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Topical diclofenac patch for postoperative wound pain in laparoscopic gynecologic surgery: A randomized study

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KEYWORDS:
Diclofenac;
Postoperative pain;
Laparoscopic surgery;
Transdermal patch

Abstract

STUDY OBJECTIVE: To compare pain management of standard analgesic and standard analgesic plus diclofenac transdermal patch in patients who undergo laparoscopic gynecologic surgery.

DESIGN: Randomized prospective study (Canadian Task Force classification I).

SETTING: University hospital.

PATIENTS: One hundred twenty patients requiring laparoscopic surgery for gynecologic benign diseases.

INTERVENTIONS: Patients were divided into two groups, one medicated with a diclofenac patch (diclofenac group) and the other medicated with standard skin medication (placebo; control group) at all incisional areas at the end of the operation.

MEASUREMENTS AND MAIN RESULTS: The principal measures of outcome were pain intensity at 6, 12, and 24 hours after surgery and consumption of analgesics. The two treatment groups were comparable with respect to demographic and intraoperative characteristics. No significant difference was observed between the two groups in mean pain intensity at 6 hours after surgery. Mean pain intensity at 12 and 24 hours, respectively, after surgery was significantly lower in the diclofenac group (3.7 ± 1.3 and 2.0 ± 0.6) than that observed in the control group (5.7 ± 1.9 and 4.6 ± 0.5) (p value, respectively, .002 and $<.001$). Twenty-one patients (35.0%) in the diclofenac group required analgesics in the first 36 hours after the operation versus 43 patients (71.7%) in the control group ($p < .001$). Hospital discharge was significantly more rapid in the diclofenac group (28 ± 5 hours vs 39 ± 3 hours; $p = .031$).

CONCLUSION: Diclofenac transdermal administration seems a valid help to standard analgesic treatment in postoperative pain control and could also help reduce the period of hospitalization of patients who undergo laparoscopic benign gynecologic surgery.
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Postoperative pain remains one of the most prevalent problems in health care today, and pain control is a topic of current interest. Although laparoscopic gynecologic surgery is often minor surgery, a high incidence of postoperative abdominal pain is reported.[1] Edwards et al[2] found that patients undergoing laparoscopic surgery reported considerable postoperative pain early after surgery. Most patients receive some form of postoperative pain management. Furthermore, it is estimated that approximately 50% to 75% of patients still have inadequate pain relief.[3]

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Inadequate treatment of pain can lead to physiologic changes that may lengthen or complicate the postoperative recovery period. Pain causes an increase in sympathetic tone, which can impair neuroendocrine and metabolic catabolism, increase myocardial oxygen consumption and prevent normal muscle function.[4,5] In addiction, negative clinical outcomes (deep venous thrombosis, pulmonary embolism, coronary ischemia) may result from ineffective pain management.[6] Uncontrolled pain also is associated with patient demoralization and dissatisfaction with hospital care.[6] In contrast, effective pain management may lead to a less-complicated postoperative course, including earlier hospital discharge, decreased resource utilization, and lower direct and indirect costs.[7] To maintain a high standard of patient care, it is essential to provide adequate pain management in patients who undergo laparoscopic surgery.

Opioids are the most commonly used medication for the treatment of patients with acute pain.[8] Patient-controlled analgesia (PCA) using microprocessor-controlled opioids infusion pumps has become one of the most widely used methods of postoperative pain management [9] and previous report demonstrated that patients prefer PCA to conventional analgesic techniques.[10] Furthermore, there are several limitations associated with PCA use[8]: a motivated, intelligent, alert and well informed patient is required; detailed instructions and education must be provided to the nursing staff; and power cables necessary to administer analgesic medication may limit patient mobility. In addiction, opioids can lead to collateral effects such as respiratory depression,[11] nausea, vomiting,[12] constipation, and urinary retention.[13]

To overcome the limitations of currently available postoperative pain management strategies, we proposed the use of a noninvasive form of non opioids analgesic therapy in the postoperative period: the transdermal route. This analgesic therapy would be expected to block the noxious somatic input caused in the area of the skin where the incision is made to insert the trocars in the abdomen. This randomized, double-blind, controlled study was designed to investigate whether transdermal diclofenac versus placebo in the surgical field would reduce the incidence, intensity, and duration of postsurgical wound pain in women undergoing laparoscopic surgery for benign gynecologic diseases.

Material and methods

Study population

This study is a randomized, controlled, clinical trial that was conducted from November 2003 through May 2005 through our department of obstetrics and gynaecology. Informed consent was obtained from each woman, and a protocol was approved by the hospital's ethics committee.

Women who were included in the study underwent laparoscopic surgery for various gynecologic benign diseases (diagnostic surgery performed to investigate the etiology of infertility, excision of ovarian cyst, oophorectomy, laparoscopic myomectomy with size of the largest myoma <7 cm). Exclusion criteria were age older than 80 or younger than 18 years, body mass index greater than 30, malignancy, stage III or IV endometriosis, previous pelvic or abdominal surgery, chronic pelvic pain, preexisting systemic or neurologic diseases, and regular medication with nonsteroidal antiinflammatory drugs or opioids. We enrolled 120 women in the study.

Randomization criteria

A pool of random numbers, sufficient for the intended size of the trial, was computer generated. Even and odd numbers were assigned the instructions "diclofenac group" and "control group," respectively. These instructions, in their original random order, were transferred to cards. Each card was then placed in an opaque envelope and sealed.

The study was double masked; the surgeon, the patient, and the person involved in pain assessment were unaware of the group to which the patient had been assigned. When an eligible woman was randomly allocated, at the end of the operation a nurse wrote the woman's name on the next envelope in the series of consecutively numbered opaque envelopes and then opened it. After allocation, patients in the diclofenac group were medicated with a diclofenac patch at all incisional areas (one transdermal patch containing 180 mg of diclofenac was divided and used for all three incisional areas); a standard medication was located on the diclofenac patch to ensure double masking. The nurse who opened the opaque envelopes and made the first medication in operating room was not involved in subsequent medications. Every 12 hours the medication was replaced by another nurse not involved in pain assessment until 36 hours after the end of the operation or until the patient's hospital discharge. Patients in the "control group" were medicated using standard skin medication at the three sites. Every 12 hours the medication was replaced until 36 hours after the end of the operation or until the patient's hospital discharge.

Surgical procedure

Laparoscopic surgery was performed under general anesthesia induced by use of propofol (Diprivan; Astrazeneca S.p.A, Milan, Italy) 2.5 mg/kg + atracurium 0.5 mg/kg + fentanyl 0.05 mg. During surgery, anesthesia was maintained with atracurium 0.01 mg/kg/30 min + remifentanil 0.2-0.5 μg/kg/min + sevoflurane 1 MAC (60% air, 40% O_2). No preanesthetic medication was prescribed.

An open-laparoscopy technique was used for laparoscopy, and a 10 mm port was inserted through the umbilicus to introduce the laparoscope. A pneumoperitoneum was obtained with carbon dioxide insufflation (heated and humidifying gas). Two additional 5-mm ports were inserted for the introduction of the surgical instruments. A uterine