

Analgesic effect of trigger point injection and EMLA for shoulder pain in patients undergoing total laparoscopic hysterectomy

A randomized controlled study

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Abstract

Background: The purpose of this study was to evaluate the effects of trigger point injection (TPI) and eutectic mixture local anesthetics (EMLA) cream on the postoperative shoulder pain in patients undergoing total laparoscopic hysterectomy.

Methods: In this randomized, single-blinded, and controlled study, total 75 patients were randomly allocated to TPI group (n=25), EMLA group (n=25), and control group (n=25). TPI group received TPIS with 2 mL of 0.2% ropivacaine, and EMLA group received an occlusive dressing with EMLA cream 2 g on both shoulders. Overall, abdominal, and shoulder pains were evaluated at rest and in motion on postoperative day 3.

Results: The incidence of shoulder pain was significantly reduced in EMLA group (56%) compared to control (88%) or TPI (88%) groups ($P = .025$ in both); the severity of shoulder pain was mitigated in EMLA and TPI groups compared to control group ($P < .001$, each). Consequently, the overall pain decreased in EMLA group and TPI group ($P = .023$). The patients with exercise habit (n=31) showed lower incidence of pain than patients without exercise habit (n=26) ($P = .002$, $P = .005$, and $P = .037$ in overall, abdominal, and shoulder pain, respectively). TPI or EMLA treatments decreased shoulder pain irrespective of exercise habit ($P = .001$ and $P < .001$, respectively), but decreased overall pain only in patients without exercise habit ($P = .019$). Lastly, EMLA lowered overall pain score at the time of first analgesic request in ward compared to control group ($P = .02$).

Conclusions: TPI and EMLA with occlusive dressing effectively reduced the shoulder pain after total laparoscopic hysterectomy.

Abbreviations: CO₂ = carbon dioxide, EMLA = eutectic mixture local anesthetics, PACU = postanesthesia care unit, PCA = patient-controlled analgesia, POD = postoperative day, SD = standard deviation, TLH = total laparoscopic hysterectomy, TPI = trigger point injection, VAS = visual analog scale.

Keywords: EMLA, laparoscopy, shoulder pain, trigger points

1. Introduction

Total laparoscopic hysterectomy (TLH) has advantages such as a smaller and more cosmetic incision, less blood loss, shorter hospitalizations, and consequently socioeconomic benefit.^[1] However, patients undergoing TLH, that is considered as a less

painful procedure, often receive in inadequate postoperative pain management and experience severe pain than in aggressive major surgeries.^[2]

Shoulder pain has been reported to frequently occur after laparoscopic cholecystectomy but is rare in exploratory surgery. Laparoscopy-related shoulder pain has been reported the incidence up to 80% with varying degree of severities.^[3] Laparoscopy-related shoulder pain is mainly due to pneumoperitoneum with carbon dioxide, subsequently irritating the diaphragm and causing referred pain in C4 dermatome on the shoulder.

Patients who undergo TLH frequently report high levels of postoperative shoulder pain, with incidence up to 90%,^[4] thus offsetting the benefit of microinvasive surgery. In this type of surgery, a steep Trendelenberg position with shoulder braces may be an additional mechanical factor of shoulder pain.^[5] Laparoscopy-related shoulder pain may be transient or persist for about 72 hours after surgery^[3,6]; in addition, it is relatively resistant to opioids, epidural analgesia, or nonsteroidal anti-inflammatory drugs.^[3,7] Complete removal of CO₂ by the end of surgery is strongly recommended to reduce the laparoscopy-associated pain of upper abdomen and shoulder. Clinical trials have reported several methods, including intraperitoneal instillation of local anesthetics or saline, pulmonary recruitment maneuver, and intraperitoneal saline infusion. In addition to the removal of residual gas, other preventive treatment for

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laparoscopy-related shoulder pain should be required, considering adequate treatment of the early postoperative pain reduces risk of developing chronic pain.^[8,9]

The trauma or irritation to muscles during surgery activates the trigger points^[10] that generates high levels of algogenic substances and constitutes a source of muscle nociception.^[11] Therefore, prophylactic trigger point injection (TPI) has potential to reduce the shoulder pain after TLH.

Eutectic mixture local anesthetics (EMLA) cream is a topical anesthetic comprising a mixture of lidocaine 2.5% and prilocaine 2.5% in an oil-in-water emulsion cream. EMLA provides not only cutaneous analgesia, but dermal analgesia through occlusive dressing for sufficient time, thus controlling surgery-related pain effectively.^[12] In addition, EMLA has also been shown to have deep analgesic effects for veno-puncture, laser treatment, skin harvesting, pediatric urologic surgeries, and shockwave lithotripsy.^[13] Based on these studies, we hypothesized that occlusive dressing with EMLA cream has an analgesic effect on laparoscopic hysterectomy-related shoulder pain.

The purpose of this study was to evaluate the effects of trigger point injection and EMLA cream on the postoperative shoulder pain in patients who underwent TLH.

2. Methods

We conducted a randomized, single-blinded, controlled study at the Severance hospital, Yonsei University Health System. The study was approved by the Severance Hospital institutional review board (protocol number: 4-2013-0101) and registered at ClinicalTrials.gov (NCT01845532). Written informed consent was obtained from all participants before randomization. A total of 75 female patients, ASA physical status I or II, aged 20 to 70 years, undergoing TLH with adenomyosis, cervical dysplasia, endometriosis, endometrial hyperplasia, myoma, or ovarian tumor were enrolled. Patients were excluded if they met at least one of the following criteria: coagulopathy, history of shoulder trauma/surgery or breast cancer, and hypersensitivity to local anesthetics.

2.1. Interventions

Using a computer-generated randomization (<http://www.random.org>), the patients were assigned into one of the 3 groups: TPI group, EMLA group, and control group. Intravenous midazolam 0.02 mg/kg was administered as premedication. Anesthesia was induced with propofol 1.5 mg/kg and remifentanyl 0.3 μg/kg. Rocuronium bromide 0.6 mg/kg was given to facilitate orotracheal intubation. Anesthesia was maintained with continuous infusion of remifentanyl at a rate of 0.01 to 0.05 μg/kg/min and desflurane 4% to 6% with air 50% in oxygen. Positive pressure ventilation in a circle system was performed maintaining end-tidal CO₂ between 35 and 40 mm Hg.

All interventions were made after 10 minutes of anesthesia induction. In a preliminary study to evaluate the pain site of shoulder developed after TLH, the most affected pain sites were the areas of upper trapezius. TPI group (n=25) received with 0.2% ropivacaine 2 mL injections each shoulder, on 3 points. The areas were covered with Hypafix (BSN Medical GmbH, Hamburg, Germany) of 10 cm × 10 cm size. In EMLA group (n=25), occlusive dressing with EMLA 2g was made using semipermeable polyurethane membrane (Tegaderm) of 6 cm × 7 cm size and covered with a same-sized Hypafix. In control group (n=25), Hypafix was applied on the same site. All application was performed by a single anesthesiologist who was not involved in outcome assessment. The surgeons, patients,

outcome assessors, and data analysts were blinded to the group allocation throughout the study period.

2.2. Operative procedures

All procedures were carried out by the same team of surgeons throughout the study period. The shoulder braces with lithotomy position were used to the patients, and the operating table was tilted to 30° Trendelenburg position. Laparoscopy were performed through 4 abdominal ports (port for camera, 2 working ports, and 1 other port) with using CO₂, which was introduced through intraumbilical Veress needle. The abdominal gas pressure was established at 12 mm Hg and adjusted by monitoring the end-tidal CO₂. TLH with or without salpingo-oorectomy was conducted using a uterine manipulator into vaginal access. Drain was inserted when needed. Vaginal vault was restored with intracorporeal suturing. After surgery end, patients were extubated and transferred to postanesthesia care unit (PACU).

2.3. Assessment

A nurse who was blinded to group allocation removed the occlusive dressing at 5 hours after the end of surgery. An investigator blinded to group allocation assessed the overall pain, shoulder pain, and abdominal pain at 30 minutes, 1, 3, and 6 hours after the end of surgery and at postoperative day (POD) 1, 2, and 3. Overall pain was defined as pain including abdominal pain and shoulder pain, and shoulder pain was evaluated at rest and in motion. The motion of shoulder pain included turning of upper body, stretching of arms, and turning of head. The degree of pain was rated on 100 mm visual analog scale (VAS) (0, no pain; 100, worst possible pain). All patients were evaluated for ordinary exercise habit including golf, aerobics, yoga, walking, fitness, swimming, and climbing.

For postoperative pain management, intravenous patient-controlled analgesia (PCA) was applied to all patients. Fentanyl of PCA was continuously infused at 0.2 μg/kg/h for 48 hours using Accufuser-Plus (WooYoung Medical, Seoul, Korea). In PACU, patients with overall (abdominal and/or shoulder) pain ≥ VAS 50 were injected the intravenous fentanyl 50 μg as a rescue analgesic. In ward, tramadol 50 mg or ketorolac 30 mg was intravenously administered when pain was ≥ VAS 50.

Adverse side effects such as erythema, pruritus, nausea, and vomiting were also evaluated. The severity of nausea was measured using a 4-point Likert scale (1 = none; 2 = mild; 3 = moderate; 4 = severe). Metoclopramide or ondansetron was administered when the patients suffered from vomiting or nausea ≥ grade 3. The duration and pain scores at the time of first analgesic request after end of surgery were recorded.

Complications known to be associated with EMLA cream (blanching, redness, pruritus, burning, purpura, contact hypersensitivity, and methemoglobinemia) or relevant to TPI (hematoma, neuropathy, and motor block) were evaluated at the times of immediate intervention, arrival in PACU, and 6 hours after the end of surgery.

2.4. Statistical analysis

Sample size calculation was based on previous study. As for shoulder pain developed after a laparoscopic gynecologic surgery, standard deviation (SD) of pain score (VAS) was 3.^[14] Mean differences of pain reduction compared with baseline after using EMLA and lidocaine injection were 2 and 3,

respectively.^[13,15] For a significant level of 5% and a power of 80%, 25 subjects were required in each group considering a 20% dropouts rate. Therefore, we enrolled a total of 75 patients.

Values were presented as mean±SD, median (range) or the number of patients (proportion). Kolmogorov–Smirnov test was used for normality. Parametric data were analyzed with ANOVA and subsequently, data was corrected by Bonferroni method. Nonparametric data were analyzed by Kruskal–Wallis test and corrected by Dunn procedure. Data comprising repeated measures were analyzed by linear mixed model with compound symmetry. The $P < .05$ was considered statistically significant. Statistics were conducted with SAS (Statistical Analysis System, 9.2 version Inc., Cary, NC).

3. Results

One patient in TPI group was dropped from the study due to change in surgical plan, and 74 patients were included in the final

analysis (Fig. 1). Patient characteristics showed no significant differences between the 3 groups (Table 1). Perioperative heart rate and mean arterial pressure were comparable throughout the study period.

The incidence of shoulder pain was significantly less in EMLA group (56%), as compared with control group (88%) or TPI group (88%) ($P = .025$, both, Table 2). Evaluation of shoulder pains at rest and in motion indicated that the pain severity progressively worsened, reaching a peak at POD1 and decreasing gradually thereafter (Fig. 2).

Shoulder pain at rest decreased at all time-points from 6 hours after the end of surgery (Fig. 2A), and shoulder pain in motion decreased at all time-points from 3 hours after the end of surgery (Fig. 2B) in both TPI and EMLA groups, as compared with control group ($P < .001$, both). Moreover, shoulder pains of EMLA group were significantly lower than that of TPI group at 6 hours after the end of surgery and POD 1 both at rest and in motion (Fig. 2A and B). Overall pain at rest significantly

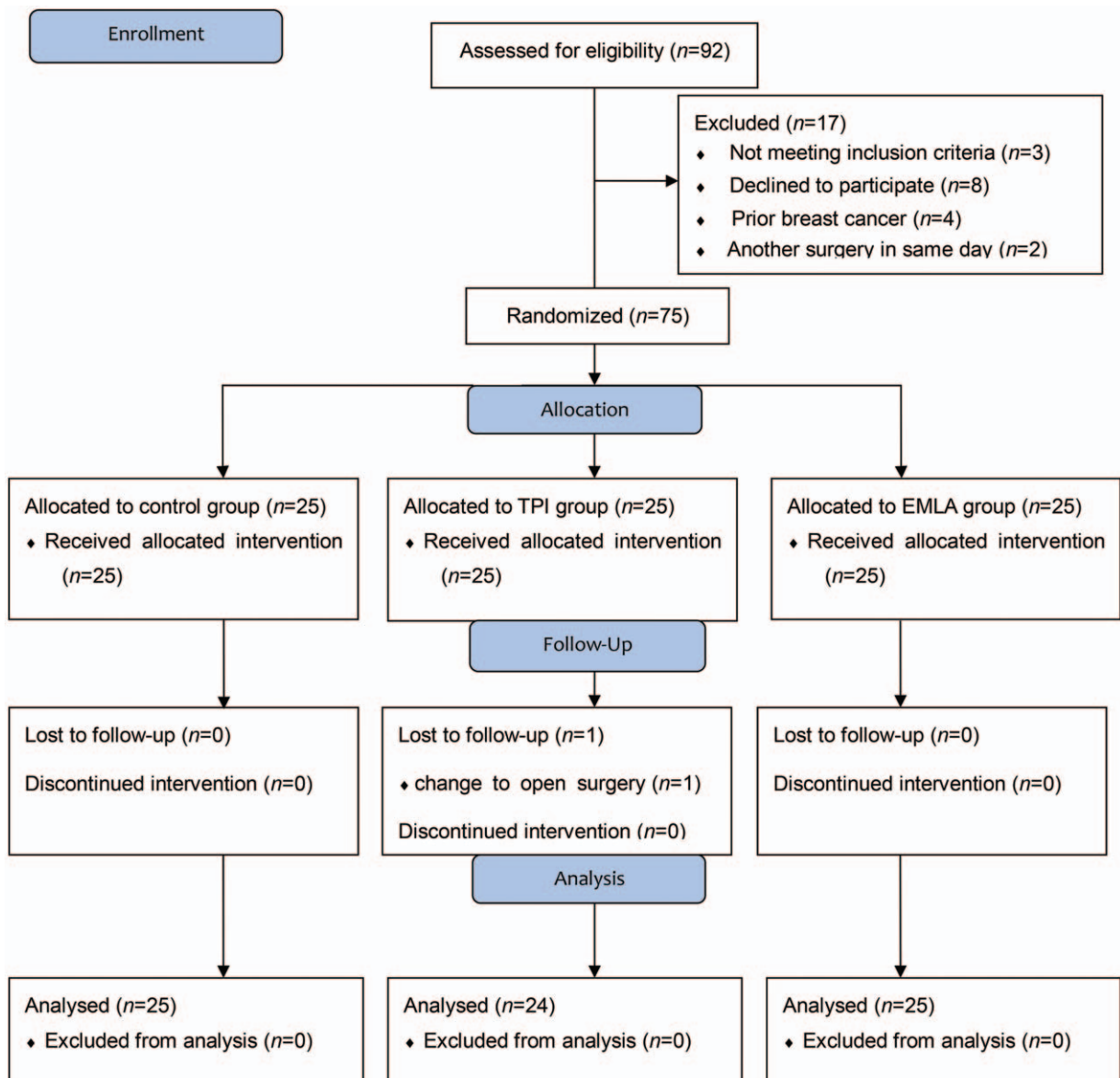


Figure 1. Flow diagram.

Table 1

Patient characteristics and operative data.

	Control (n=25)	TPI (n=24)	EMLA (n=25)	P
Age, y	51 ± 8	48 ± 9	46 ± 8	.130
Weight, kg	61 ± 13	59 ± 10	58 ± 7	.688
Height, cm	159 ± 4	160 ± 5	158 ± 5	.478
Diagnosis				
Myoma	16 (64%)	16 (67%)	15 (60%)	.888
Cervical dysplasia	3 (12%)	5 (21%)	5 (20%)	.744
Ovarian cyst	6 (24%)	5 (21%)	8 (32%)	.714
Adenomyosis	6 (24%)	7 (29%)	7 (28%)	.947
Endometriosis	2 (8%)	0	1 (4%)	.769
Endometrial hyperplasia	2 (8%)	0	2 (8%)	.537
Ovarian tumor	1 (4%)	0	2 (8%)	.769
Adnexal mass	2 (8%)	1 (4%)	2 (8%)	>.999
Operation				
TLH	9 (36%)	17 (71%)	14 (56%)	.052
TLH+BSO	13 (52%)	6 (25%)	8 (32%)	.149
TLH+RSO or LSO	3 (12%)	1 (4%)	3 (12%)	.687
Additional salpingectomy	4 (16%)	6 (25%)	8 (32%)	.415
Additional cystectomy	0	2 (9%)	1 (4%)	.315
Intraoperative fluid balance				
Crystalloid, mL	596 ± 236	702 ± 449	622 ± 254	.499
Packed RBC, unit	0	0	0	>.999
Urine output, mL	85 (10–250)	110 (50–600)	60 (10–600)	.428
Bleeding, mL	50 (10–500)	50 (5–500)	50 (10–500)	.990
Operation time, min	85 (40–160)	85 (30–181)	78.5 (38–165)	.414
Anesthesia time, min	115 (70–175)	115 (50–200)	105 (55–200)	.729
Uterine weight, g	247 ± 200	299 ± 197	196 ± 89	.117
Drain insertion	2 (8%)	3 (13%)	2 (8%)	.788
Exercise history	13 (52%)	7 (29%)	11 (44%)	.260

Values are presented as mean ± SD, median (range), or number (proportion).

BSO=bilateral salpingo-oophorectomy, LSO=left salpingo-oophorectomy, RBC=red blood cell, RSO=right salpingo-oophorectomy, TLH=total laparoscopic hysterectomy.

decreased at all time-points from POD 2 in TPI group and POD 1 in EMLA group, as compared with control group ($P=.023$).

Patients with exercise habit ($n=31$) showed lower overall, abdominal, and shoulder pains, as compared to patients with no exercise habit ($n=26$), with most significant effect on shoulder pain ($P=.002$, $P=.005$, and $P=.037$ in overall, abdominal, and shoulder pains, respectively, Fig. 3). Interestingly, overall pain decreased after TPI or EMLA interventions in patients with no exercise habit ($P=.019$, Fig. 4B). However, TPI or EMLA interventions significantly decreased shoulder pain ($P=.001$ and $P<.001$, Fig. 4C and D), but not abdominal pain irrespective of exercise habit.

Mild skin erythema was recorded in 3 patients of EMLA group (1 patient in PACU, and 2 patients in ward at operative day), which disappeared on the following day without any treatment. Fifteen patients complained of nausea (6, 6, and 3 patients in control, TPI, and EMLA groups, respectively) and 5 patients

received antiemetics (3 and 2 patients in TPI and EMLA groups, respectively). None of the patients showed pruritus or vomiting. The number of patients requesting additional analgesics in PACU and time to request first analgesic in ward were comparable between the 3 groups ($P=.858$ and $P=.647$). However, overall pain score at the time of first analgesic request during ward stay was lower in EMLA group, as compared with in control group ($P=.02$).

4. Discussion

In this study, EMLA with occlusive dressing significantly reduced the incidence and severity of post-TLH shoulder pain compared with control group. Although TPI decreased the severity of shoulder pain, the incidence of pain was similar to control group. And also, overall pain score at the time of first analgesic request was lower in EMLA group than in other groups. Thus, EMLA

Table 2

Incidence of shoulder pain and abdominal pain.

	Control (n=25)	TPI (n=24)	P*	EMLA (n=25)	P*	P†
Shoulder pain	22 (88%)	21 (88%)	>.999	14 (56%)‡,§	.025	.025
Abdominal pain	25 (100%)	24 (100%)	>.999	25 (100%)	>.999	>.999

Values are presented number (proportion).

EMLA=eutectic mixture local anesthetics, TPI=trigger point injection.

* Compared with control group.

† Compared with TPI group.

‡ $P<.05$ compared with control group.

§ $P<.05$ compared with TPI group.

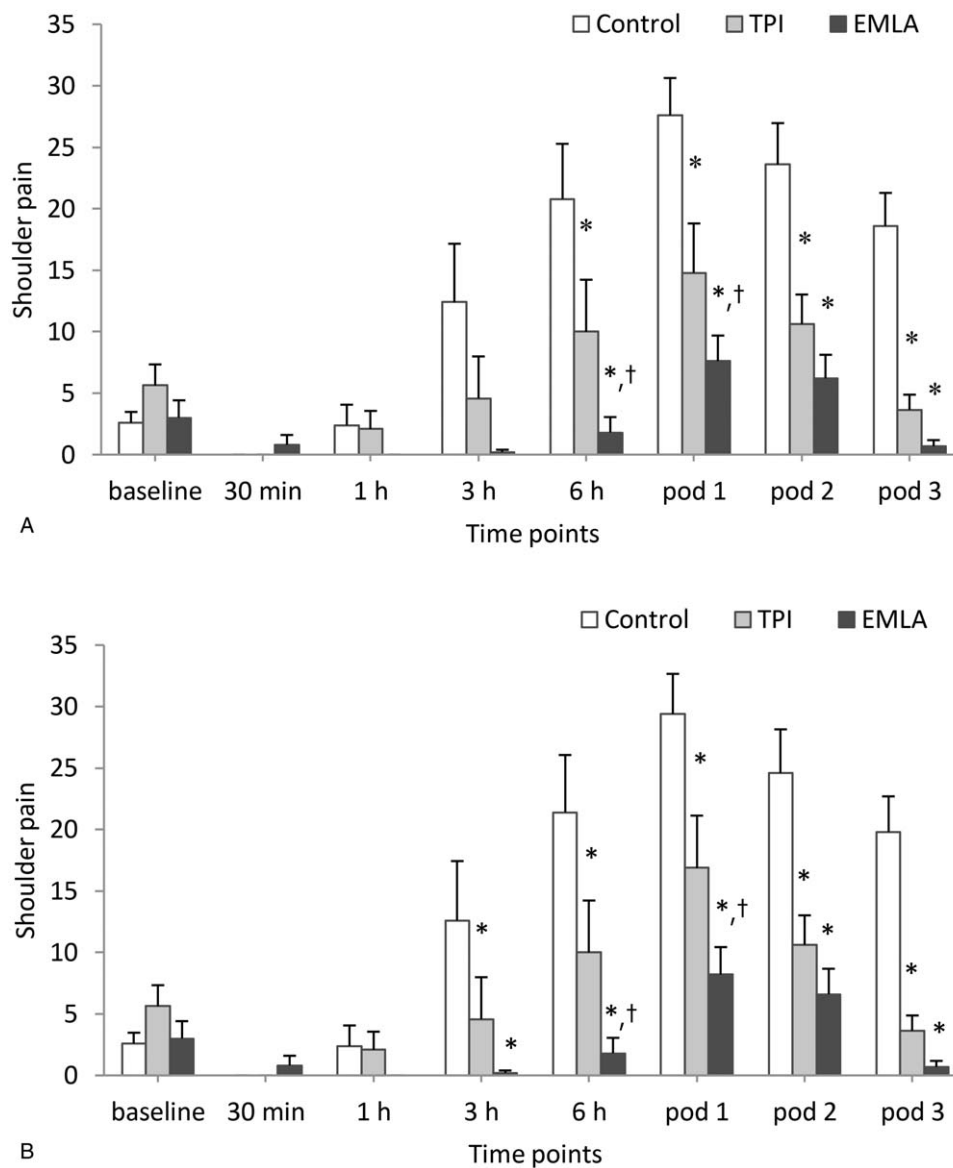


Figure 2. Shoulder pain at rest (A) and in motion (B). [†]*P* < .05 compared with TPI group, ^{*}*P* < .05 compared with control group. baseline=before anesthesia induction, 30 min=30 minutes after surgery, 1 h=1 hour after surgery, 6 h=6 hours after surgery, pod 1=postoperative day 1, pod 2=postoperative day 2, pod 3=postoperative day 3.

with occlusive dressing reduced the overall pain. This beneficial effect of TPI and EMLA on shoulder pain was irrespective of ordinary exercise habit. However, the overall pain was reduced in patients with ordinary exercise habit compared with the patients without exercise habit.

Shoulder pain after laparoscopy is generally considered as referred pain. The phrenic nerve (C3–5) and the supraclavicular nerve (C3–4) conducting sensory input of skin above acromion process converge on cervical and thoracic spinothalamic tract. Thus, irritation of the diaphragm leads to referred pain in the top of the shoulder. Although the exact mechanism remains unclear,^[3] it possibly involves subdiaphragmatic CO₂ entrapment, remnant fluid or blood, traumatic overstretching of the diaphragmatic muscle or nerves, and inflammations. In addition, post-TLH shoulder pain may be aggravated with external compression and intraoperative position. Trendelenburg position in gynecologic surgery is reportedly associated with the

development of the brachial plexus injury.^[16] Substantial compression and stretch of the plexus occurs between the first rib and clavicle by the shoulder brace-induced caudad pressure, which can lead to ischemia in brachial plexus.^[16] Finally, laparoscopic shoulder pain was reported to have the higher incidence and severity, in cases of long operative duration ≥45 minutes or females.^[3] In present study, all patients were females and the operative duration in 3 groups were similar, approximately 80 minutes.

Numerous strategies have been attempted in order to reduce the incidence and severity of shoulder pain after gynecological laparoscopy; pulmonary recruitment maneuver, extended assisted ventilation, low pneumoperitoneum pressure, intraperitoneal installation of local anesthetics or normal saline, gasless laparoscopy, drain, and insufflation with humidified and heated CO₂.^[14,17,18] However, the effectiveness of these interventions are conflicting and there is no consensus on preventive measures.

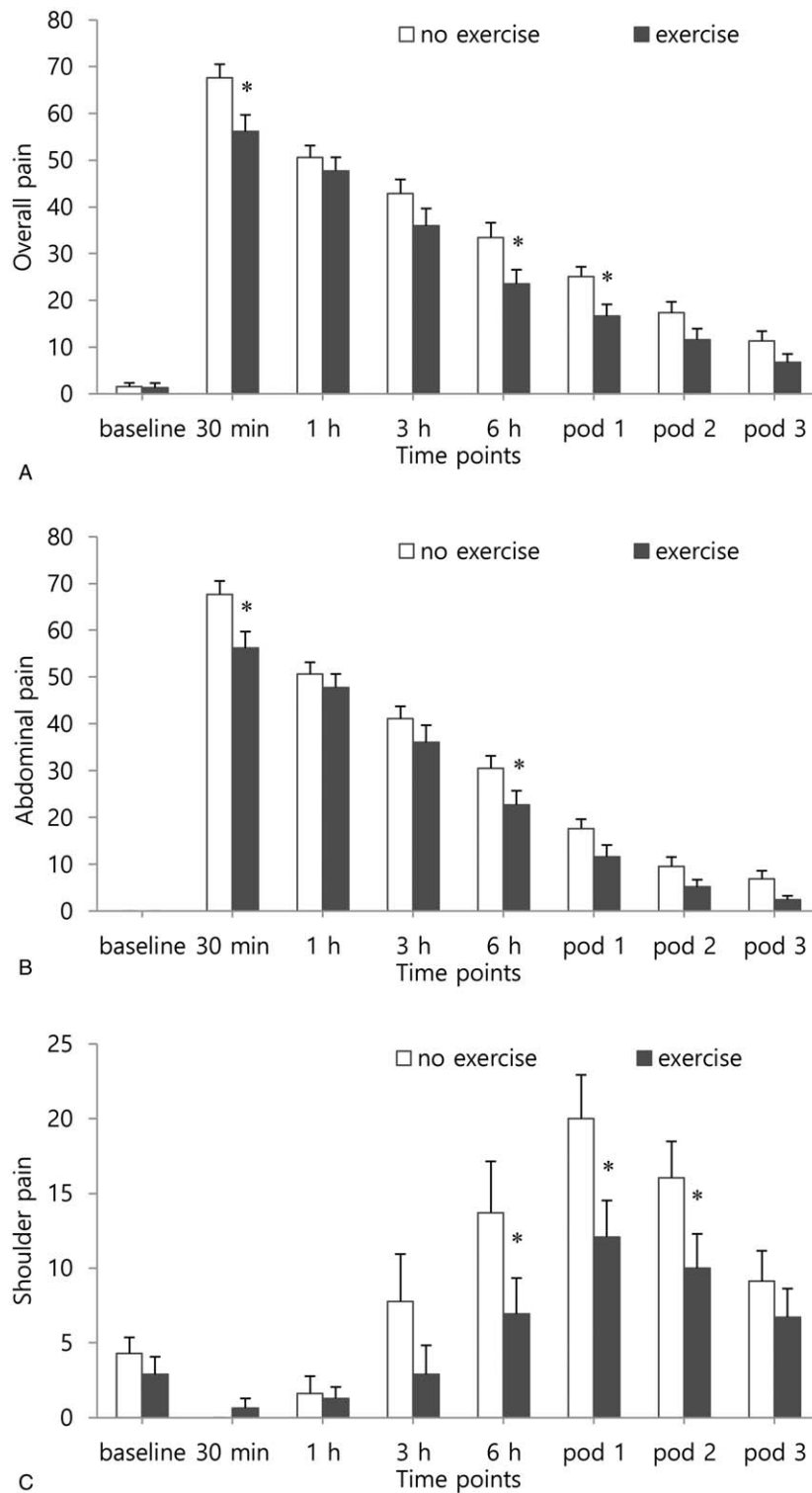


Figure 3. Effects of exercise habit on overall pain (A), abdominal pain (B), and shoulder pain (C). * $P < .05$ compared with control group. baseline = before anesthesia induction, 30 min = 30 minutes after surgery, 1 h = 1 hour after surgery, 6 h = 6 hours after surgery, pod 1 = postoperative day 1, pod 2 = postoperative day 2, pod 3 = postoperative day 3.

Referred pain is generated by both central and peripheral systems.^[19,20] Referred pain occurs despite complete sensory loss in referred area by using anesthetic block. And stimulus intensity and size of area of initial pain are significantly correlated with those of referred pain.^[21] Thus, reduction of diaphragm irritation by the abovementioned interventions naturally decreases the

shoulder pain. Referred pain is also dependent on spontaneous input from cutaneous receptors to some degree via peripheral control. EMLA cream, if applied over referred skin area, decreases intensity of referred pain by 23%.^[22] Blocking the afferent nerve from referred area reduces intensity of referred pain by 40%.^[23] Therefore, in the present study, we anticipated a

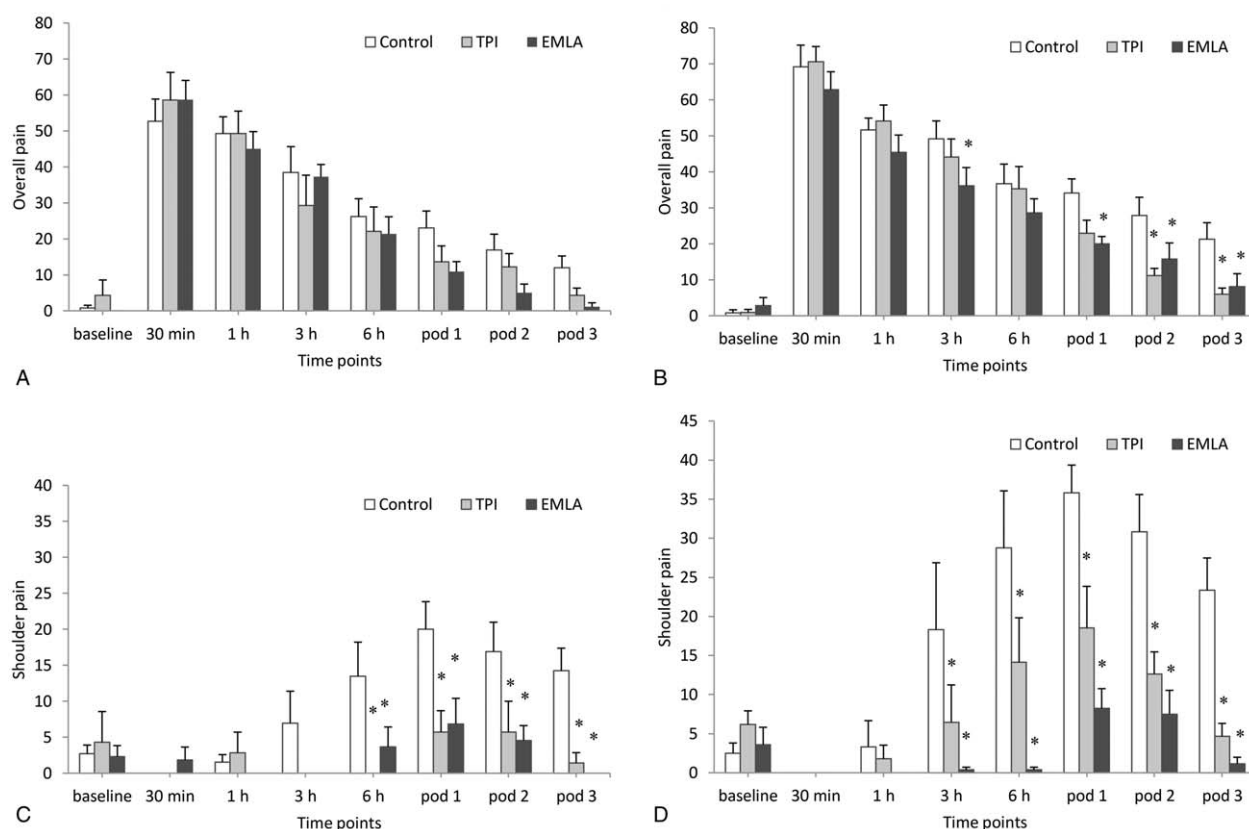


Figure 4. Effects of TPI and EMLA interventions on overall pain in patients with exercise habit (A) or no exercise habit (B) and shoulder pain in patients with exercise habit (C) or no exercise habit (D). * $P < .05$ compared with control group. Baseline=before anesthesia induction, 30 min=30 minutes after surgery, 1 h=1 hour after surgery, 6 h=6 hours after surgery, pod 1=postoperative day 1, pod 2=postoperative day 2, pod 3=postoperative day 3.

decrease in referred pain intensity by depleting peripheral input from referred area (shoulder), although visceral referred pain is in the deep tissues of referred site. Consequently, TPI and EMLA cream significantly reduced the shoulder pain.

Trigger point is a focal area of sustained contraction in the muscle, probably secondary to microtrauma. Continued contraction of muscle provokes a ischemia,^[24] which produces a release of algogenic substances that are responsible for the local tenderness.^[11] Local anesthetic infiltration in TPI acts as strong sensory block, especially at the muscle level, through 2 mechanisms: mechanical disruption of the trigger point and delivery of the local anesthetic.^[10] Trigger points are usually identified with palpation of a taut band before treatment or local twitch response during treatment. In the present study, taut band of patients was examined in PACU and marked on the shoulder. After anesthesia induction, TPI was performed mainly over the site of the marked taut bands, or over trapezius muscle, as this region was defined as the site of post-TLH shoulder pain in the preliminary study. The latter might belong to a local needling in the muscle. However, local needling also shows relief of the pain, although the extent is less when comparing with TPI.^[25,26] Therefore, in the present study, TPI showed some degree of analgesic effect, although all trigger points were not disrupted mechanically. Of note, this is considered one of factors whereby EMLA with occlusive dressing shows more analgesic effect than TPI.^[10]

EMLA suppresses the initiation and transmission of nerve impulses by increasing the threshold for nerve excitation, and

provides cutaneous analgesia by targeting free nerve endings in the dermis. In the present study, EMLA effectively decreased pain threshold associated with referred muscle pain. Because the skin thickness in the back of Korean (epidermis plus dermis) is approximately 2 mm,^[27] and the depth of skin analgesia is 6 mm after 4 hours of EMLA application,^[28] EMLA is predicted to deliver sufficient local anesthetics to block large myelinated sensory fibers.

Skin redness and edema are commonly observed in the area of EMLA application. EMLA shows a biphasic vascular response including an initial blanching due to vasoconstriction and late erythema due to vasodilation. Usually vasodilation occurs if application time is longer than 3 hours. In the present study, 3 patients showed erythema on EMLA application sites, which was tolerable and disappeared naturally after 1 day.

Preoperative exercise therapy is known to reduce hospital stay or postoperative complication and to improve functional competence or muscle strength. However, few reports focus on whether ordinary exercise habit before the surgery influences postoperative pain. In the present study, exercise habit was considered as physically activity in leisure-time,^[29] rather than occupational physical activities that are associated with reduced pain threshold.^[30] Physical activities at leisure-time involve dynamic contractions of large muscles to increase cardiac output and entire body metabolism with voluntary resting on experiencing stress or fatigue.^[31] In addition to its well-known health benefits,^[32] ordinary exercise habit reduced the overall post-TLH pain, including abdominal and shoulder pain in present study.

On questionnaire, the majority of patients reported only abdominal pain because they regarded the shoulder pain as unrelated to the surgery. However, shoulder pain deserves consideration because decreased shoulder pain was consequently related to reduction of overall pain in the present study. To our best knowledge, this study is the first clinical trial on whether a treatment on shoulder, not diaphragm, is effective for reducing shoulder pain after TLH. EMLA with occlusive dressing may be preferable to TPI in terms of potent analgesic effect and noninvasiveness.

5. Conclusions

TPI and EMLA with occlusive dressing reduced the incidence and severity of the shoulder pain and improved the quality of recovery after TLH.

Author contributions

Conceptualization: Hae Keum Kil.

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Investigation: Ji Eun Kim.

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