의학석사 학위 논문

복강경 질식 자궁 적출술시 양측 자궁천골인대부위 로피바케인 주입의 수술 후 진통효과 분석

Postoperative pain control with ropivacaine following laparoscopic assisted vaginal hysterectomy: A randomized double blind study

울 산 대 학 교 대 학 원

의 학 과

곽 재 영

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이 논문을 의학석사 학위 논문으로 제출함

2017년 11월

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Abstract

Immediate post-operative pain control through injection of ropivacaine into both of uterosacral ligaments in laparoscopic vaginal hysterectomy

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Background: Although laparoscopic hysterectomy, a world popular technical method, ensures faster recovery and less post-operative pain rather than laparotomic hysterectomy, immediate postoperative pain control has been still required to improve a quality of postoperative care. We introduce an effective method, intraoperative injection of ropivacaine into both of uterosacral ligaments to control immediate postoperative pain.

Materials and Methods: We performed a prospective, double-blind, and randomized study. We analyzed 40 cases of laparoscopic vaginal hysterectomy performed between July 2015 and November 2016, by a single surgeon (Y.S.Kwon). Enrolled patients were randomized into the ropivacaine injection group and the saline injection group. Before closure of the abdominal wall, 7.5% ropivacaine (5mL) or saline (5mL) was administered into both of uterosacral ligament. The primary outcomes included the post-operative pain intensity expressed by Numeric Ranking Scale (NRS) values at 2, 6, 12 and

24 hours after injection. The secondary outcomes included the amount of analgesics demanded for pain control during 24 hours after the surgery.

Results: The pain intensity at 2 hours after injection was significantly lower in the ropivacaine injected group (p=.0234). There was no difference in pain intensity at 6, 12, and 24 hours after injection and the amount of analgesics used. However, the total amount of used opioid analgesic was lower in the ropivacaine injected group, as compared to the placebo injected group. (p=.0251).

Conclusion: Intraoperative ropivacaine injection into both of uterosacral ligament during laparoscopic hysterectomy can reduce early post-operative pain and consumption of analgesics to improve a quality of postoperative care.

Key words: laparoscopic hysterectomy, ropivacaine, postoperative pain, uterosacral ligament

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Introduction

In gynecologic surgery, laparoscopic surgery is the preferred option except in patients with known contraindication. Although laparoscopy ensures faster recovery, fewer complications, and less pain than laparotomic surgery, post-operative pain control is still a major problem in post-operative care because it can reduce the advantages of the minimally invasive approach; hence, some trials have been conducted to develop strategies to reduce pain after laparoscopic surgery.[1)]

Intraperitoneal local anesthetic was introduced in the early 1950s, and has since been used in various surgical procedures.[2)] In gynecologic laparoscopy, local anesthetic instillation into the intraperitoneal space and local injection into the incisional site is common.[3-8)] After uterine surgery, visceral pain intensity is maximal and most of the patients complain of lower abdominal pain.[4)] Visceral pain is transmitted by pelvic visceral plexus that are derived from hypogastric plexus associated with uterus, vagina, rectum and bladder. The uterus receives primary innervation from the uterosacral plexus (Lee-Frankenhauser plexus), which is located near the lateral side of the uterine cervix within the uterosacral ligament and plays an important role in pain transmission.[9)] Systematic analgesics, such as nonsteroidal anti-inflammatory drug (NSAID) and opioids, cannot directly block the visceral nociception despite dose-regulation under patient controlled analgesia (PCA). It is reasonable that direct block of uterosacral plexus through injection of prolonged half-life analgesic can improve pain relief to make enhanced recovery protocols and to reduce opioid addiction without systemic side effects. Systematic opioid analgesics can induce adverse effects including nausea, dizziness, and respiratory depression.

Bupivacaine and ropivacaine are local analgesics that are commonly used for nerve block and intraperitoneal application. Ropivacaine is a kind of long-acting amino amide, local anesthetic drug with duration of drug action of approximately 2 to 8-hours. Ropivacaine has been shown to effectively reduce pain without clinical toxicity. Compared with bupivacaine, ropivacaine acts preferentially on pain and sensory nerves than motor nerve block, so it is suitable for immediate pain control after uterine surgeries. Also, ropivacaine shows lower systemic and cardiac toxicity than bupivacaine, because of its higher clearance rate.[10-14)]

In the current study, ropivacaine infiltration into bilateral uterosacral ligaments was conducted at the end of laparoscopic hysterectomy in an attempt to evaluate the efficacy of intraoperative local ropivacaine injection for managing early post-operative painin patients with laparoscopic hysterectomy.

Material and Methods

1. Setting and participants

We conducted a single center, randomized, double-blind, placebo-controlled study. The Ethical Committee of Ulsan University Hospital approved the study on June 26th, 2015 (IRB File No.2015-05-016-003). We analyzed 40 cases of laparoscopic assisted vaginal hysterectomy (LAVH), performed between July 2015 and November 2016 by a single surgeon. All patients provided informed consent. Patients aged over 18 years and below 80 years who underwent LAVH were eligible for inclusion in the study. Exclusion criteria included laparotomic conversion during the surgery; combined endometriosis with consequent severe adhesion leading to inability in the discrimination and injection of the uterosacral ligament; confirmed malignancy; patients with history of allergy to NSAIDs, opioids, and other medication; patients who received analgesics 12 hours before the surgery. Patients were recruited one day before the surgery and written consent was obtained. The sample size was estimated as 22 per each group, using https://stattools.crab.org/ sample size calculator at 0.90 power and type I error of 0.05 (two-sided) with a difference value of 2 based on the reduction of NRS score >2 percieved to be clinically relavant and variance estimate of 2.0. Considering a drop-out rate of 10%, we included a total of 50 patients with 25 patients in each group.

2. Randomization and blinding

Enrolled patients were assigned into two groups in a random 1:1 ratio sequence as the ropivacaine injection group and saline injection group. The research assistant picked a sealed paper with the allocation number. The sealed paper was handed to the person in charge of designating group-assignments based on the allocated number before the surgery. The ropivacaine or saline solution was delivered to the operation room just before the administration. All researchers who participated in the surgery and data collection were blinded until completion of data analysis.

3. Interventions

General anesthesia was induced, and the patient was placed in a dorsal lithotomy position with endotracheal intubation. A uterine manipulator (Hangzhou Shikonghou Medical Equipment Co. Ltd., Beijing, China) was placed in the uterine cavity, to facilitate moving the uterus into the optimal position during excision and suturing. Intra-abdominal pressure was maintained at 13 mmHg with carbon dioxide gas. In the all LAVH procedure, three 5 mm trocar access was uniformly performed. To reduce bias, all surgical procedures were conducted by a single surgeon. When removal of uterus was completed, ropivacaine (10 mL) or saline solution (10 ml) was injected into the lateral side of the both uterosacral area, 5 cc each transvaginally before stump closure in the LAVH. Ropivacaine hydrochloride 7.5% (7.5 mg/mL) manufactured by Reyon Pharmaceutical. Co., Ltd. (South Korea) was used in the ropivacaine group and the saline group was administered sodium chloride solution (9 g/1000 mL) manufactured by JW Pharmaceutical (South Korea).

Ropivaciane and saline solutions cannot be discriminated visually, since they are colorless and transparent.

All participants were managed with standardized protocol. In the post-anesthesia care unit (PACU), fentanyl citrate 78.5 μg/mL (50 μg as fentanyl) (Myungmoon Pharmaceutical Co., South Korea) was administered once. Subsequently, the pain was controlled by NSAID, ketorolac tromethamine 15mg (Ketorac®1 ampoule: 30mg/mL) manufactured by Hanmi Pharmaceutical. Co., Ltd. (South Korea) and opioid, meperidinechloride 25mg (Pethidine®,1 ampoule: 25mg/0.5mL) manufactured by Jeil Pharmaceutical. Co., Ltd. (South Korea). Two hours after the injection, the patients arrived in the ward where they were evaluated for pain score; and 15mg of ketorolac tromethamine was injected once routinely. If the patient experienced subsequent pain, ketorolac was the first choice for prorenata (PRN). Pain scores were re-evaluated after 30minutes; and if pain persists NSAID was administered again. After 30minutes after NSAID injection pain score was re-evaluated. Opiod was administered when the pain score was checked >4 NRS. Participants were not permitted patient controlled analgesia (PCA) for monitoring analgesic usage, but if the patients were unable to tolerate pain despite injection of intravenous analgesia, PCA was allowed optionally. Patients under PCA were excluded from the analysis. Metoclopramide was used as a post-operative antiemetic as occasion demands.

4. Outcome assessment

Baseline data included patients' age, body mass index (BMI), duration of the surgery, duration of anesthesia, hemoglobin level of pre/post-operation and estimated blood loss during the surgery. The primary outcomes included

post-operative pain intensity expressed by the 11-point numeric scale (NRS) at 2, 6, 12 and 24 hours after the injection. An 11-point numeric scale (NRS) with 0 representing “no pain” and 10 representing “worst pain imaginable” was used. The score was measured by using a numbered scale bar matched with figures of facial expressions. The secondary outcomes included the amount of analgesics administered during 24 hours after the surgery. The treatment duration and amount in milligrams of administered analgesics (ketorolac tromethamine and meperidinechloride) were recorded.

5. Statistical Analysis

Data analysis was performed using MedCalc statistical software version 17.2 (MedCalc Software bvba, Ostend, Belgium; https://www.medcalc.org; 2016). All data were expressed as mean ± standard deviation for continuous variables and percentage for categorical variables. Continuous variables were compared using the Student’s t test for parametric data or the Mann-Whitney test for non-parametric data. $P \leq 0.05$ was considered as statistical significance. The comparison of categorical variables was performed using the Chi-square test or Fisher’s extract test.

Results

Among 50 eligible patients, all were randomized, and ten patients were excluded. Among the 10 patients, two patients, one each in the ropivacaine and saline groups, were excluded because of the operative finding of grade Ⅳ endometriosis, one patient in the saline group was excluded because of injection of other analgesics and the other seven patients opted for PCA after the surgery despite their pre-surgery agreement to not use PCA; of these, three patients were from the ropivacine group and four patients from the saline group. Thus, we analyzed 21 patients who received ropivacaine and 19 patients who received the placebo (Figure 1). In each group, ropivacaine and saline sub-groups showed no statistical difference in patients' characteristics (Table 1).

Pain intensity showed significant difference in postoperative pain at 2 hours after administration of ropivacaine or placebo solution (p=.023). The ropivacaine group showed a mean NRS score of 4.60 ± 1.54 and the saline group, 6.32 ± 2.38. However, there was no difference in NRS pain score at 6, 12, and 24 hours after injection (Table 2). There was no difference between the two groups in the total amount of additional NSAIDs for additional pain control. However, The patients who received saline required a higher amount of opioid (13.04 ± 19.76mg, Pethidine hydrochloride), as compared to those who received ropivacaine injection (3.26 ± 11.44mg, Pethidine hydrochloride) (p=.025) (Table 3).

Figure 1. Flow sheet for analysis

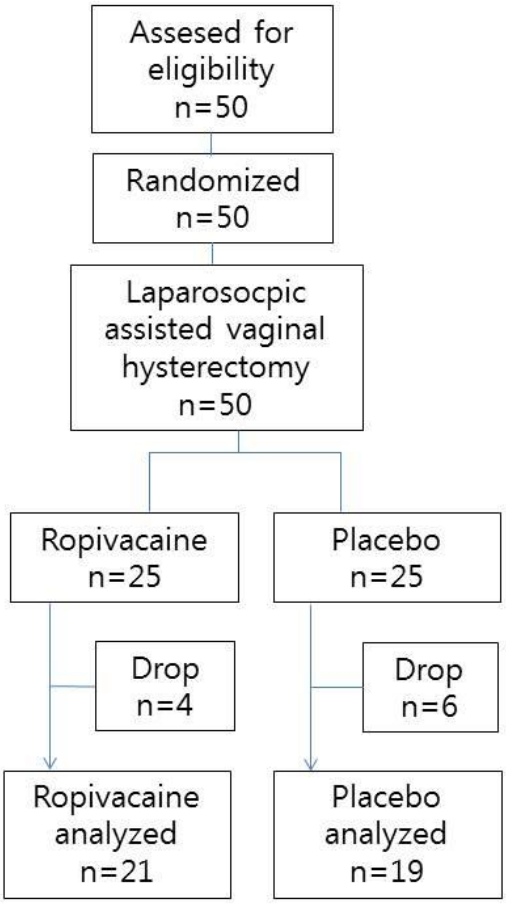

Table1. Patient Characterisctics of patients who underwent laparoscopic assisted vaginal hysterectomy (LAVH)

Characteristics	Ropivacaine (N=21)	Placebo (Saline) (N=19)	*p*
Age, years†	48 (40-67)	48 (39-61)	*.304*
BMI, kg/m^2 *	24.9±2.6 (21.7-31.0)	25.2 ± 3.2 (20.8-32.2)	*.740*
Surgical time, min†	65 (30-165)	60 (35-130)	*.673*
Anesthetic time, min†	97 (60-200)	90 (60-170)	*.735*
Preoperative Hb, mg/dL*	12.42±1.42 (10.3-15.2)	12.23±1.73 (8.9-14.5)	*.696*
Postoperative Hb, mg/dL*	11.29±1.21 (8.4-13.3)	11.28±1.52 (8.5-13.1)	*.989*
Preop Hb - Postop Hb*	1.14±1.00	0.95±0.92	*.536*
Estimated blood loss†	50 (20-500)	50 (10-100)	*.462*

* Data was expressed as mean value ± Standard Deviation (range)

† Data was expressed as median (range)

BMI, Body mass Index; Hb, Hemoglobin

Table 2. Pain score between the ropivacaine group and placebo group.

Hours	Ropivacaine N=21	Placebo (Saline) N=19	*p*	95% CI
2	4.6 ± 1.5 (2-8)	6.3 ± 2.3 (3-10)	*0.023*	0.422 to 3.009
6	4.4 ± 2.3 (1-8)	4.3 ± 1.7 (1-7)	*0.199*	-1.404 to 1.235
12	4.0 ± 1.9 (1-8)	3.3 ± 1.5(1-9)	*0.947*	-2.014 to 0.640
24	2.9 ± 0.8 (2-5)	2.5 ± 1.4 (1-6)	*0.113*	-1.102 to 0.355

Data was expressed as mean value ± Standard Deviation (range)

Table 3. Total amount of analgesics

	Ropivacaine N=21	Placebo (Saline) N=19	*p*
Additional NSAID			.
ketorolac treomethamine (mg)	13.7 ± 17.5 (0-45)	13.0 ± 12.2 (0-45)	*.676*
Opiod			
Pethidine hydrochloride (mg)	3.3±11.44 (0-50)	13.04±19.76 (0-75)	*.025*

Data was expressed as average ± S.D (range)

NSAID, Non-steroidal anti-inflammatory drug

Discussion

Compared with laparotomic surgery, laparoscopic surgery has less pain at the incision and approach sites but postoperative visceral pain still needs to be controlled immediately after operations. Various factors are involved in the post-operative pain of laparoscopic surgery that includes visceral pain induced by dissection, shoulder and scapular pain, stretching pain due to pneumoperitoneum, and incisional pain from the trocar site.[1,15] Intraperitoneal administration of analgesics has been a focus of studies since the 1950s. Previous studies used instilled or nebulized delivery modes for peritoneal distribution.[5,7,11,14-16] With the advent of laparoscopic surgery, intraperitoneal administration of local anesthetics have focused on the distribution in the peritoneum such as nebulization or spraying.[17] Moreover, a study of continuous infusion of 0.5% levobupivacaine into the peritoneal cavity following laparoscopic hysterectomy indicated that there were no opioid-sparing effects.[18] With regards to the mode of intraperitoneal administration, we focused on the direct effect of the intraperitoneal lesion using the nerve-block concept, which is different from previous studies. Infiltration has the potential to directly block neural transmission of pain by transiently blocking the pelvic afferent sensory nerve fibers of the Lee-Frankenhauser nerve plexus, an important structure in signaling pathways of pain.

Visceral pain intensity is maximal during the first few hours immediate after the surgery; moreover, ropivacaine infiltration is effective in the control of early postoperative pain, since it is most effective during the immediate post-operative period. In our study, there was significant difference in pain

intensity in the case of laparoscopic hysterectomy, at the first 2 hours, immediate postoperative recovery period. Immediate pain control improves quality of postoperative care during the hospital stay period. Ropivacaine infiltration to the uterosacral area was effective in hysterectomy, suggesting that local injection might mostly affect focal visceral pain control, as compared to directly blocking the afferent nerve pathway. Although the exact mechanism remains unknown, the decreased amount of opioid in the ropivacaine group is partly indicative of the effect of early post-operative pain control within the first 24 hours after the surgery.

Only a few trials of intraperitoneal infiltration of local anesthetics directly to the site of operation have been reported. Local intraperitoneal infiltration was applied in the studies of cholecystectomy,[19] appendectomy,[20] and laparoscopic sterilization.[21] The systemic levels of intraperitoneal local anesthetics are detectable in the serum after 2 minutes, reaching a maximal concentration after 10 to 30 minutes. Systemic toxicity can occur, while local anesthetics have a relatively wide safety margin. In a review study, Kahokher at al. reported the dose-range of ropivacaine of 100 to 300 mg and mean Cmax of 0.66 to 3.76 ìg/mL in the previous studies. Tmax was achieved at 15-35 minutes post-administration. On the basis of previous study and the permitted dose by the Korea Food and Drug Administration (7.5 - 225 mg) for infiltrative anesthesia, we injected a total dose of 75 mg ropivacaine as 10 cc of ropivacaine hydrochloride 7.5% solution (7.5 mg/mL). Because of the lack of clinical toxicity studies, careful consideration was required for dosing to prevent a potential toxic effect.[2]

A limitation of this study is that it had been designed as the small sized study. This study was focused on the visceral pain alone, and the various types of pain were not considered. However, in our experience, most of the

patients complain of abdominal pain immediately after the surgery, and shoulder or back pain reveals after an immediate period of time. Immediate post-operative pain is the most intense and acute pain that must be controlled. Therefore, early management of post-operative pain would be the crucial point of pain control after the surgery. And visceral pain is the primary point for early post-operative pain control, hence the pain score was evaluated at the first 24 hours after injection of ropivacaine. Effective intraoperative local injection is not only for pain control but also to reduce the release of stress hormone and neurotransmitters that disturb post-operative recovery. Pain control in the early post-operative stage facilitates normal respiration and prevents post-operative pulmonary complications.

Conclusion

Intraoperative local ropivacaine injection that targets the uterine nerve plexus can be considered to reduce early postoperative pain and analgesic consumption in patients who undergo laparoscopic assisted hysterectomy.

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국문 요약

복강경 질식 자궁적출술은 수술 직후 통증을 조절해 줄 경우 조기 보행을 가능하게 하여 재원 기간을 줄이고 비용을 절감할 수 있다. 현재 알려진 바로 자궁의 통증기전에 관여하는 구심성 신경 전달체계 중 자궁경부 직상방의 자궁천골인대(uterosacral ligament) 부위에 위치한 Lee-Frankenhauser plexus가 중요한 역할을 담당하고 있어 일차성 생리통의 치료로써 자궁천골인대 부위를 소작하는 방법이 효과적인 것으로 보고된 바 있다. 이에 주요 통증의 전달경로로 생각되는 자궁천골인대 부위에 국소마취제인 Ropivacaine을 주입함으로써, 수술 직후 골반 부위 통증 경감 효과가 있을 것으로 예상된다.

본 연구는 복강경 질식 자궁 적출술 (laparoscopic vaginal hysterectomy)시에 자궁천골인대 (uterosacral ligament)부위 로피바케인 주입 (Ropivacaine injection)의 수술 후 진통효과를 분석하기 위하여 무작위 배정을 통하여 복강경 질식 자궁적출술에 대한 시험군 ropivacaine injection과 대조군 saline injection (22/22) 총 44명 배정하여 통증점수와 진통제 투여량을 확인하여 시험군의 통증 감소 효과를 통계적으로 분석하도록 설계하였으며 이중 눈가림법을 이용한 무작위 대조군 실험으로 진행하였다. 무작위 배정한 대상 환자의 수술 종료 직전 복강 내로 접근하여 자궁천골인대부위에 로카인 주 7.5mg/ml (ROCAINE INJ 7.5mg/ml) 또는 생리식염수 10cc를 주사하고 수술 후 통증 점수 (NRS score)를 1, 6, 12, 24시간 후 기록하고 진통제 투여량을 확인하였다.

중도 탈락자를 제외한 시험군과 대조군 각각 20명의 통증 점수와 진통제 투여량을 비교하였다. 복강경 질식 자궁적출술 직후 2시간 후 측정한 통증점수는 로피바케인을 주사한 군에서 생리식염수를 주사한 군보다 통계적으로 유의하게 (p-value=0.0234) 낮았다. 마약성 진통제의 총 투여량 또한 로피바케인을 주사한 군에서 생리식염수를 주사한 군 보다 통계적으로 유의하게(p-value=0.0251) 적었다.

연구 결과에 따라 자궁적출술 후 로피바케인을 양측 자궁천골인대에 주입하는 것은 수술 직후 통증 조절에 효과가 있으며 마약성 진통제의 사용도 줄일 수 있

었고 이는 다른 부인과 수술 영역에도 응용하여 수술 후 통증 경감을 위한 방법으로 적용할 수 있을 것으로 사료된다.

중심단어: 복강경 자궁적출술, 수술 후 통증, 자궁천골인대, 로피바케인.