

Meta-analysis of the Ease of Care From a Patients' Perspective Comparing Fentanyl Iontophoretic Transdermal System Versus Morphine Intravenous Patient-Controlled Analgesia in Postoperative Pain Management

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Purpose: The purpose of this meta-analysis was to evaluate patients' assessment of fentanyl iontophoretic transdermal system (ITS) and morphine intravenous patient-controlled analgesia (IV PCA) ease of care (EOC) using a validated patient EOC questionnaire. Fentanyl ITS is a preprogrammed, needle-free PCA system used for the management of acute pain in postoperative patients.

Methods: This meta-analysis assessed the patient EOC of fentanyl ITS and morphine IV PCA using data from three randomized, active-comparator trials in adult postoperative patients with moderate-to-severe pain. All three studies utilized a validated patient EOC questionnaire which consists of 23 items grouped into seven subscales (confidence with device, comfort with device, movement, dosing confidence, pain control, knowledge/understanding, and satisfaction). Each item is scored on a six-point Likert scale. The weighted mean difference between treatments was calculated for the overall EOC and for each of the seven subscales.

Results: The EOC analyses were based on responses to questionnaires from 1,943 patients treated with either fentanyl ITS ($n = 961$) or morphine IV PCA ($n = 982$). There was a statistically significant advantage in favor of fentanyl ITS over morphine IV PCA in terms of overall EOC (weighted mean difference = 0.28; 95% confidence interval (0.22 to 0.34); $P < 0.0001$). Five of the seven subscales (confidence with device, comfort with device, movement, dosing confidence, and knowledge/understanding) on the patient EOC questionnaire showed a statistically significant advantage for fentanyl ITS versus morphine IV PCA. The two subscales that did not show any difference were pain control ($P = 0.7303$) and satisfaction (0.0561).

Conclusion: In this meta-analysis, fentanyl ITS is associated with some advantages in terms of an EOC profile from a patients' perspective when compared with morphine IV PCA.

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Conflict of Interest: P.L. has no relevant conflicts of interest to disclose. The remaining authors are or were employees of The Medicines Company who makes Fentanyl ITS.

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EFFECTIVE POSTOPERATIVE PAIN MANAGEMENT is critical to successful outcomes including early mobilization, increased patient satisfaction, and reduced hospital stay and costs.¹ Conversely, ineffective postoperative pain management can have some long-term consequences including the development of chronic pain.² Patient-controlled analgesia (PCA) is commonly used to treat postoperative pain as part of a multimodal treatment regimen.^{3,4} However, with either intravenous (IV) or epidural PCA systems, there are potential pitfalls which include reduced mobilization as the patient is connected to the PCA pump and the potential for programming errors.⁵⁻⁹

Fentanyl iontophoretic transdermal system (ITS) is a noninvasive PCA system that is utilized for the treatment of postoperative pain (Figure 1). Fentanyl ITS is a preprogrammed, needle-free delivery system that utilizes iontophoresis whereby the drug is delivered through the skin via a nearly imperceptible electric current.¹⁰ The health care provider assembles the system by snapping the controller (the top half of the device containing all electronics) and drug unit (the bottom half

containing the 10.8 mg of fentanyl HCl) together immediately before application to the patient. The system is held on the skin with adhesive. Fentanyl ITS delivers a preprogrammed analgesic dose based on the patients control. The use of fentanyl ITS reduces the need for venous access for pain management, eliminates the potential for programming errors, and minimizes the potential for medication errors.¹¹ In addition, staff time spent on PCA administration may be reduced with the fentanyl ITS and therefore can be utilized for direct patient care.^{12,13} Postoperative patient mobility is essential to recovery and is important for preventing complications after major surgery.¹⁴ Fentanyl ITS has the potential to increase patients' mobility since no IV or epidural lines or equipment such as pumps and poles are needed for analgesia.

The efficacy and safety of fentanyl ITS have been well studied. In four phase 3B randomized, active-comparator trials, fentanyl ITS demonstrated an equal efficacy and similar safety profile to morphine IV PCA.¹⁵⁻¹⁸ From a dosing perspective, in the phase 3B trials, a fentanyl ITS 40 mcg dose over 10 minutes for up to six doses/hour was approximately equianalgesic with morphine IV PCA 1-mg morphine bolus doses for up to 10 doses/hour with a 5- or 6-minute lockout periods between doses.

A previous report on the patients' perspective of ease of care (EOC) has been reported using data from two of the phase 3B studies.¹⁹ That analysis was performed using a simple pooled analysis technique (ie, the analysis was performed as if the data were derived from a single sample). In this current analysis, we are using data from three of the four phase 3B trials (the fourth study did not collect the patient EOC questionnaire), and we are utilizing a meta-analytic technique. Meta-analysis allows detection of treatment effects with greater power and estimates these effects with greater precision.²⁰ This report represents the first ever conducted meta-analysis comparing fentanyl ITS with morphine IV PCA EOC from a patients' perspective.



Figure 1. Illustration of the fentanyl ITS controller and drug unit and assembled system. The device is approximately the size of a credit card. The controller and drug unit are assembled by the health care professional immediately before application. ITS, iontophoretic transdermal system. This figure is available in color online at www.jopan.org. Reprinted with permission from The Medicines Company (Parsippany, NJ).

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