Fentanyl Transdermal System: Unsafe in Inexperienced Hands

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PROBLEM: Those trying to manage patients with severe or chronic pain have occasionally prescribed the fentanyl transdermal system to opiate-naive patients with serious and sometimes fatal results. For example, several years ago, an on-call physician prescribed 100 mcg/hour (hr) fentanyl (Duragesic, Janssen) patches for a 17-year-old girl who remained uncomfortable after sinus surgery, despite steadily increasing doses of propoxyphene (Darvon, Eli Lily). Twelve hours after patch application, the girl was found dead.

More recently, a 53-year-old opiate-naive outpatient with myelocytic leukemia and bone pain was started on 100 mcg/hr fentanyl patches. The next day, the patient could not be aroused and required hospitalization. Even when patients are opiate-tolerant, incorrect conversion from an oral opiate to fentanyl patches, difficulty titrating doses, combined oral–topical therapy, and variability in absorption have led to reported overdoses.

In one case, an elderly patient who was taking Du Pont's Percocet (oxycodone, acetaminophen) for two months was converted to fentanyl patches after hospitalization. He was started on 50 mcg/hr rather than the recommended dose of 25 mcg/hr. The dose was increased from 50 mcg/hr to 75 mcg/hr after three days, but a 50 mcg/hr patch was applied in error. Two days later, morphine sulfate (MS Contin, Purdue Frederick) was ordered concurrently because of continuing pain. The next day, the 50 mcg/hr patch, which had been applied in error, was removed, and a 75 mcg/hr patch was applied. The following morning, the patient experienced respiratory depression and was treated with naloxone (Narcan, Du Pont Pharm). It is uncertain whether or not the patient's death later that day was related to the overdose.

In another case, a hospitalized opiate-tolerant patient was started on 50 mcg/hr fentanyl patches. The dose was adjusted twice within 72 hours and the patient was discharged on a 100 mcg/hr dosage. At home, the patient experienced somnolence and confusion, fell, and finally had to be admitted to the hospital.

Errors have occurred because of improper disposal of patches as well. The Institute for Safe Medication Practices (ISMP) received an error report about a failed resuscitation attempt on a 31-year-old patient who was brought to the emergency room in cardiac arrest. Because the death was suspicious, postmortem toxicological studies were performed. The studies indicated lethal levels of fentanyl. Investigators later learned that the patient had worked as a transporter for a funeral home. One day prior to his death, he had transported a deceased nursing home patient who was wearing a 75 mcg/hr patch and a 100 mcg/hr patch. The patches had not been disposed of by nursing home staff and were still on the body when it left the home.

SAFE PRACTICE RECOMMENDATIONS: Transdermal fentanyl is often used contrary to product labeling and without knowledge of patient selection criteria, contraindications, proper dose adjustment, administration procedures, and expectations for therapy. Dosing should not exceed 25 mcg/hr in opiate-naïve patients (the company will soon market a 12.5 mcg/hr strength that is more appropriate for some patients). However, fentanyl patches are best reserved for opiate-tolerant patients with chronic pain. The initial dose should be based on the total daily dose, route, potency, and characteristics of the drug the patient has been taking previously; on narcotic tolerance; and on the patient's general condition.

In addition, prescribing should be limited to a pain management service or to those with expertise. New prescriptions should be accompanied by a dose calculation sheet and verified by a pharmacist. Computer systems should warn about concurrent opiate therapy and should require comment.

Patients should be monitored and doses adjusted no more frequently than three days after the initial dose or every six days thereafter. If changing to another form of opiate, initial doses should be decreased accordingly.

An entry should be placed on the medication administration record (MAR) to remind nurses to remove and discard patches. Patients and staff should be educated about patch removal before each application, and about proper disposal. Patches should be rendered unusable through proper disposal methods, such as cutting them with scissors before disposing of them in toilets.

Finally, remember that vasodilation and the extent of vascularization in the patch area will influence absorption. Thus, using a heating pad over the area will significantly increase absorption. If absorption variability is a problem, staff members should consider using subcutaneous opiates. ■