

ISMP Medication Error Report Analysis

Topical Lidocaine Gel and Mammography Methotrexate Overdose Safety Caps That Do Not Protect Children

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These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness of personnel and procedural safeguards, they can be avoided. You should consider publishing accounts of errors in your newsletters and/or presenting them at your inservice training programs.

Your assistance is required to continue this feature. The reports described here were received through the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Any reports published by ISMP will be anonymous. Comments are also invited; the writers' names will be published if desired. ISMP may be contacted at the address shown below.

Errors, close calls, or hazardous conditions may be reported directly to ISMP through the ISMP Web site (www.ismp.org), by calling 800-FAIL-SAFE, or via e-mail at isminfo@ismp.org. ISMP guarantees the confidentiality and security of the information received and respects reporters' wishes as to the level of detail included in publications.

TOPICAL LIDOCAINE GEL AND MAMMOGRAPHY

The US Food and Drug Administration (FDA) issued an advisory in January that reminds patients, health care professionals, and caregivers about potentially serious hazards associated with overuse of topical anesthetics.¹ The FDA report specifically mentions a study that used topical lidocaine to reduce discomfort during breast mammography.² Breast tenderness, anxiety, and anticipation of discomfort during the procedure often discourage women from being screened. In the study of 418

women, some received a placebo gel, some received a premammogram over-the-counter (OTC) analgesic such as acetaminophen, and some received a premammogram OTC analgesic along with lidocaine gel. The OTC analgesics alone did not reduce breast discomfort, but women who also received lidocaine gel experienced about 20% less pain and discomfort.

In the alert the FDA expresses concern that as more women learn about this study via the Internet, other media sources, and word of mouth, improper use of topical anesthetics before mammography

will rise. Excessive absorption of the drug may cause life-threatening side effects such as cardiac arrhythmia, seizures, breathing difficulties, coma, and even death. There are several topical anesthetics available by prescription or OTC, including lidocaine in up to a 5% concentration.

The FDA also mentions fatal events involving young women who died after receiving pharmacy-compounded topical lidocaine and tetracaine creams before laser hair removal. Improper use of these products may result from the following:

- Applying too much topical anesthetic
- Using highly concentrated topical anesthetics
- Applying to a large area of skin
- Applying to irritated or broken skin
- Covering the skin with a wrap or using a heating pad after applying the topical anesthetic (Skin temperature can also increase during exercise.)

The FDA notes that if a topical anesthetic is recommended, patients should do the following:

- Apply the topical anesthetic sparingly.
- Use a topical anesthetic that

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contains the lowest possible amount of medication that will relieve the pain.

- Apply the topical anesthetic only to areas where pain exists or is expected.
- Do not apply the topical anesthetic to broken or irritated skin.
- Be aware that if wrapping or covering the skin with any type of material or dressing is recommended or considered, this can increase the chance of serious side effects, as can applying heat to the treated area while the medication is still present.
- Ask the doctor what side effects are possible and how to lower the chance of life-threatening effects from anesthetic drugs.

METHOTREXATE OVERDOSE

A 72-year-old woman with a history of rheumatoid arthritis and multiple hospital admissions for pulmonary problems began taking oral methotrexate 10 mg once weekly. Three months into therapy, the dose was increased to 10 mg twice a day once weekly on Mondays. When the patient was admitted to the hospital for pulmonary infections 1 month after the dose adjustment, her medication reconciliation form correctly listed oral methotrexate 10 mg twice a day on Mondays. However, the prescription was transcribed on the discharge medication list as “methotrexate 10 mg PO BID.” The patient began taking the methotrexate as erroneously listed on the discharge sheet given to her: 10 mg twice daily.

After taking methotrexate 10 mg twice daily (using the tablets she had at home), the patient was seen by a visiting nurse who discovered the error after the patient complained of mucositis and diar-

rhea. The patient was told to stop the methotrexate and to go to the emergency department. On admission her complete blood count revealed pancytopenia, which was considered the result of methotrexate toxicity, with a white blood cell count of 1,000 cells/mm³, an absolute neutrophil count of 200 cells/mm³, and a hemoglobin level of 8.2 g/dL. Filgrastim and darbepoetin were started to support the patient’s white and red blood cell counts, respectively.

Despite previous prescriptions for methotrexate, the patient never had been given clear instructions regarding adherence to a weekly dosage schedule that named the day of the week for administration. Perhaps if the prescription had been written more clearly, such as “morning and evening every Monday,” the error would not have occurred. To ensure that patients taking methotrexate understand the weekly dosing schedule, encourage follow-up phone calls. The Institute for Safe Medication Practices firmly believes that prescribing and dispensing the drug as a dose pack (eg, *Rheumatrex* by DAVA Pharmaceuticals) helps reinforce the weekly dosing schedule. The dose pack contains a 1-month supply of methotrexate tablets in 4 *weekly* unit-dose blister cards to help ensure that patients take the proper dose at the right time.

Before discharging patients who have been hospitalized, medications on discharge lists should be reconciled with the lists provided on admission and discrepancies should be resolved. When discharge lists are given to patients, a nurse, pharmacist, or physician should review the medications, giving patients an opportunity to ask questions about changes to medications and doses they were previously taking. Em-

phasis should be placed on the weekly dosing schedule for patients who are discharged with prescriptions for methotrexate.

SAFETY CAPS THAT DO NOT PROTECT CHILDREN

The US Consumer Product Safety Commission (CPSC) requires that oral prescription drugs be dispensed in child-resistant packaging unless the drug is exempted or the patient or prescriber requests otherwise. However, there are dual-purpose caps available that can be used as child-resistant caps or flipped over for use as non-child resistant caps. Although these caps meet the requirements set in the Poison Prevention Packaging Act (PPPA), the CPSC discourages their use. ISMP agrees with the CPSC’s stance on use of these caps. Dual-purpose caps still can result in child poisoning if the nonresistant side is used. Moreover, their use actually may increase the risk of poisoning because adults who previously never had problems opening child-resistant caps may now be using these caps. For more information about the PPPA, go to the CPSC Web site at www.cpsc.gov/BUSINFO/pppainfo.html.

REFERENCES

1. US Food and Drug Administration. FDA public health advisory: potential hazards of skin products containing numbing ingredients for relieving pain from mammography and other medical tests and conditions. http://www.fda.gov/cder/drug/advisory/topical_anesthetics2009.htm. Published January 16, 2009. Accessed April 20, 2009.
2. Lambertz CK, Johnson CJ, Montgomery PG, Maxwell JR. Premedication to reduce discomfort during screening mammography. *Radiology*. 2008;248(3):765-772. ■