological laparoscopy for post-operative pain relief.

2. Materials and methods

This study was a randomized open label controlled study conducted at Aswan University Hospitals from August 2016 to March 2017. All patients who had undergone laparoscopic surgery in the laparoscopy unit, either diagnostic or operative, were included in the study after obtaining informed consent. Patients with medical disorders, chronic pelvic pain, previous pelvic or abdominal surgery and allergy to local anesthetics were excluded. Seventy-two patients in the child bearing period with ASA I and undergoing diagnostic (infertility cases) and operative gynecological laparoscopy (ovarian cystectomy, ovarian drilling) participated in our study. They were classified into two groups: group A (patients underwent diagnostic laparoscopy) and group B (patients underwent operative laparoscopy).

Each group was randomized to two sub groups, 1 or 2. Subgroup 1 (control) comprised 18 patients who were given routine care for surgery and 50 ml normal saline intraperitoneal washing and sub-group 2 (study), which included 18 patients who were given routine care plus pre- and post-incisional subcutaneous injection of 2% lidocaine HCl (xylocaine[®], AstraZeneca, Egypt) 1 ml at each portal site and 10 ml 2% intraperitoneal lidocaine (200 mg) in 50 ml normal saline. All intraperitoneal drugs were instilled immediately after the laparoscopic procedure and after performing complete removal of the peritoneal aspiration solution used for irrigation and before wound closure.

A statistician prepared computer generated randomization tables and placed the allocation data in serially numbered closed opaque envelopes. Each envelope had a card noting the intervention type inside. The envelopes were opened only by the principal investigator administering the study medications according to the order of attendance of women. After acceptance of eligible women to participate in the study, we assigned them randomly in a 1:1 ratio to both arms of the study.

2.1. General anesthesia

Before starting anesthesia, one of the study investigators explained the standard 10-cm visual analogue scale (VAS) to the participants for pain scoring. The severity of pain was assessed with VAS (with 0 = no pain and 10 = worst imaginable pain). For all included patients general anesthesia was induced by intravenous thiopentone sodium of 5 mg/kg, and all patients were given intravenous 100 µg fentanyl; endotracheal intubation was facilitated using intravenous atracurium besylate 0.5 mg/kg. Maintenance of anesthesia was performed by inhalational isoflurane 0.5–1.5% in 100% oxygen, and a state of muscle relaxation was maintained by infusion of 0.5 mg/kg/h atracurium besylate with controlled mode of mechanical ventilation and adjusted parameters to keep end-tidal CO₂ at normal values.

All patients were continuously monitored by electrocardiography and pulse oximetry. Intravenous infusion of Ringer's lactate solution BP was given at a rate of 3.6 ml per hour. Recovery was performed by discontinuation of general anesthetics and reversal of neuromuscular blockers, extubation was performed after ensuring adequate motor power and no analgesics were given to patients before recovery.

After recovery, patients were monitored for heart rate (HR) and arterial blood pressure measurement every 15 min during the first hour from recovery and then every 4 h for 24 h. Patients were assessed for severity of pain using VAS after (1, 2, 4, 6, 8, 10, and 12 h) post-operatively. The study investigator who assessed the pain using VAS scores was blinded by the group as to where patients were allocated. Only the severity of the abdominal pain was assessed using the VAS score and recorded on a separate sheet at each time. If VAS was 3 or more, intravenous infusion of 1 g paracetamol was given. Any complications such as respiratory depression, nausea, vomiting and/or itching were also recorded. Presence of shoulder tip pain was recorded at any time the patient suffered from it. Also, intestinal peristalsis auscultation, movement from bed, passing flatus and the total dose of consumed postoperative analgesics were reported.

2.2. Surgical technique

All operations were carried out by the same team. Patients were placed in the supine position, insufflation pressure was initiated and maintained from 12 to 15 mmHg, the three trocar technique was used, a 10 mm umbilical port was introduced for 10 mm diameter telescope, two ports of 5 mm were placed in the left and right iliac fossae for a panoramic view of the pelvis, tubal patency test, irrigation and aspiration were done finally 50 ml intraperitoneal normal saline washing for the control group (A1) and control group (B1). However additional operative procedures in the form of simple ovarian cystectomy (n = 8), ovarian drilling (n = 10) were done for B1.

In the study group pre-incisional subcutaneous injection of lidocaine was given 1 ml at each port site then the same three trocar technique was used as mentioned above. Leaving 200 mg lidocaine in 50 ml normal saline intraperitoneally after closure of the wound, another dose of subcutaneous injection of lidocaine at port sites was given for study group A2 and study group B2, however additional operative procedures in the form of simple ovarian cystectomy (n = 9) or ovarian drilling (n = 9) were done for B2. Ovarian cystectomy was done through incision of the cyst wall then cyst excision & cauterization of any bleeding sources while ovarian drilling was done by electrocautery at four puncture points. The power used for cauterization was adjusted at 40 Watts and maintained for 4 s only at time.

2.3. Statistical analysis

Data were entered and statistically analyzed using the Statistical Package for Social Sciences (SPSS) version 21. Quantitative data were described as medians after testing for normality by Shapiro-Wilk test. Mann Whitney test was used for comparison between groups. Qualitative data were described as numbers and percentages. Fisher's exact test and Chi square test were used for comparison between groups, as appropriate. P-value ≤ 0.05 was considered to be statistically significant.

3. Results

Our study started with 90 patients who were asked to participate, 5 patients refused and 13 patients were excluded as they had cardiac, hepatic disease, chronic pelvic pain, allergy to local anesthetics or previous abdominal or pelvic surgery. Among the remaining 72 patients, 36 patients underwent diagnostic laparoscopic surgery for infertility (group A) and 36 patients underwent operative laparoscopic surgery (group B), each group was randomized to two subgroups: Group A [subgroup A1 (control, n = 18), subgroup A2 (study, n = 18)] & group B [sub group B1 (control, n = 18), subgroup B2 (study, n = 18)] (Fig. 1).

The demographic data of the studied groups are shown in Table 1. There was no significant difference between sub group A1 and A2 and sub group B1 and B2 in relation to weight, height, age, gravidity and parity.

There was significant reduction of the pain 1, 2, 4 and 8 h post-operatively by VAS pain scores in subgroup B2 compared to subgroup B1 and in subgroup A2 compared to subgroup A1 (p = 0.000) (Table 2).

There was no significant difference in the incidence of nausea, vomiting, shoulder tip pain; also, no significant difference regards time to resumption of intestinal peristalsis and operation duration between subgroups (Table 3).

4. Discussion

Early post-operative pain after laparoscopic procedures originates from nociceptive stimuli from the injured tissue, bowel manipulation, inflammation, sensitization of peripheral and central neurons, and inhibition of descending inhibitory pathways. Response to nociception contributes to activation and perpetuation of the stress response to surgery with its multiple negative consequences.

Poorly controlled acute surgical pain is a risk factor for chronic pain. Because pain can be somatic, visceral, or neuropathic, a multimodal approach to pain is included throughout the Enhanced recovery after surgery (ERAS) program and involves the preoperative, intra-operative, and post-operative phases. A related goal is to avoid opioid side effects such as ileus, urinary retention, nausea, vomiting, sedation, and respiratory depression that will all delay recovery. Common components include local and regional blocks and intraoperative IV lidocaine [9].

The ease of use and safety of local anesthetics (LA) is well recognized, and collectively they serve as one of the most important classes of drugs in perioperative care. The main advantage of LA agents is that they do not have the adverse effects of systemically administered opioids, such as post-operative sedation, nausea, gastrointestinal paralysis, and respiratory suppression, and they act directly on the tissue that they are applied to. LA are commonly administered in abdominal surgery by skin infiltration or epidural administration, blocking somatic afferents and providing significant benefits in reducing post-operative pain and improving recovery. It is also possible, however, to instil LA solutions into the peritoneal cavity, thereby blocking visceral afferent signalling and potentially modifying visceral nociception and downstream illness responses. Peripheral techniques of using LA also seem to be gaining popularity. However, the practice of Intraperitoneal local anesthesia (IPLA) is not routine in modern-day laparoscopic surgery [10].

Many trials of peripheral pain treatment with local anesthetics after laparoscopic procedures have been published. However, despite the substantial amount of published data, results from these trials are difficult to assess because of the variety of clinical settings, drugs, doses, application sites, comparators, and pain outcomes reported.

In this study, we tried to evaluate the effect of peripheral local anesthetics (Intraperitoneal and preincisional port site LA) for post-operative abdominal pain relief after gynecologic laparoscopic surgery and enhanced recovery after laparoscopic surgery compared with placebo.

We found that significant reduction of the abdominal pain (at 1, 2, 4, 8 h post-operatively) in patient received LA compared with

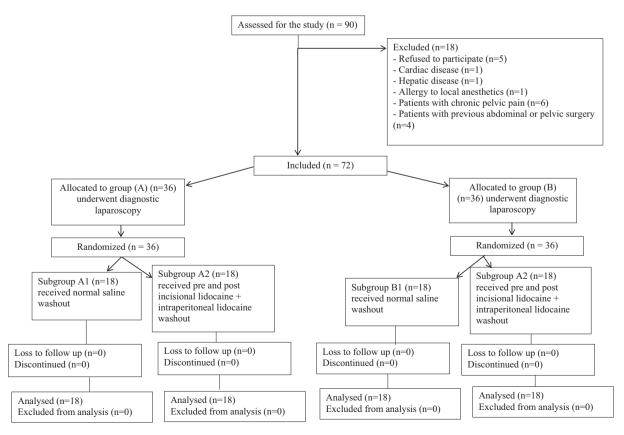


Fig. 1. The study flowchart.

Table 1

Demographic data of the study participants.

Parameters	A1	A2	p-value	B1	B2	p-value
Weight (kg)	75.78 ± 7.74	74.94 ± 7.296	0.77	74.61 ± 5.46	74.94 ± 6.78	0.62
Height (cm)	164.06 ± 3.24	163.78 ± 3.21	0.79	163.89 ± 4.04	164.83 ± 3.59	0.27
Age (year)	25.89 ± 2.22	26.11 ± 1.88	0.18	26.0 ± 2.06	26.67 ± 2.33	0.59
Gravidity	0.67 ± 0.77	0.63 ± 0.47	0.91	0.89 ± 0.76	0.92 ± 0.9	0.56
Parity	0.17 ± 0.38	0.22 ± 0.43	0.42	0.33 ± 0.49	0.32 ± 0.59	0.67

Data are presented as mean ± SD.

Table 2

(VAS) visual analogue scale of the severity of abdominal pain in the four groups at 1, 2, 4, 6, 8, 10, 12 h post-operatively.

VAS score	A1	A2	p-value	B1	B2	p-value
1st h	7.28 ± 0.75	2.28 ± 1.32	0.000	7.23 ± 1.02	2.89 ± 1.45	0.000
2nd h	5.61 ± 0.92	1.67 ± 0.69	0.000	6.00 ± 0.77	2.47 ± 0.59	0.000
4th h	4.11 ± 0.83	1.04 ± 0.56	0.000	4.12 ± 0.77	1.11 ± 0.32	0.000
6th h	2.83 ± 0.86	1.51 ± 0.33	0.000	2.50 ± 0.51	1.09 ± 0.41	0.000
8th h	2.39 ± 0.52	1.34 ± 0.44	0.004	2.17 ± 0.79	1.22 ± 0.31	0.000
10 h	1.43 ± 0.64	1.11 ± 0.34	0.07	1.32 ± 0.55	1.27 ± 0.49	0.13
12 h	1.22 ± 0.63	1.16 ± 0.44	0.35	1.11 ± 0.47	1.09 ± 0.55	0.28

Data are presented as mean ± SD.

Table 3
Rate of post-operative complications, operation duration and time to resumption of intestinal peristalsis in the study groups.

Parameters	A1	A2	p-value	B1	B2	p-value
Nausea (yes, no)	6/12	7/11	0.73	8/10	6/12	0.49
Vomiting (yes, no)	3/15	2/16	0.94	2/16	1/17	0.91
Shoulder tip pain (yes, no)	7/11	8/10	0.74	6/12	6/12	-
Operation duration	40.39 ± 2.83	40.06 ± 2.83	0.90	58.56 ± 4.11	59.22 ± 3.65	0.59
Intestinal peristalsis	10.28 ± 1.74	10.00 ± 1.61	0.88	10.28 ± 1.93	10.28 ± 1.57	0.52

Data are presented as mean ± SD or number of patients.

placebo. Some studies have reported that administration of Intraperitoneal local anesthetics do not provide adequate post-operative analgesia [2,10].

Ali et al. 1998 concluded that intraperitoneal lidocaine did not decrease pain after laparoscopic hysterectomy. In contrast, Sharon et al. used continuous intraperitoneal insufflation of lidocaine, and they found that it could reduce pain significantly in the initial stage of post-operative recovery [11]. In addition, Zadah et al. used 10 ml 2% lidocaine intraperitoneally, and found that provided effective analgesia [12].

Mraovic et al. used 15 mL 0.5% bupivacaine intraperitoneally for post-operative analgesia after laparoscopic cholecystectomy. They reported that intraperitoneal administration of bupivacaine was an effective and easy method to reduce post-operative pain [13].

We found that there was no significant difference in the incidence of shoulder pain in patients given lidocaine compared with the control group. In agreement with our results, Lepner et al. and Gupta et al. reported no significant differences in the mean shoulder pain scores between patients given intraperitoneal lidocaine and those who were not given local anesthetics [14,15].

However; Narchi et al., Kim et al., and Kang et al. reported that intraperitoneal lidocaine was more effective in reducing postoperative shoulder pain compared with patients given nothing or those given intraperitoneal saline [4,16,17].

The incidence of post-operative nausea and vomiting was not significantly different between lidocaine and control groups. In agreement with this result, many studies did not find a significant difference between patients given either intraperitoneal lidocaine and the control patients with respect to the incidence of post-operative nausea and vomiting [11,14,15,17,18].

Therefore, we think that pre-incisional and intraperitoneal infiltration of LA is an easy, safe, inexpensive, and noninvasive method that provides good analgesia during the early post-operative period and also provides early recovery from laparoscopic surgery, early ambulation, avoiding the complications of long recumbency, women return to their normal lives earlier and calmly with a painless post-operative recovery, avoiding complications of postoperative anxiety and agitation, minimizing usage of nonsteroidal anti-inflammatory drugs (NSAIDs), avoiding their systemic side effects, and decreasing the length of post-operative stay at hospital.

The strengths of this study include that it was a randomized controlled trial with standardized dose and route of administration of medications. The study had its limitations including that women were asked to verbalize their pain scores, which is a subjective parameter. Also, the study was not blinded, so there was a risk of bias either from the participants or from the study investigators. Finally, we didn't evaluate its efficacy in long duration surgeries as laparoscopic myomectomy and hysterectomy.

5. Conclusions

Utilization of intraperitoneal and port sites Lidocaine HCl can decrease the post-operative pain scores for women after gynecological laparoscopic surgery. Hence, we advocate its use as a routine procedure for minor gynecologic laparoscopic surgery such as diagnostic laparoscopy or short duration operations as drilling or cystectomy.

Conflict of interest

The authors declare that they have no conflict of interest.

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