GENERAL GYNECOLOGY

Randomized trial comparing 3 methods of postoperative analgesia in gynecology patients: patient-controlled intravenous, scheduled intravenous, and scheduled subcutaneous

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OBJECTIVE: The objective of the study was to determine whether any of 3 routes of opioid administration (patient-controlled analgesia [PCA], scheduled intermittent intravenous [IV], or scheduled intermittent subcutaneous [SQ]) provides superior pain relief and satisfaction among patients undergoing abdominal gynecologic surgery.

STUDY DESIGN: Patients were randomized to intravenous hydromorphone by PCA, IV hydromorphone via scheduled nurse-administered doses, or SQ hydromorphone via scheduled nurse-administered doses. Self-reported pain and satisfaction were recorded over 48 hours following arrival at the nursing unit. Linear mixed effects modeling was used to compare outcomes among the groups.

RESULTS: Neither pain scores nor satisfaction differed by group. PCA patients had higher total opioid use ($P < .0001$) and a higher rate of pruritus ($P = .04$).

CONCLUSION: Given these findings as well as those in previous literature, no specific method of postoperative analgesia appears to be superior.

Key words: hydromorphone, patient-controlled analgesia, postoperative analgesia, route of administration

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Postoperative pain is a major medical, economic, and social problem.[1] In addition to causing obvious suffering, postoperative pain can be associated with adverse reactions such as pulmonary dysfunction or pneumonia; myocardial ischemic events; ventricular tachycardia; myocardial insufficiency; and gastrointestinal complications including nausea, vomiting, and distension.[1-3]

The goals of postoperative pain management are to provide subjective pain relief while minimizing analgesic-related side effects and to allow the patient to return to ambulation and some normal daily activities as soon as possible. In addition, successful management of pain may shorten hospital stay, reduce hospital costs, and increase patient satisfaction.[4,5] Opioids, the most commonly used postoperative analgesics, act via receptors in the central nervous system. Unfortunately, unfavorable side effects of respiratory depression, nausea, and vomiting are also mediated through these receptors. In addition, opioid receptors in the gastrointestinal tract are responsible for constipation and ileus.[6]

Currently the route of opioid administration varies by physician preference without any known evidence-based clinical practice guidelines. Patient-controlled analgesia (PCA) has grown in popularity over the past several years at our institution because of the perception that it provides greater patient satisfaction. However, the literature provides no comparative data on PCA vs 2 other popular methods: scheduled intravenous (IV) and scheduled subcutaneous (SQ) injections. The goal of this study was to determine whether any of these 3 routes of opioid administration (PCA, IV, or SQ) would provide superior pain relief and satisfaction among patients undergoing abdominal gynecologic surgery. The hypothesis was that PCA would be superior because of both its capability to continuously infuse the analgesic and the patient's ability to control the timing of demand analgesic.

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Materials and Methods

Patients

The study was approved by our hospital's institutional review board. The population of interest included patients 18 years of age or older who were scheduled to undergo a major transabdominal gynecologic operation. Exclusion criteria were allergy to hydromorphone, patient age younger than 18 years, and chronic pelvic pain (ie, noncyclical pelvic pain of 6 or more months' duration that is serious enough to require medical care).

Treatment Groups and Randomization

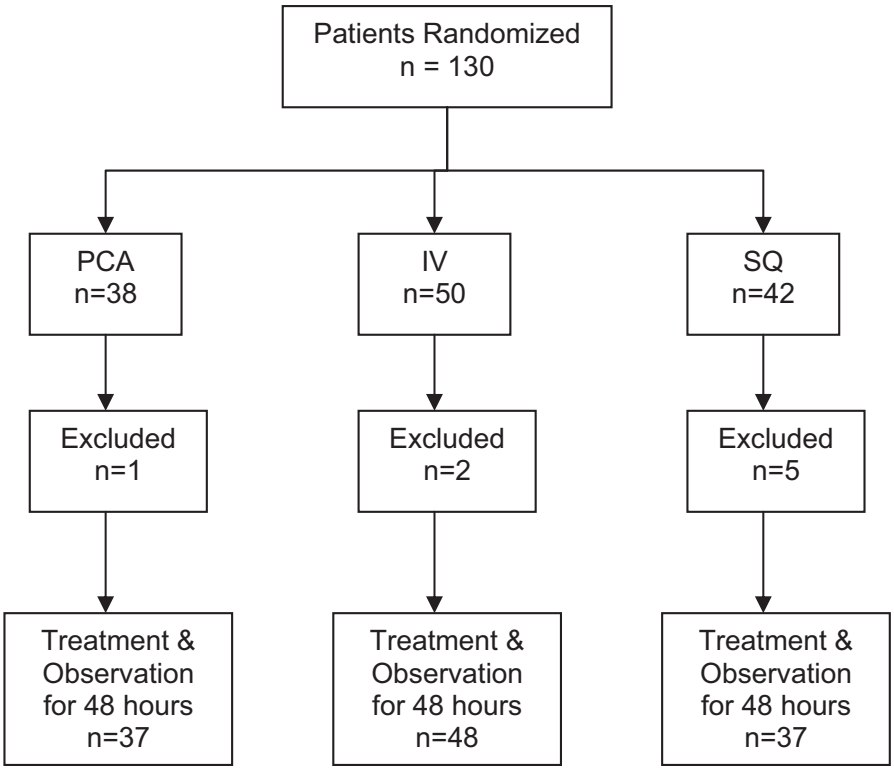
A study nurse obtained consent in the preoperative room. All patients received general anesthesia; neuraxial methods were not allowed. The study epidemiologist developed a blocked randomization scheme, and treatment assignments were placed in opaque sealed and sequentially numbered envelopes. After obtaining patient consent, the study nurse used the envelopes to assign the patient to 1 of 3 study groups: (1) IV hydromorphone by a PCA device, using a schedule of 0.2 mg every 8 minutes PRN by patient demand in addition to 0.3 mg/hour continuous infusion for the first 24 hours postoperatively, followed by 0.2 mg every 8 minutes PRN by patient demand alone for the next 24 hours; (2) IV hydromorphone via floor nurse–administered doses scheduled every 3 hours for the first 24 hours postoperatively, followed by PRN every 3 hours for the next 24 hours; and (3) SQ hydromorphone via floor nurse–administered doses scheduled every three 3 hours for the first 24 hours postoperatively, followed by PRN every 3 hours for the next 24 hours.

For the IV and SQ groups, all doses were determined by a sliding scale of the patient's pain assessment on a 0-10 point scale: 0.5 mg for pain rated 0-4, 1 mg for pain rated 5-7, and 1.5 mg for pain rated 8-10. Patients received half the scheduled dose every hour as needed for breakthrough pain. If the patient reported a pain rating of 8-10 after the second IV or SQ dose of 1.5 mg, the scheduled dose was increased by 0.5 mg for all subsequent treatments. Patients who had a reaction to hydromorphone were switched to hydromorphone-equivalent doses of morphine. Nonnarcotic analgesics were not included in the preprinted orders for the 48 hour observation period of the study.

Outcomes

The primary outcome of the study was patient self-assessment of pain as measured on a scale of 0-10, recorded by a research nurse at the patient's arrival at the nursing unit (baseline) and at 12, 24, and 48 hours thereafter. The secondary outcome was patient satisfaction, measured concurrently with the pain measurements on a 5-point Likert-type scale (1 = very satisfied to 5 = very dissatisfied). Additional patient-reported outcomes obtained concurrently with the pain measurement by the research nurse were the occurrence of nausea, vomiting, itching, ileus (defined as absence of flatus), and ambulation (defined as being out of bed and walking without assistance). These patient-reported events were treated statistically as dichotomous outcomes. Total narcotic usage over the 48 hour study period was also calculated.

FIGURE 1
Flow participants through the trial



Bell. Randomized trial comparing 3 methods of postoperative analgesia in gynecology patients. AJOG 2007.

Statistical Analysis

The minimum clinically important difference in pain scores was chosen as 1.5 on a scale of 0-10. This difference is compatible with previous reports documenting the minimum decrease in pain relevant to patients.[7,8] To achieve 90% power to detect this difference among the groups, the study required 41 patients in each group, on the basis of an estimated variance of 4.25 and a type I error of 5%. A linear mixed-effects model was used to examine the pain scores over time; the linear mixed-effects model can account for the correlation in pain scores associated with multiple pain measurements within an individual patient. Because most satisfaction scores clustered in the "very satisfied" and "satisfied" responses, a dichotomous outcome was created by grouping "very satisfied" with "satisfied" vs "neither," "dissatisfied," and "very dissatisfied."

A generalized linear mixed-effects model was used to examine the dichotomous satisfaction outcome as well as the itching and nausea/vomiting outcomes over time. All nonstudy narcotics received by patients were converted to hydromorphone-equivalent doses.[9,10] Differences in the amounts of narcotic medication were assessed using the Wilcoxon rank sum test. Patients who did not receive their randomly assigned pain-control method