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Fentanyl Patches to Supplement Ultrasound-Guided Nerve Blocks for Improving Pain Control After Foot and Ankle Surgery: A Prospective Study

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ABSTRACT

The analgesic effects of preoperative ultrasound-guided nerve blocks wear off after about 12 hours, leaving some patients in substantial pain. Transdermal fentanyl concentrations peak at 12 to 24 hours after application and maintain this concentration for approximately 72 hours. We sought to determine whether combining the use of a transdermal fentanyl patch with either a sciatic or femoral–sciatic nerve block would improve pain control in patients undergoing foot and/or ankle surgery. Consecutive patients in the no-patch control group (n = 104) were enrolled from July 2011 to October 2011, and those in the treatment group (n = 232) were enrolled from November 2011 to May 2012 and received a transdermal patch (4.125 mg/7.5 cm^2 releasing 25 μg of fentanyl per hour) applied to their chest postoperatively. Pain was assessed using a visual analog scale at 6, 12, 24, and 48 hours after surgery. The primary outcome measure was the number of requests for additional postoperative pain medication. Additional postoperative analgesia was requested by 49 of the 104 control patients (47.1%) and 63 of the 232 treated patients (27.1%; $p = .002$). The mean pain scores were also lower in the treatment group, with a statistically significant difference ($p < .05$) at 12, 24, and 48 hours. Thus, patients receiving a fentanyl patch combined with an ultrasound-guided nerve block required less supplemental analgesia to maintain adequate pain control than did those receiving a nerve block alone. In conclusion, a fentanyl patch is a useful adjunct to an ultrasound-guided nerve block in foot and ankle surgery.

General anesthesia is often used in bone and joint surgery; however, it can cause postoperative complications such as nausea, vomiting, pulmonary compromise, decreased bowel motility, and urinary retention. Spinal anesthesia is an effective alternative but can cause back pain or severe headache (1–5). Preoperative ultrasound-guided nerve block offers several advantages over general and spinal anesthesia, including a faster onset and a longer duration of intra- and postoperative analgesia (1–5). The procedural benefits of guided injections include fewer needle manipulations, which reduces both the procedure time and procedure-related pain. Recently, ultrasound-guided femoral-sciatic nerve block was shown to provide satisfactory anesthesia without intra- or postoperative complications. It controlled the pain postoperatively for an average of about 12 (range 8 to 19) hours, after which the effect of the nerve block wore off, and some patients suddenly experienced substantial pain (6,7).

The pharmacodynamics of the fentanyl transdermal patch suggest that the highest blood concentration occurs approximately 12 to 24 hours after application and is maintained for up to 72 hours, considerably longer than the 8 to 19 hours reported for nerve blocks. Theoretically, a fentanyl patch applied after surgery that was performed with the patient under nerve block anesthesia could provide the highest blood concentration of the synthetic opiate at approximately 12 hours after application, and this could potentially extend and enhance postoperative pain control.

We report the results of a prospective study in which we followed 2 groups of patients who had undergone foot and ankle surgery performed with an ultrasound-guided sciatic or a femoral-sciatic nerve block, with or without the addition of a transdermal fentanyl patch applied immediately after the surgery. We hypothesized that the addition of the fentanyl patch would result in greater and prolonged pain control after foot and ankle surgery.

Patients and Methods

The institutional review board of the Chungnam National University Hospital approved study, and all the patients provided written informed consent to participate in the clinical research investigation.

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Conflict of Interest: None reported.
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Sample Selection

Patients undergoing foot and ankle surgery under sciatic or femoral-sciatic nerve block from July 2011 to May 2012 at Chungnam National University Hospital (Daejeon, Korea), who provided informed consent to participate in the study, were eligible. Patients with a history of psychiatric disorders, neurologic or neuromuscular disease, severe fear or anxiety about needle injections, or signs of infection at the nerve block site were excluded from the present study. We created 2 groups based solely on the date of surgery. Consecutive patients in the control group were enrolled from July 1, 2011 to October 31, 2011 and did not receive a fentanyl patch. Those in the treatment group were consecutively enrolled from November 1, 2011 to May 31, 2012 and received a fentanyl patch.

Intervention

All the patients received a nerve block preoperatively in the ward or outpatient clinic (Fig. 1). A sciatic or femoral–sciatic nerve block was performed by the same orthopedic surgeon (C.K.) under ultrasound guidance (Figs. 2 and 3). The block was established with 20 mL of 1% lidocaine and 0.75% ropivacaine (combined for a total of 40 mL) injected through a 50-mL syringe with a venous catheter connected to a 23-gauge spinal needle. All the procedures were performed with the patient in the supine position, and the anesthetic drugs were injected after the needle tip had approached the perineural sheath.

The femoral nerve block was administered just lateral to the femoral artery at the femoral triangularis of the distal part of the inguinal ligament with the patient in the supine position. After positioning the patient in 30° to 45° of hip flexion, we moved the ultrasound probe to the proximal part of the thigh to identify the point at which the tibial and peroneal nerves merge with the sciatic nerve. The anesthetic was then injected inwardly from the lateral surface of the thigh on the posterior border of the iliotibial tract. The anesthetic was injected until it had infiltrated the perineural sheath, forming a doughnut shape as viewed on the ultrasound image. To decrease anxiety and induce sedation, 1 hour before surgery, midazolam 3 mg was injected intramuscularly in every patient. The patients' pulse rate, oxygen saturation, and blood pressure were monitored from the first injection of midazolam to the end of surgery (but not recorded as outcomes of interest for the purposes of the present investigation) (6).

In the postanesthesia recovery room, a transdermal patch (Duragesics®, Janssen Pharmaceuticals, Inc., a subsidiary of Johnson & Johnson, Somerville, NJ) containing 4.125 mg/7.5 cm^2 releasing 25 μg of fentanyl per hour, was applied to the chest of the patients in the treatment group. The treatment group patients who reported nausea, vomiting, and/or dizziness (common side effects of the fentanyl patch) received metoclopramide HCl, 10 mg orally, as an antiemetic.

All the patients were admitted to the hospital during the initial postoperative period, including the study-designed observation period, regardless of the surgical procedure. Also, regardless of group allocation, any patient who experienced postoperative pain could request an additional analgesic, and an intramuscular injection of diclofenac 75 mg/3 mL was administered.

Outcome Measures

The primary outcome measure was the difference in the number of requests for additional postoperative pain medication. The secondary outcome of interest was the degree of postoperative pain assessed using a 10-cm visual analog scale (VAS) anchored at "no pain" at 1 end and "severe pain" at the other. Pain was assessed at 6, 12, 24, and 48 hours postoperatively. The patients marked the VAS themselves, and 1 of us (C.K.) measured the distance from the ordinate (extreme left terminal of the scale, indicative of no pain). This endpoint was necessary to establish that both groups had received adequate pain control with the anesthetic block before application of the fentanyl patch. Complications believed to result from the simultaneous use of a fentanyl patch and midazolam, in particular, respiratory depression, were considered after the patch was applied. Also, the patients receiving this treatment were monitored for this potential complication. All the data were collected by 1 of us (J.H.S.), who was aware of the intervention groups.

Statistical Analysis

The data are presented as medians and ranges. The number of patients requesting analgesics in addition to the nerve block was compared between the 2 groups with the chi-square test. The median pain scores at each time point were compared between the 2 groups using the Kruskal-Wallis and Wilcoxon rank sum tests. Alpha was set at 0.05, and all tests were 2-tailed. Statistical analysis was performed using the SPSS, version 10.0, software for Windows (IBM Corp., Armonk, NY). The sample size was calculated by power analysis using The R package software, version 3.0.1 (general public license). In all analyses, $p \leq .05$ indicated statistical significance.

Results

From July 1, 2011 to October 31, 2011, 104 patients with a mean age of 45 (range 19 to 77) years, 68 (65.39%) of whom were male, were enrolled in the control group. From November 1, 2011 to May 31, 2012, 232 patients with a mean age of 52 (range 15 to 82) years, 151 (65.09%) of whom were male, were enrolled in the treatment group. A variety of foot and ankle surgeries were performed, including rotational flap, Achilles tendon repair, ankle arthroscopy, distal tibial fracture fixation, pilon fracture fixation, calcaneus fracture fixation, ankle malleolar fracture fixation, tarsal fracture fixation, hallux valgus correction, and chronic lateral ankle instability correction (Table 1).

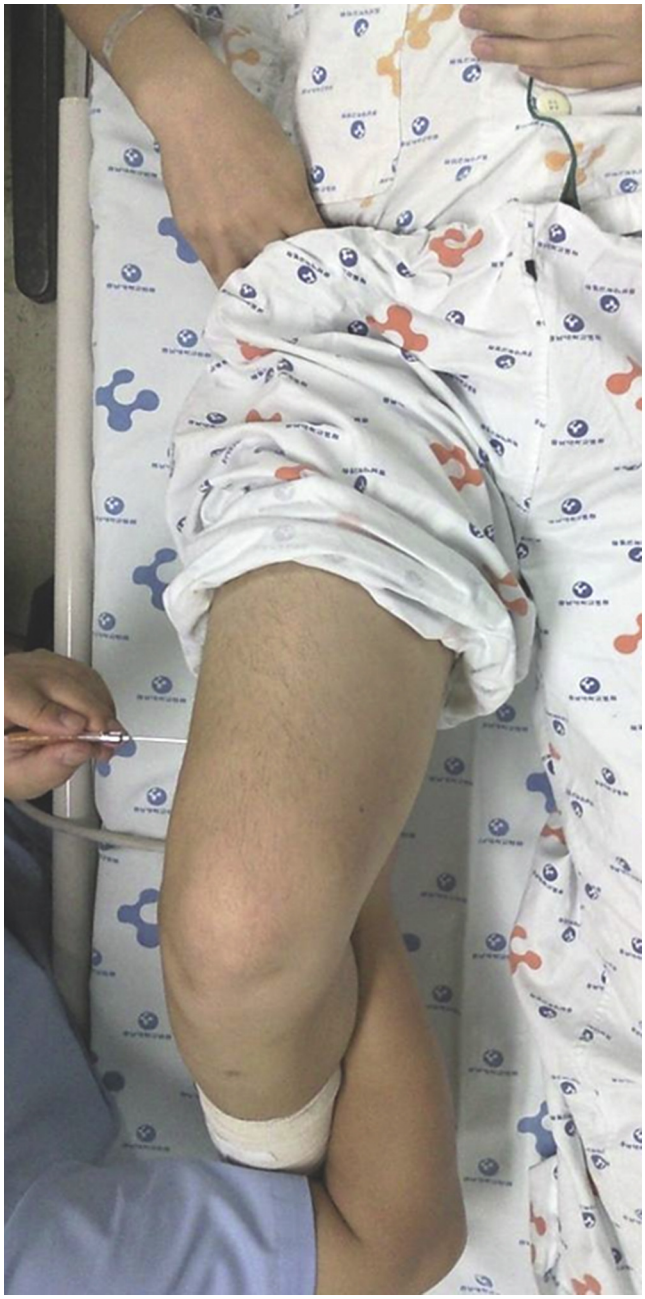

Fig. 1. Preoperative sciatic nerve blocks were performed with the patient's hip in 30° to 45° of flexion.

The number of patients requesting postoperative analgesia was 49 (47.12%) in the control group and 63 (27.16%) in the treatment group, a statistically significant difference ($p = .002$; Table 2). The mean pain scores were lower in the treatment group, with statistically significant differences at 12, 24, and 48 hours (Table 3). Also, clinical differences