

การวิจัยแบบสุ่มที่มีกลุ่มควบคุมและปกปิดสองทางเพื่อเปรียบเทียบแรงกล้ามเนื้อขาและความสามารถในการลุกเดินหลังผ่าตัด ระหว่างสองความเข้มข้นของยาชา Bupivacaine ขณะให้ยาชาเหนือช่องไขสันหลังอย่างต่อเนื่องในผู้ป่วยผ่าตัดมะเร็งนิ่ว

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บทคัดย่อ

การผ่าตัดของผู้ป่วยมะเร็งนิ่วเป็นการผ่าตัดใหญ่ การระงับปวดที่ดีและการดูแลซึ่งทำให้ผู้ป่วยฟื้นตัวเร็วขึ้น การลุกเดินหลังผ่าตัดได้เร็ว ช่วยลดภาวะแทรกซ้อนของการผ่าตัดได้ การใส่สายระงับปวดที่ช่องเหนือไขสันหลัง ช่วยลดความปวดหลังผ่าตัดได้ดี แต่การใช้ยาชาในการระงับปวด พบผลข้างเคียงที่พบบ่อยคือ มีกล้ามเนื้อขาอ่อนแรงได้ ซึ่งอาจเป็นอุปสรรคในการลุกเดินหลังผ่าตัด การวิจัยแบบสุ่มที่มีกลุ่มควบคุมและปกปิดสองทางนี้มีวัตถุประสงค์หลักของการศึกษาเพื่อเปรียบเทียบแรงกล้ามเนื้อขาและวัตถุประสงค์รองเพื่อศึกษาความสามารถในการลุกเดินหลังผ่าตัด คะแนนความปวดและผลข้างเคียงระหว่างสองความเข้มข้นของยาชา Bupivacaine ผู้ป่วย ASA I-II จำนวน 110 ราย ที่เข้ารับการผ่าตัดมะเร็งนิ่ว โดยใช้การระงับความรู้สึกแบบทั่วไปร่วมกับใส่สายระงับปวดที่ช่องเหนือไขสันหลัง และมีการให้ยาชาในช่วงระหว่างผ่าตัด หลังผ่าตัดแบ่งเป็น 2 กลุ่ม กลุ่ม A ให้ยาชา 0.1% Bupivacaine ร่วมกับ Fentanyl 2 ไมโครกรัมต่อมิลลิลิตร กลุ่ม B ให้ยาชา 0.0625% Bupivacaine ร่วมกับ Fentanyl 2 ไมโครกรัมต่อมิลลิลิตร ในช่วง 48 ชั่วโมงหลังผ่าตัด มีการบันทึก แรงกล้ามเนื้อขา ความสามารถในการลุกเดินหลังผ่าตัด คะแนนความปวด อุบัติการณ์คลื่นไส้ อาเจียน คัน ความดันโลหิต ผลพบว่าแรงกล้ามเนื้อขาโดยการวัดด้วยวิธี Modified Bromage scale ของกลุ่ม A และ B ไม่มีความแตกต่างกันอย่างมีนัยสำคัญ จำนวนผู้ป่วยที่ลุกเดินได้ในกลุ่ม A ร้อยละ 52.9 กลุ่ม B ร้อยละ 68.8 ($p=0.110$) ที่ 24 ชั่วโมงหลังผ่าตัด และจำนวนผู้ป่วยที่ลุกเดินได้ในกลุ่ม A ร้อยละ 92 กลุ่ม B ร้อยละ 94 ($p=0.679$) ที่ 48 ชั่วโมงหลังผ่าตัด ซึ่งไม่มีความต่างกันทางสถิติ นอกจากนี้ คะแนนความปวด ความดันโลหิต อุบัติการณ์คลื่นไส้ อาเจียน คัน ไม่แตกต่างกันอย่างมีนัยสำคัญ สรุป แรงกล้ามเนื้อขาของทั้งสองกลุ่มไม่ต่างกันอย่างมีนัยสำคัญ จำนวนผู้ป่วยที่ลุกเดินได้หลังผ่าตัดไม่ต่างกันอย่างมีนัยสำคัญ ร่วมกับคะแนนระดับความปวด และภาวะแทรกซ้อนของทั้งสองกลุ่มไม่แตกต่างกัน ดังนั้น แนะนำว่าอาจใช้ 0.0625% Bupivacaine ร่วมกับ Fentanyl 2 ไมโครกรัมต่อมิลลิลิตรได้ในการระงับปวดหลังผ่าตัดของผู้ป่วยมะเร็งนิ่ว

คำสำคัญ: ผ่าตัดมะเร็งนิ่ว; การใส่สายระงับปวดที่ช่องเหนือไขสันหลัง; แรงกล้ามเนื้อขา; ความสามารถในการลุกเดินหลังผ่าตัด

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Comparison of postoperative muscle strength and ambulation ability between two different concentrations of bupivacaine in patients undergoing gynecologic oncology surgery under combined general-epidural anesthesia: A double blinded, randomized-controlled study

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Abstract

Gynecologic oncology operations constitute major surgery. Optimizing pain management and enhancing patient recovery with early ambulation can reduce postoperative complications. Epidural analgesia is a good technique to control pain; however, it can have some side effects. One of the most common side effects is lower motor weakness, which can impede early ambulation. The primary outcome of this double-blinded, randomized controlled study was to compare muscle strength, and secondary outcomes were to study the ability to ambulate, pain score, and complications between two concentrations of bupivacaine. One hundred and ten patients ASA I-II who underwent surgery and received epidural analgesia were included and randomly assigned to two groups. Patients in group A were treated with 0.1% bupivacaine plus fentanyl 2 mcg/ml. Patients in group B received 0.0625% bupivacaine plus fentanyl 2 mcg/ml. At 24 and 48 hours postoperatively, muscle strength, ambulation ability, pain score, and complications were compared. The results indicated that muscle strength, as assessed using the Modified Bromage scale measurement, showed no statistical difference between the two groups. Furthermore, there was no statistical significance in ambulation ability between both groups (at 24 hours, group A=52.9% vs group B=68.8% ($p=0.110$) and at 48 hours, group A=92% vs group B=94% ($p=0.679$)). Additionally, the pain score, incidence of hypotension, nausea, vomiting, and itching results were also not significantly different. In conclusion, both concentrations of bupivacaine had comparable characteristics of pain management in terms of muscle strength, ambulation ability, pain score, and side effects. Therefore, 0.0625% bupivacaine plus fentanyl 2 mcg/ml may be used in patients undergoing gynecologic oncology surgery to optimize pain control and promote enhanced patient recovery.

Keywords: gynecologic oncologic surgery; epidural analgesia; muscle strength; ambulation ability

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Introduction

The mainstay of treatment for early stages of gynecologic malignancy is surgery, as it significantly increases survival rates.^{1,2} Postoperative pain is one of the major concerns in these operations; therefore, optimization of pain management and acceleration of patient recovery are important considerations for anesthesiologists.³

Perioperative epidural analgesia is one of the core components of enhanced recovery after surgery.³ Studies have demonstrated that in major surgeries, postoperative pain is less severe in patients who receive perioperative epidural analgesia than in those who are given only patient-controlled analgesia with intravenous opioids.^{4,5,6,7} With the use of epidural analgesia, the amount of opioids can be reduced, with an attendant decrease in opioid-related side effects such as sedation, respiratory depression, nausea, and vomiting.^{3,7} More importantly, epidural analgesia gives effective pain control, which enables earlier ambulation.³ Much of the evidence in the literature supports the suggestion that early ambulation reduces pulmonary and venous thromboembolic complications, facilitates the return of bowel function, and reduces length of hospital stay.⁸ Conversely, epidural analgesia can cause some side effects, the most common of which is lower motor weakness. Although this condition is not serious and is reversible, it may present an impediment to early ambulation and increase the risk of falling. There was study⁹ claimed that addition of 0.1% bupivacaine to epidural fentanyl

infusion for gynecologic oncology surgery was beneficial in early postoperative period. Nonetheless, fewer patients could mobilize when comparing with patient receiving epidural fentanyl alone. Reducing local anesthetic concentration could decrease the incidence of lower motor weakness.¹⁰ There was study reported that epidural infusion of bupivacaine 0.0625% bupivacaine with fentanyl provided better analgesia than patient controlled intravenous morphine after gynecological laparotomy.¹¹ There is no study comparing both concentrations of bupivacaine concerning muscle strength and ambulation ability in patients undergoing gynecologic oncology surgery with epidural analgesia.

The hypothesis of this study was decreasing drug concentrations may preserve effective pain control and reduce undesired side effects, such as motor weakness, and also facilitate early ambulation. This primary outcome of this study aimed to compare the effects of two concentrations of bupivacaine for epidural analgesia on lower motor muscle strength and the secondary outcomes were ability to ambulate, pain score and complications in patients undergoing gynecologic oncology surgery.

Material and methods

After receiving approval from the hospital Ethics Committee, This prospective randomized, double-blind controlled trial study was conducted between June and December 2020 in Rajavithi Hospital. All participants were informed about the protocol

of the study, and after presentation of the purposes, written informed consent was obtained prior to their participation. Inclusion criteria were patients with American Society of Anesthesiologists Physical Status I to II, age 20 to 75 years, ability to walk 3 meters independently without assistance, and lower motor power grade V. Exclusion criteria were patients who had contraindications for epidural anesthesia; history of allergy to drugs (bupivacaine, fentanyl, cisatracurium, propofol, sevoflurane, ondansetron, meperidine, or chlorpheniramine); NYHA status of more than 2; pre-existing heart disease, neurologic disorders or myopathy in the lower extremities; inability to extubate; or complications due to epidural anesthesia and patients with chronic opioid use. In this double-blind study, the first investigator used computer-generated permuted block randomization with block size of 4 and patients were assigned to one of two groups: those receiving 0.1% bupivacaine plus fentanyl 2 mcg/ml (Group A); and those receiving 0.0625% bupivacaine plus fentanyl 2 mcg/ml (Group B). Epidural analgesic medications used for the postoperative period were prepared by the first investigator in identical disposable infusion pumps (Coopdech) of the same volume, and the Coopdech injector was identified with each patient's name and hospital registration number. Anesthesiologists were blinded to group assignments and were responsible for epidural administration, anesthetic induction, intraoperative management via the same anesthetic protocol, and emergence. The

second investigators, who were also blinded to the group allocations, assessed lower motor strength, ambulation ability, and severity of pain at the ward.

During operation, all patients underwent non-invasive blood pressure, pulse oximetry, and 3-lead electrocardiogram. Epidural anesthesia was administered in the lateral position using the loss of resistance technique at the T10-T11, T11-12, or T12-L1 level with an 18-gauge Tuohy needle under sterile conditions at a depth of 5 cm in the epidural space. A single injection of 3 ml of 2% lidocaine with ADR (1:200,000) was administered as a test dose. The patient was placed in the supine position after receiving epidural anesthesia. The level of sensory blockade was assessed by the cold and pinprick sensation test and 2% lidocaine with ADR (1:200,000) was injected through epidural catheter until the anesthetic level achieved T8-L1 after which preoxygenation with 100% oxygen was applied. Anesthesia was induced with propofol (1.5-2.5 mg/kg), cisatracurium (0.15 mg/kg) was administered for intubation, and 0.03 mg/kg of cisatracurium was added as needed for maintenance of anesthesia. In patients with increased risk of pulmonary aspiration, 1.5 mg/kg of succinylcholine was administered for intubation. Anesthesia was maintained with sevoflurane (1-2%) in a mixture of N₂O 60% and oxygen 40%, and the end-tidal concentration of sevoflurane was adjusted in order to maintain a target of 1-2 MAC. Maintenance of epidural anesthesia was achieved with continuous epidural infusion of 0.25% bupivacaine in the

same dose with 2% lidocaine with ADR (1:200,000) that achieve the target level of analgesia (T8-L1). Thereafter, blood pressure, heart rate, SpO₂, and ETCO₂ were monitored every 5 minutes. The anesthetic time, operative time, estimated blood loss, and intravenous fluid administration were also recorded. A balanced salt solution was used during the intraoperative period, and ephedrine was given to maintain MAP > 65 mmHg. At the end of surgery, muscle relaxation was reversed with neostigmine (2.5 mg) in combination with atropine (1.2 mg). Patients had met the criteria before extubation and were observed in the recovery room for 2 hours. Infusion of 0.25% bupivacaine was stopped after patients had extubated in the operating room.

After finished operation, continuous epidural infusion of study drugs were started when patients arrived recovery room. They divided into two groups (Group A received 0.1% bupivacaine plus fentanyl 2 mcg/ml, while Group B were given 0.0625% bupivacaine plus fentanyl 2 mcg/ml) at a rate of 8 ml/hour for postoperative pain control in 48 hours. In case of persistent pain despite epidural administration, 1% lidocaine with ADR (1:200,000) 5 ml was injected via epidural catheter to assess whether it was functioning properly. If there was still inadequate analgesia, the epidural catheter was removed, and the patient was withdrawn from the study. Anesthesiologists and physical therapists (second investigators), who were blinded to group assignment, assessed the muscle strength of each patient using modified

Bromage scale (0 = no detectable weakness of hip flexion with full flexion of knees; 1 = partial block, just able to move knees or feet; 2 almost complete blocks, able to move feet only; 3 = complete block, unable to move feet or knees); ambulation ability; severity of pain using a numerical rating scale (0 = no pain; 10 = greatest amount of pain) at rest and at movement; incidence of nausea, vomiting, and itching; and orthostatic hypotension. For safety reasons, before patients performed ambulation, assessment was made of core stability (minimum of 1 min sitting); orthostatic hypotension (standing without assistance for 1 min, without syncope, dizziness, nausea, or vomiting); and motor power (hamstring muscle motor power of at least grade 3.¹² If three tests for ambulation were passed, patients were first asked to stand and then walk several steps with a support person at each side. Ambulation ability was defined as managing to walk 3 meters with no or minimal assistance (not more than a hand lightly touching the patient's arm). Patients were not asked to ambulate if they could not pass all three tests. Motor power and ambulation ability were assessed at 24 and 48 hours postoperatively.

Patients were given meperidine 15 mg intravenously if they reported a numerical rating scale of more than three, and they were asked to assess their pain at 6 hours, 24 hours, and 48 hours after surgery. Meperidine doses were recorded until 48 hours after surgery. Other side effects, such as nausea, vomiting, and itching were recorded. Ondansetron 4 mg was given to patients every six hours if they

had nausea or vomiting. If there was persistent vomiting, metoclopramide 10 mg was given. Chlorpheniramine 10 mg was administered for itching every 6 hours.

Sample size calculation and statistical analysis

The two-proportion formula¹³ was used for calculation of sample size in this study. The incidence of motor weakness was 36.5% and 12.5% in patients receiving 0.1% and 0.0625% bupivacaine respectively as shown in previous study.¹⁰ The level of significance was set at 0.05 and the power was 80%. When a 10% dropout rate was included, the required sample size was 55 patients per group. All statistical analyses were performed using SPSS v22 (SPSS, Inc., Chicago, IL, USA). Continuous data, using student t-test or Mann-Whitney U test depending on the normality of data distribution. Categorical data was analyzed by the Chi-square test, and $p < 0.05$ was considered to indicate a statistically significant difference.

Results

One hundred and ten patients were recruited and were included for this study. However, 103 patients were analyzed. There were 52 patients in group A (two had catheter dislodgement and one requested that the catheter be removed before the completion of the study, so these three individuals were withdrawn from the analysis). In Group B, four patients were withdrawn, leaving 51 participants (one patient changed operation, one had catheter dislodgement, one patient's epidural catheter did not work, and one had accidental dural puncture), as shown in Figure 1. This study was per-protocol analysis.

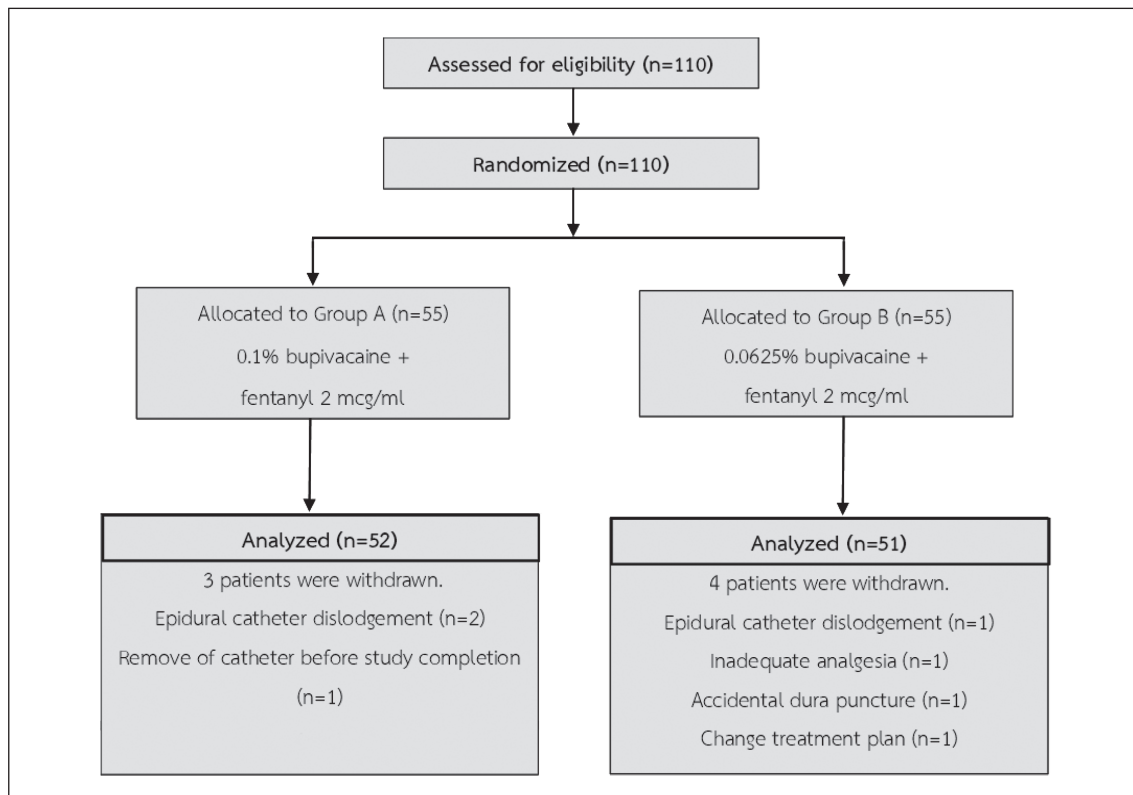


Figure 1 Consort flow diagram

Patient demographic data and intraoperative details are shown in Table 1.

There were no statistically significant differences between these characteristics in the two groups.

Table 1 Patient demographic data and intraoperative details

	Group A (N=52)	Group B (N=51)	p-value
Age	48.96±11.33	52.8±13.57	0.122
Weight (kg)	59.79±12.48	62.8±15.56	0.281
Height (cm)	155.65±6.47	156.65±6.59	0.442
BMI	24.61±4.66	25.59±6.05	0.358
Systolic BP	123.08±14.73	124.75±16.04	0.584
Diastolic BP	76.94±11.55	76.47±10.78	0.831
Prior abdominal surgery	22 (42.3%)	30 (58.8%)	0.095
Surgical time (min)	195.54±13.59	169.55±44.46	0.087
Diagnosis			
CA endometrium	12 (23.1%)	22 (43.1%)	0.081
CA ovary	27 (51.9%)	19 (37.3%)	
CA cervix	13 (25%)	10 (19.6%)	

Table 1 Continued

	Group A (N=52)	Group B (N=51)	p-value
Operation			
Modified RHND	14 (26.9%)	8 (15.7%)	0.222
TAH BSO pelvic and paraaortic LN sampling omentectomy	29 (55.8%)	32 (62.7%)	
peritoneal washing			
TAH with BSO and omentectomy with tumor debulking	9 (17.3%)	11 (21.6%)	
IV fluid			
Crystalloid	1,973.08±810.25	1,850.98±552.22	0.375
Colloid	67.31±172.32	29.41±155.29	0.244
Blood loss	479.23±382.48	389.61±361.55	0.225
Level of epidural			
T10-11	3 (5.8%)	3 (5.9%)	0.159
T11-12	21 (40.4%)	29 (56.9)	
T12-L1	28 (53.8%)	19 (37.3%)	

Data were expressed as mean ± SD or number of patients and (%).

BP=blood pressure; CA=cancer; RHND=radical hysterectomy with node dissection; TAH=total abdominal hysterectomy; BSO=bilateral salpingo-oophorectomy; IV=Intravascular

Muscle strength was assessed using the Modified Bromage scale at 24 and 48 hours postoperatively. There were no statistically significant differences between muscle strength in the two groups, as shown in Table 2.

Table 2 Modified Bromage Scale at 24 and 48 hours postoperatively

Muscle strength (leg)	Group A left	Group B left	p-value	Group A right	Group B right	p-value
Bromage scale at 24 hours						
0	48 (92.3%)	49 (96.1%)	0.41	48 (92.3%)	47 (92.2%)	0.977
1	2 (3.8%)	1 (2%)	0.57	2 (3.8%)	3 (5.9%)	0.635
2	2 (3.8%)	0 (0%)	0.16	1 (1.9%)	0 (0%)	0.324
3	0	1 (2%)	0.315	1 (1.9%)	1 (2%)	0.989
Bromage scale at 48 hours						
0	51 (98.1%)	49 (98%)	0.98	51 (100%)	49 (98%)	0.984
1	0	1 (2%)	0.31	0 (0%)	1 (2%)	0.315
2	1 (1.9%)	1 (1.9%)		1 (1.9%)	1 (1.9%)	
3	0	0		0	0	

Data were expressed as number of patients and (%).

More than 90% of patients had a Modified Bromage scale of 0 at 24 hours postoperatively.

There was no significant difference in ambulation ability at 24 and 48 hours postoperatively. (after 24-hours, Group A=52.9% vs Group B=68.8%, $p=0.110$, while after 48-hours, group A=92.0% vs. group B=94.1%, $p=0.679$) (Table 3).

Table 3 Ambulation ability at 24 and 48 hours postoperatively

	Group A	Group B	<i>p</i> -value
Ambulation ability at 24 hours			
Could not walk	24 (47.1%)	15 (31.3%)	0.110
Could walk	27 (52.9%)	33 (68.8%)	
Ambulation ability at 48 hours			
Could not walk	4 (8.0%)	3 (5.9%)	0.679
Could walk	46 (92.0%)	48 (94.1%)	

There was a significant difference between Numerical Rating Scale at 6 hours at rest in the two groups ($p=0.04$), but not in NRS

at 6 hours during movement, 24 hours, or 48 hours postoperatively, as shown in Table 4.

Table 4 Pain score at 6, 24, and 48 hours postoperatively

Postoperative pain score		Group A	Group B	<i>p</i> -value
6 hours	Rest	0 (0-3)	2 (1-3)	0.040
	Movement	3 (1-5)	3 (2-4)	0.275
24 hours	Rest	2 (1-4)	2 (1-3)	0.973
	Movement	3 (1-5)	4 (1-5)	0.211
48 hours	Rest	2 (1-4)	0 (0-2)	0.225
	Movement	3.5 (2-6)	3 (1-4)	0.413

Systolic blood pressure after 6 hours in group A was significantly lower than in group B, but there were no differences in diastolic

blood pressure at 6 hours postoperatively or in blood pressure at 24 or 48 hours postoperatively (Table 5).

Table 5 Postoperative blood pressure at 6, 24, and 48 hours postoperatively

Postoperative blood pressure		Group A	Group B	p-value
6 hours	Systolic	111.08 ± 15.30	117.45 ± 14.99	0.035
	Diastolic	68.35 ± 13.23	67.45 ± 8.19	0.568
24 hours	Systolic	115.67 ± 17.13	118.69 ± 16.80	0.370
	Diastolic	68.35 ± 13.23	68.10 ± 9.46	0.913
48 hours	Systolic	118.00 ± 16.06	118.96 ± 13.92	0.749
	Diastolic	69.80 ± 9.76	71.08 ± 9.96	0.516

The incidence of nausea, vomiting, and itching were not significantly different in the two groups.

Discussion

Epidural analgesia is one of the techniques used to control perioperative pain in patients undergoing gynecologic oncology surgery. However, patients receiving epidural analgesia are more likely to experience epidural analgesia-associated complications, such as lower limb motor weakness, orthostatic hypotension which may be a barrier to their mobilization.

In this study, Modified Bromage scale was not significant between both groups. However, there were patient had motor power less than grade 4 (left leg group A 9.6% vs. group B 4.0%; right leg group A 19.3% vs. group B 7.9%). This result was similar with the study from Badner NH and et al.¹⁴ They found that incidence of motor block was resemble in 0.125% bupivacaine and 0.25% bupivacaine but degree of blockade was more pronounced with the 0.25% concentration. This corresponds with the results of a study of Ahmed A. et al.,

which claimed that a higher concentration of local anesthetics can cause more lower motor weakness.¹⁰

The ambulation ability was not different in these two groups. Nonetheless, there were some patients in this study who passed criteria for walking test but they refused to walk due to pain and fear. That corresponds to the study from Cohen S et.al. said that significant factors to be aware of which impede ambulation ability during the postoperative period include not only motor weakness but also pain and fear of ambulation.^{15,16} These factors are modifiable, but there are others which are not, such as advanced age, physical/performance status, and malnutrition.¹⁸ There are some strategies that can help individuals with modifiable risk factors to achieve ambulation; for example, optimizing pain control before ambulation, conducting educational programs to inform patients about the benefits of early ambulation, and using abdominal binders and other wearable technology with real-time feedback that improve mobilization and exercise prehabilitation.^{17,18} In the future, in order to

improve patients' ambulation during the postoperative period, these strategies should be included in the protocol.

Fentanyl 2 mcg/mg combination with bupivacaine was used in this study. The incidence of nausea and vomiting was around 10-30%, and the incidence of itching was around 10-35%. These were less than the incidence from study of TSUI SL.¹¹ that combination of fentanyl 3.3 mcg/ml in bupivacaine was used. Study from Panyakumlerd Y. et al.¹⁹ reported that fentanyl 2 mcg/ml combined with 0.0625% bupivacaine was the optimal concentration that provided excellent analgesia and few side effects after lower abdominal surgery. So, it may imply that concentration of fentanyl used in this study was suitable.

Systolic blood pressure after 6 hours in group A was significantly lower than in group B (Group A; 111.08 ± 15.30 and Group B; 117.45 ± 14.99 mmHg). This difference was no clinical significance. Also, there was no difference in blood pressure and no incidence of hypotension in other periods. This corresponds with the suggestion from study of Peach MJ⁹ that hypotensive episode may be in part of dose-dependent, and although modest fall in systolic blood pressure may occur with low dose bupivacaine, significant hypotension has not been reported with combination infusion including up to 0.2% bupivacaine.

This study had some limitations. First, some patients passed the criteria for ambulation but they refused to walk due to pain, so the real number of patients who

could have ambulated might have been underestimated. Second, this investigation was a single-center study, and its results may not be generalizable to other populations.

Conclusion and recommendation

In conclusion, there were no statistical difference between muscle strength, ambulation ability in these groups of patients. In addition, pain score, incidence of hypotension, nausea, vomiting, and itching were also not significantly different; therefore, 0.0625% bupivacaine plus fentanyl 2 mcg/ml may be used in patients undergoing gynecologic oncology surgery in order to optimize pain control and accelerate their recovery.

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