Intrathecal Fentanyl in Spinal Anesthesia for Appendectomy

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Objective : *The authors assessed the effectiveness of the administration of fentanyl in spinal anesthesia for appendectomy.*

Material and Method : *Forty patients randomized double-blind, were recruited to receive either 4 ml of 0.5 % hyperbaric bupivacaine + 20 mg of fentanyl (Group F) or 4 ml of 0.5 % hyperbaric bupivacaine 0.5 % + 0.4 ml normal saline (Group S).*

Results : *There were no significant differences in the highest analgesic level between the groups. The number of segments regressed at 60 min in Group F was statistically less than in Group S (0 vs. 2; P 0.002). Group F showed significantly lower median VNS pain scores than Group S (0 vs. 3; P 0.004). Time to first required postoperative analgesics in Group F was significantly higher than in Group S (13.6 vs. 6.3 h; P < 0.001). The incidence of shivering in Group F was significantly lower than Group S (35 % vs. 70 %; P 0.023). There were no significant differences in the incidence of nausea, vomiting, hypotension and urinary retention. No patient developed respiratory depression or PDPH. The patients' satisfaction of spinal anesthesia was 100 % in Group F and 80 % in Group S.*

Conclusion : *Intrathecal 20 μg fentanyl significantly improved the quality of analgesia; it prolonged the duration of bupivacaine in spinal anesthesia and delayed the analgesics requirement in the early postoperative period. Shivering was less frequently found in the fentanyl group.*

Keywords : *Intrathecal, Fentanyl, Spinal anesthesia, Appendectomy*

J Med Assoc Thai 2004; 87(5): 525-30

Spinal anesthesia is commonly employed for appendectomy in Thailand. The advantage of SA includes the simplicity of technique, its rapid onset and the exclusion of aspiration. Some patients complained of pain when the appendix was retracted or the swab was put in the abdomen.

Experimental studies have shown that opioids administered intrathecally were able to relieve visceral pain[1-6].The clinical efficacy of intrathecal opioids to relieve visceral pain has also been demonstrated[7-8].

Fentanyl is well known for its rapid onset and shorter duration of action following intrathecal administration[9-10].

This study was designed to evaluate the effects of intrathecal fentanyl 20 μg on the improvement of analgesia of hyperbaric bupivacaine in patients who were undergoing appendectomy.

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Material and Method

After obtaining approval from the Ethics Committee of the Faculty of Medicine and informed consent from each patient, this prospective, randomized, double-blind, placebo-controlled study was conducted at King Chulalongkorn Memorial Hospital. Patients of ASA physical status I who were scheduled for appendectomy under spinal anesthesia were recruited into the study. The exclusion criteria employed in the study were; known history of bupivacaine or fentanyl allergy, past history of severe headache or backache, narcotic dependence, inability to qualify pain by verbal numeric scale (VNS).

The patients were randomly allocated into 2 Groups; Group F (n = 20) received fentanyl 20 μg (0.4 ml) in 4 ml of 0.5% hyperbaric bupivacaine intrathecally, while those in Group S (n = 20) received 0.4 ml of

normal saline in 4 ml of 0.5% hyperbaric bupivacaine intrathecally. The randomization sequence was selected based on a table of random number. Randomly allocated coded syringes of drugs were prepared by an anesthesiologist who was not involved in the spinal block or recording of the outcome.

After the standard monitors were placed and intravenous access was established, patients were preloaded with 20 ml/kg normal saline solution. Spinal block was performed with a 27-gauge spinal needle of the L3-4 interspace in the lateral decubitus position and 4 ml of 0.5% hyperbaric bupivacaine with 0.4 ml of the studied drug was injected. The total volume of the subarachnoid injection was 4.4 ml. Patients were immediately returned to supine position after completing the blocking procedure.

Noninvasive blood pressure was monitored every 5 min. Oxygen saturation, EKG and respiratory rate were monitored continuously. The analgesic level was determined by loss of pinprick sensation in the midline of the body every 5 min for the first 15 min and then every 15 min for 1 hr.

The patient was asked to quantify their most severe intraoperative pain by using VNS pain scores with 0 corresponding to no pain and 10 to the worst imaginable pain. The most severe intraoperative pain was also divided to a 4-point rating score (0 = absence of pain; 1-3 = mild pain; 4-6 = moderate pain; > 6 = severe pain and therapy incremented dose of 25 μg fentanyl IV was then given). The patients were scored for sedation using a 4-point rating score (0 = fully awake; 1 = somnolent, responds to call; 2 = somnolent, responds to tactile stimuli; 3 = deep sedation, responds to painful stimuli), itching by a 4-point rating score (0 = no itching; 1=mild itching; 2 = moderate itching, treatment not requested; 3 = severe itching, treatment requested), nausea and vomiting by a 4-point rating score (0 = no nausea and vomiting; 1 = nausea; 2 = retching; 3 = vomiting), shivering by 4-point rating score (0 = no shivering; 1 = mild shivering; 2 = moderate shivering, treatment not requested; 3 = severe shivering, treatment requested). Intravenous metoclopramide 10 mg was used to treat vomiting. Intravenous pethidine 20 mg was used to treat shivering. Intravenous nalbuphine 3 mg was used to treat itching.

Episodes of perioperative side effects such as hypotension (SBP < 30% from baseline), bradycardia (HR < 50 bpm), desaturation (SpO2 < 90%) and respiratory depression (RR < 12 bpm) were recorded. Hypotension was treated with bolus of fluid and incremented dose of ephedrine 6 my IV and bradycardia was treated with atropine 0.6 my IV.

At 24 hr postoperative, the patients were evaluated for the duration of effective analgesia (time from subarachnoid injected to the first request of analgesics) and the pain score at that time by VNS. The episodes of PDPH, urinary retention and patient's satisfaction of spinal anesthesia were also recorded.

The number of patients required in each group was determined by power analysis based on the following assumptions: the rate of pain-free episodes the primary end point) in patients receiving placebo was 50%; an improvement from 50% to 100% was clinically important; and $\alpha = 0.05$ with a power (1-β) of 80%. Based on these assumptions, it was determined that 20 patients were required per group. All statistical analysis was performed with SPSS version 7.0. Data were present as mean $\pm$ SD, median (range) value, and number (percent). Catagorical scales were compared by Independent-Sample t-test. Ordinal scales were compared by Mann-Whitney U-test. Nominal scales were compared by Chi-Square test. The P value < 0.05 was considered statistically significant.

Result

The two groups were not statistically different in age, weight, height, NPO time and duration of surgery (Table 1).

There were no significant differences in median analgesic level at 5, 10, 15, 30 and 45 min after spinal block between the groups. The median time to achieve T6 sensory level was 5 min in both groups. The highest sensory level had no significant difference between the groups. The number of segments that had regressed at 60 min in Group F was significantly less than in Group S (0 vs. 2; P = 0.002) (Table 2).

All the patients in Group F had completed intraoperative analgesics with 0 VNS pain score. While 7 patients in Group S experienced pain during surgery. Group F showed significantly lower median VNS pain scores than Group S (0 vs. 3; P = 0.004) (Table 3). The administration of 25-50 μg of fentanyl IV in 2 patients Group S whose pain scores were greater than 6 when the appendix was retracted or the abdominal swab was applied in the abdominal cavity. Time to first requirement of postoperative analgesics in Group F was significantly longer than in Group S (13.6 hr vs. 6.3 hr; P < 0.001). There was no difference in median VNS pain scores at the time of request for analgesics.

Table 1. Patient parameters

	Group F (n = 20)	Group S (n = 20)	P value
Age (yr)	30.6 6.6	31.8 8.6	0.612
Weight (kg)	61.4 9.9	55.5 9.0	0.055
Height (cm)	163.9 9.9	161.3 9.0	0.402
NPO time (h)	9.1 1.7	9.2 2.6	0.150
Duration of surgery (min)	54.2 15.5	62.0 17.7	0.944

Values are mean SD
No statistical difference

Table 2. Onset and regression of sensory blockage

	Group F (n = 20)	Group S (n = 20)	P value
Onset time T6 (min)	5 (5-10)	5 (5-10)	0.231
The highest sensory level (maximal block height)	T4 (T1-T4)	T3 (T1-T4)	0.376
The level at 60 min (dermatome)	T4 (T2-T6)*	T5 (T2-T8)	0.015
Number of segment regression in 60 min	0 (0-2)*	2 (0-6)	0.007

Values are median (range)
* P < 0.05 considered significant

Table 3. Intraoperative and postoperative analgesia

	Group F (n = 20)	Group S (n = 20)	P value
The most severe pain during operative (VNS scores)	0 (0-0)*	0 (0-9)	0.004
0 (no pain) (n)	20	13	
1-3 (mild pain) (n)	0	4	
4-6 (moderate pain) (n)	0	1	
7-10 (severe pain) (n)	0	2	
Time to first require postoperative analgesia (h)	13.6 (4-24)*	6.3 (2.5-20)	< 0.001
The pain at the time request of postoperative analgesics (VNS scores)	5 (0-8)	5 (0-10)	0.429

Values are median (range)
* P < 0.05 considered significant

Table 4. Intraoperative side effects

	Group F (n = 20)	Group S (n = 20)	P value
Nausea/vomiting	5 (25%)	9 (45%)	0.077
nausea	3	3	
retching	0	1	
vomiting	2	5	
Shivering	7 (35%)*	14 (70%)	0.023
mild	1	2	
moderate	2	0	
severe	4	12	
Hypotension	8 (40%)	7 (35%)	1.000
Bradycardia	1 (5%)	0 (0%)	1.000
Urinary retention	2 (10%)	1 (5%)	1.000

Values are members of patient (percent)
* P < 0.05 considered significant

During operation, there was no difference in the incidences of nausea and vomiting. Metoclopramide was administered to treat vomiting in 2 patients in Group F and 5 patients in Group S (Table 4). Shivering was found significantly less than in the Group F (7 patients or 35% vs. 14 patients or 70%; P = 0.023). 4 patients in Group F and 12 patients in Group S experienced severe shivering requiring treatment with intravenous pethidine 20 mg. There was no difference in the incidence of hypotension between the groups. 8 patients in Group F and 7 patients in Group S had hypotension and required treatment with 6-18 mg of ephedrine. One patient in Group F had bradycardia and 0.6 mg of intravenous atropine was given. None developed respiratory depression (RR < 12 bpm), desaturation (SpO2 < 90%), itching and sedation effects.

The patients could void in mean time of 6.3 hr and 6.9 hr in Group F and Group S respectively. There were 2 patients in Group F and 1 patient in Group S who needed intermittent urinary catheterization. There was no postdural puncture headache. One patient in Group S complained of backache. There was no statistically significant difference in patient satisfaction between the two groups. All patients in Group F were satisfied with the spinal analgesia. Four patients in Group S were dissatisfied because of inadequate analgesia (2 patients), severe shivering (1 patient) and backache (1 patient), (Table 5).

Table 5. Patient's satisfaction in spinal anesthesia

	Group F (n = 20)	Group S (n = 20)
Yes	20 (100%)	16 (80%)
No	0	4 (20)

Values are members of patient (percent)
No statistical difference

Discussion

The result indicated that the addition of 20 μg fentanyl to hyperbaric bupivacaine for spinal anesthesia in patients who underwent appendectomy significantly improves the quality of intraoperative as well as immediate postoperative analgesia without increasing the side effects such as itching, nausea, vomiting, hypotension, bradycardia, or urinary retention.

In the present study all the patients who received intrathecal fentanyl did not experience any pain during operation. This compared to 13 of 20 patients in Group S (65%) who had no pain.

Fentanyl is a lipophilic opioid similar to meperidine, which is more readily eliminated from the CSF than hydrophilic opioids, such as morphine[11-12]. However, opioids that are lipophilic have a potential of a short duration of action. Duration of action of fentanyl may be dose dependent[9-10]. Hunt et al reported that the addition of fentanyl $\geq$ 6.25 μg (6.25, 12.5, 25, 37and 50 μg) to hyperbaric bupivacaine was shown to reduce the intraoperative opioid supplement IV from 67% to 0% and provide postoperative analgesia of 3-4 hr in patients who underwent caesarean delivery under spinal anesthesia[7]. Dahlgren et al also reported that fentanyl 10 μg added in hyperbaric bupivacaine spinal block produced complete analgesia and increased the duration of analgesia in the early postoperative period compared to placebo[13]. In the present study, the authors found that the addition of fentanyl 20 μg to bupivacaine in spinal block for appendectomy provided excellent surgical anesthesia. Improved perioperative analgesia following co-administration of fentanyl and bupivacaine can be explained by a synergistic inhibitory action of these two agents on A-gamma and C-fiber conduction[6].

The authors found that there was no statistically significant difference in the onset and the highest level between the groups. Despite a previous demonstration of faster onset of the block by intrathecal fentanyl[14], the effect was not observed in this study. The number of segments that regressed at 60 min in Group F was less than in Group S. The median duration of analgesia measured by the return of moderate pain which required narcotics after 13.6 hr in Group F and 6.3 hr in Group S. Analysis of the median values showed clear evidence in quality of analgesia obtained by patients in Group F. The mechanism responsible for the longer duration of sensory blockage in Group F compared with Group S may be an example of synergism between fentanyl and the local anesthetic[15].

Most anesthesiologists agree that a dense block to at least T6 is needed for lower abdominal surgery in order to avoid visceral pain. In the present study all of the patients had the highest sensory level of T4 or higher. One might have suspected an associated between injected volume and level of sensory blockage[15]. Adding the study drug 0.4 ml in the standard dose of 0.5% bupivacaine 4 ml resulted in the total volume of 4.4 ml of spinal block and too high sensory blockage. To prevent too high sensory blockage, the volume of the study drug or bupivacaine should be reduced.

There are several other potential adverse effects from intrathecal opioid administration, such as nausea, vomiting, sedation, itching, respiratory depression and urinary retention. Belzarena et al demonstrated that fentanyl 0.25 μg/kg with bupivacaine 0.5% provided excellent surgical anesthesia with a few side effects[14]. Gielen et al and Sudarshan et al also reported that intrathecal fentanyl is one of the safest opioids not associated with any troublesome side effects[16-17].

Hunt et al reported there was a significant increase of the incidence of nausea in only the group that received 6.25 μg fentanyl but Dahlgren et al reported that the addition of intrathecal fentanyl 60 μg for caesarean section reduced the need for intraoperative antiemetic medication. In this study the incidence of nausea and vomiting did not increase.

Itching is another frequent complication of subarachnoid and epidural opioid administration. Hunt et al observed a significant increase in the overall incidence of itching in the 25 μg and 50 μg fentanyl groups. In another study there was no evidence of itching after an intrathecal injection of 10 μg fentanyl during intraoperative and postoperative[13]. Rueben et al reported 50% of patients who received a high dose (50 μg) of intrathecal fentanyl added in lidocaine complained of itching, only 20% of the patients in each 10 and 40 μg fentanyl, and none in

5 μg and 20 μg[10]. In the present study none of the patient experienced itching.

In spite of the intravenous administration of 10 ml/kg of normal saline solution, comparable decrease in blood pressure was found in both groups. This supports the finding that prehydration does not regularly preclude hypotension induced by sympathetic block from spinal anesthesia with or without fentanyl[18]. This result also reported in geriatric patients, that 25 μg of spinal fentanyl does not alter the cardiovascular response to the spinal block[19].

None of the patients who received intrathecal fentanyl up to 50 μg experienced respiratory depression, even in elderly patients who had coexisting cardiac and pulmonary diseases[10]. The same as in the present study, none of the patients experienced RR <12 BPM, SpO2 < 90% during operation.

The authors found that the incidence of intraoperative shivering decreased when fentanyl was added to intrathecal bupivacaine. However, another study of intrathecal fentanyl never assessed the incidence of shivering. Alfousi et al reported intravenous fentanyl 1.7 mg/kg was effective in the treatment of postoperative shivering in patients who underwent abdominal or orthopedic surgery in about 77%[20]. Wheelahan reported adding epidural fentanyl to epidural lidocaine decreases the shivering threshold compared with epidural lidocaine alone[21]. The spinal cord makes a major contribution to afferent thermal input and also involves in integration of thermal input[22]. So the cause of reduction in shivering in the present study may be from the effect of fentanyl added in the subarachnoid space on thermoregulator. The disadvantage of adding fentanyl to epidural lidocaine increases the risk of hypothermia. In the present study the authors did not monitor the body temperature of the patients. Most patients who undergo appendectomy have fever, so the effect of fentanyl on thermoregulator may be useless in reducing the body temperature.

In conclusion, the present study revealed a beneficial effect of the addition of fentanyl to bupivacaine in spinal block for appendectomy. There was significant improvement in intraoperative anesthesia without any effect on the height of the sensory level and also reduced the incidence of shivering.

Acknowledgement

This study was supported by a research grant from the Rachadapiseksompoj Fund (Silver Jubilee of MH. King Bhumibhol), Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand.

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การผสม fentanyl ในยาชาเพื่อฉีดเข้าช่องไขสันหลังในการผ่าตัดไส้ติ่ง

อัญชลี เตชะนิเวศน์, ปกรณ์ อุรุโสภณ, ปรีดี เกียรติกังวาฬไกล, รุ่งรัตน์ โฆษะวิบูลย์ผล

วัตถุประสงค์ *: เพื่อทดสอบสมมุติฐานที่ว่า การให้ fentanyl ร่วมไปกับการฉีดยาชาเข้าช่องไขสันหลัง ในการผ่าตัดไส้ติ่ง สามารถเพิ่มคุณภาพของการระงับความรู้สึกลดความปวดระหว่างการผ่าตัดหรือไม่ และมีอาการข้างเคียงอะไร*

วิธีการดำเนินการวิจัย *: ผู้ป่วยที่มารับการผ่าตัด appendectomy จำนวน 40 ราย ผู้ป่วยทุกรายต้องไม่มีข้อห้ามในการทำ spinal anesthesia และไม่เคยมีประวัติแพ้ fentanyl หรือยาชา ผู้ป่วยได้รับการอธิบายถึงการศึกษา และได้รับการยินยอมเป็นลายลักษณ์อักษร ผู้ป่วยจะถูกแบ่งเป็น 2 กลุ่ม โดยการสุ่มตัวอย่าง กลุ่ม S ได้รับการฉีด normal saline 0.4 มล ร่วมกับ 0.5% bupivacaine 4 มล ทางช่องไขสันหลังเป็นกลุ่มควบคุม, กลุ่ม F จะได้รับการฉีด fentanyl 20 ไมโครกรัม (0.4 มล) ร่วมกับ 0.5 % bupivacaine 4 มล โดยวิสัญญีพยาบาลจะเป็นผู้ผสมยาให้ และวิสัญญีแพทย์ผู้ซึ่งไม่ทราบว่าผู้ป่วยอยู่ในกลุ่มใดจะเป็นผู้ที่ฉีดยาเข้าช่องไขสันหลัง*

ผลการวิจัย *: หลังการฉีดยาชาเข้าช่องไขสันหลังพบว่าระดับการชาที่ 5, 10, 15, 30, 45 นาทีและระดับชาสูงสุดไม่แตกต่างกัน แต่ที่ 60 นาทีพบว่าระดับชาในกลุ่ม F ลดลงน้อยกว่ากลุ่ม S (0 และ 2 ระดับ; P 0.002) ในระหว่างการผ่าตัดพบว่าผู้ป่วยทุกรายในกลุ่ม F ไม่มีอาการปวด ในขณะที่พบ 13 รายในกลุ่ม S (ร้อยละ 100 และร้อยละ 65; p < 0.05) โดยมีระดับความปวดเฉลี่ย (VNS scores) ในกลุ่ม F ต่ำกว่ากลุ่ม S (0 และ 3; P 0.004) หลังผ่าตัดพบว่าผู้ป่วยกลุ่ม F เริ่มขอยาแก้ปวดครั้งแรกช้ากว่ากลุ่ม S (13.6 และ. 6.3 ชม.; P < 0.001) อาการข้างเคียงได้แก่ อาการสั่นระหว่างการผ่าตัดพบว่ากลุ่ม F พบน้อยกว่ากลุ่ม S (ร้อยละ 35 และร้อยละ 70; P 0.023) ภาวะความดันโลหิตลดลง อาการคัน คลื่นไส้ อาเจียน และปัสสาวะคั่งค้างพบไม่แตกต่างกัน ไม่พบอาการปวดศีรษะ หรือ การกดการหายใจ ผู้ป่วยทุกรายในกลุ่ม F และ 16 รายในกลุ่ม S พึงพอใจในการให้ยาชาระงับความรู้สึก*

สรุป *: การผสม fentanyl เข้าไปกับยาชาในการทำ spinal anesthesia ในผู้ป่วยผ่าตัดไส้ติ่งช่วยเพิ่มคุณภาพการชา, เพิ่มระยะเวลาการชา, ลดความปวดหลังการผ่าตัด และลดอาการสั่น*